

# Legislative Analysis

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## **PRODUCT LIABILITY: REMOVE BAN ON ACTIONS INVOLVING FDA-APPROVED DRUGS**

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### **House Bill 4044**

**Sponsor: Rep. Mike Simpson**

### **House Bill 4045**

**Sponsor: Rep. Gary McDowell**

**Committee: Judiciary**

**Complete to 2-12-07**

## **A SUMMARY OF HOUSE BILLS 4044 AND 4045 AS INTRODUCED 1-22-07**

Together, the bills would eliminate the current ban on product liability lawsuits involving prescription drugs approved by the federal Food and Drug Administration (FDA) and would create a three-year window in which claims could be filed for injuries attributable to FDA-approved drugs during the time the ban was in place.

House Bill 4044 would amend Section 2946 of the Revised Judicature Act (MCL 600.2946) to delete subsection (5). Currently, Section 2946(5) presumes 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 are not liable in a product liability action when 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Act that, had the information been accurately submitted, the drug would not have been approved or the FDA would have withdrawn approval.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.

**FISCAL IMPACT:**

These bills 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.

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