Legislative Analysis

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PRODUCT LIABILITY: REMOVE CURRENT IMMUNITY FOR FDA-APPROVED DRUGS

House Bill 4044 as introduced
Sponsor: Rep. Mike Simpson

House Bill 4045 as introduced
Sponsor: Rep. Gary McDowell

House Bill 4046 as introduced
Sponsor: Rep. Mary Valentine
Committee: Judiciary

Complete to 2-21-07

A SUMMARY OF HOUSE BILLS 4044 - 4046 AS REPORTED FROM COMMITTEE

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; and 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 4044 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Act that, had the information been accurately submitted, the drug would not have been approved or the FDA would have withdrawn approval.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 4045 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 4044. The three-year period would run after the effective date of House Bill 4044. The bill is tie-barred to House Bill 4044.

House Bill 4046 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 4046 would add to that list:

Failing 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.")

FISCAL IMPACT:

House Bills 4044 and 4045 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. A fiscal analysis is in process for House Bill 4046.

POSITIONS:

Associations and organizations testifying in support of or indicating support for the bills on 2-14-07 were:

The DIME Coalition
The Michigan Citizen Action
Michigan Trial Lawyers Association
Michigan State AFL-CIO
International Union, UAW
Henry Greenspan, Ph.D., lecturer and founding member of Justice in Michigan (an organization of physicians and academics who teach at institutions of higher learning in Michigan)

Associations and organizations indicating, testifying, or submitting written testimony in opposition to the bills on 2-14-07 were:

Pfizer
PhARMA
MICHBIO
Michigan Lawsuit Abuse Watch (M-LAW)
Michigan Dental Association
Eli Lilly & Co.
Michigan Chamber of Commerce
Michigan Academy of Family Physicians
Wyeth
Michigan Retailers Association
Michigan Osteopathic Association
Grand Rapids Chamber of Commerce
Abbot Laboratories
GlaxoSmithKline
Sanofi-Aventis
Merck, Inc.
Michigan Association of Health Plans
Michigan Academy of Physicians Assistants
Michigan State Medical Society
Consumer Healthcare Products Association
Kalamazoo Regional Chamber of Commerce
Insurance Institute of Michigan
National Federation of Independent Business
Takeda Pharmaceuticals America, Inc.
Johnson & Johnson
Novartis Pharmaceuticals Corporation
Michigan Manufacturers Association
Schering-Plough Corporation
National Federation of Small Businesses
Detroit Regional Chamber
Michigan College of Emergency Physicians

Legislative Analyst: Susan Stutzky
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Robin Risko

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.