Legislative Analysis

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PRODUCT LIABILITY: REMOVE IMMUNITY FOR FDA-APPROVED DRUGS

House Bill 4316
Sponsor: Rep. Lisa Brown

House Bill 4317
Sponsor: Rep. Deb Kennedy

House Bill 4318
Sponsor: Rep. Dian Slavens

Committee: Judiciary

Complete to 3-17-09

A SUMMARY OF HOUSE BILLS 4316-4318 AS INTRODUCED 2-17-09

Together, the bills would:

- Eliminate the current immunity against product liability lawsuits that specifically applies to drugs approved by the federal Food and Drug Administration (FDA).

- Create a three-year window in which claims could be filed for injuries attributable to FDA-approved drugs during the time the immunity was in place.

- Allow civil suits to be filed under the Consumer Protection Act if a business misrepresented risks associated with a drug, herb, dietary supplement, or botanical supplement.

Specifically, the bills would do the following:

House Bill 4316 would amend Section 2946 of the Revised Judicature Act (MCL 600.2946) **to delete subsection (5)**. Currently, Section 2946(5) says that a drug approved for safety and efficacy by the United States Food and Drug Administration (FDA) is not defective or unreasonably dangerous and the manufacturer or seller is not liable in a product liability action if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer.

The immunity from civil liability does not extend to a drug sold in the U.S. after the effective date of an FDA order removing the drug from the market or an order withdrawing FDA approval. The civil immunity also does not extend to a defendant who, at any time before the event allegedly causing the injury, either bribed an official or FDA employee in order to secure or maintain approval of the drug or intentionally withheld from or misrepresented to the FDA information required to be submitted under the federal Food, Drug, and Cosmetic Act that, had the information been accurately submitted, the drug would not have been approved or the FDA would have withdrawn approval.

House Bill 4317 would amend Section 5805 of the Revised Judicature Act (MCL 600.5805) to establish a three-year period during which a cause of action could be filed based on drug product liability that had been barred by Section 2946(5). This would apply to causes of action that otherwise could have been commenced on or after January 2, 1996 (the effective date of the legislation that created the ban) and before the effective date of House Bill 4316. The three-year period would run after the effective date of House Bill 4316. The bill is tie-barred to House Bill 4316.

House Bill 4318 would amend the Michigan Consumer Protection Act (MCL 445.902 and 445.903). The act contains a list of actions that constitute unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, and that are unlawful. House Bill 4318 would add to that list:

Failure, on the part of a manufacturer or producer, to accurately represent the risks involved in the intended use of a prescription or over-the-counter drug or medication or an herbal product, dietary supplement, or botanical extract.

The bill also would define the term "goods" to include a legal pharmaceutical product.

(The act refers to "goods" and "services" throughout. For example, the phrase "trade or commerce" is defined in the act as "the conduct of a business providing goods, property, or service primarily for personal, family, or household purposes and includes the advertising, solicitation, offering for sale or rent, sale, lease, or distribution of a service or property, tangible or intangible, real, personal, or mixed, or any other article, or a business opportunity.")

The Michigan Consumer Protection Act is enforced by the Attorney General and by local prosecutors. Also, individuals, firms, and other entities can bring private actions to enforce the law in some circumstances.

FISCAL IMPACT:

House Bills 4316 and 4317 would have an indeterminate fiscal impact on the judiciary; any fiscal impact would be related to increased caseload which would depend on the number and complexity of lawsuits that might be brought under these bills.

House Bill 4318 would have an indeterminate impact on the Department of Attorney General, the courts, and local prosecutors depending on the extent to which it results in litigation concerning enforcement of the new pharmaceutical provisions in the Consumer Protection Act. Any fiscal impact to the Attorney General would be from possible increased caseload based on legal actions that the Attorney General might bring under the new provisions of the bill.

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