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## **HOUSE BILL No. 4811**

May 19, 2005, Introduced by Reps. Drolet, Ward, Byrum and Anderson and referred to the Committee on Commerce.

A bill to amend 1961 PA 236, entitled

"Revised judicature act of 1961,"

by amending section 2946 (MCL 600.2946), as amended by 1995 PA 249.

## THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

- 1 Sec. 2946. (1) It -shall be IS admissible as evidence in a
- 2 product liability action that the production of the product was in
- 3 accordance with the generally recognized and prevailing
- 4 nongovernmental standards in existence at the time the specific
- 5 unit of the product was sold or delivered by the defendant to the
- 6 initial purchaser or user.
  - (2) In a product liability action brought against a
  - manufacturer or seller for harm allegedly caused by a production
  - defect, the manufacturer or seller is not liable unless the

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- 1 plaintiff establishes that the product was not reasonably safe at
- 2 the time the specific unit of the product left the control of the
- 3 manufacturer or seller and that, according to generally accepted
- 4 production practices at the time the specific unit of the product
- 5 left the control of the manufacturer or seller, a practical and
- 6 technically feasible alternative production practice was available
- 7 that would have prevented the harm without significantly impairing
- 8 the usefulness or desirability of the product to users and without
- 9 creating equal or greater risk of harm to others. An alternative
- 10 production practice is practical and feasible only if the
- 11 technical, medical, or scientific knowledge relating to production
- 12 of the product, at the time the specific unit of the product left
- 13 the control of the manufacturer or seller, was developed,
- 14 available, and capable of use in the production of the product and
- 15 was economically feasible for use by the manufacturer. Technical,
- 16 medical, or scientific knowledge is not economically feasible for
- 17 use by the manufacturer if use of that knowledge in production of
- 18 the product would significantly compromise the product's usefulness
- 19 or desirability.
- 20 (3) With regard to the production of a product that is the
- 21 subject of a product liability action, evidence of a philosophy,
- 22 theory, knowledge, technique, or procedure that is learned, placed
- 23 in use, or discontinued after the event resulting in the death of
- 24 the person or injury to the person or property, which if learned,
- 25 placed in use, or discontinued before the event would have made the
- 26 event less likely to occur, is admissible only for the purpose of
- 27 proving the feasibility of precautions, if controverted, or for

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- 1 impeachment.
- 2 (4) In a product liability action brought against a
- 3 manufacturer or seller for harm allegedly caused by a product,
- 4 there is a rebuttable presumption that the manufacturer or seller
- 5 is not liable if, at the time the specific unit of the product was
- 6 sold or delivered to the initial purchaser or user, the aspect of
- 7 the product that allegedly caused the harm was in compliance with
- 8 standards relevant to the event causing the death or injury -set
- 9 forth CONTAINED in a federal or state statute or was approved by,
- 10 or was in compliance with regulations or standards relevant to the
- 11 event causing the death or injury promulgated by, a federal or
- 12 state agency responsible for reviewing the safety of the product.
- 13 Noncompliance with a standard relevant to the event causing the
- 14 death or injury -set forth CONTAINED in a federal or state statute
- 15 or lack of approval by, or noncompliance with regulations or
- 16 standards relevant to the event causing the death or injury
- 17 promulgated by, a federal or state agency does not raise a
- 18 presumption of negligence on the part of a manufacturer or seller.
- 19 Evidence of compliance or noncompliance with a regulation or
- 20 standard not relevant to the event causing the death or injury is
- 21 not admissible.
- 22 (5) In a product liability action against a manufacturer or
- 23 seller, a product that is a drug is not defective or unreasonably
- 24 dangerous, and the manufacturer or seller is not liable, if the
- 25 drug was approved for safety and efficacy by the United States food
- 26 and drug administration, and the drug and its labeling were in
- 27 compliance with the United States food and drug administration's

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- 1 approval at the time the drug left the control of the manufacturer
- 2 or seller. However, this subsection does not apply to a drug that
- 3 is sold in the United States after the effective date of an order
- 4 of the United States food and drug administration to remove the
- 5 drug from the market or to withdraw its approval. This subsection
- 6 does not apply if the defendant at any time before the event that
- 7 allegedly caused the injury does any of the following:
- 8 (a) Intentionally withholds from or misrepresents to the
- 9 United States food and drug administration information concerning
- 10 the drug that is required to be submitted under the federal food,
- 11 drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301
- 12 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360,
- 13 360b to 376, and 378 to 395, and the drug would not have been
- 14 approved, or the United States food and drug administration would
- 15 have withdrawn approval for the drug if the information were
- 16 accurately submitted.
- 17 (b) Makes an illegal payment to an official or employee of the
- 18 United States food and drug administration for the purpose of
- 19 securing or maintaining approval of the drug.