SUBSTITUTE FOR

HOUSE BILL NO. 4048

A bill to amend 1961 PA 236, entitled "Revised judicature act of 1961," by amending sections 2946 and 5827 (MCL 600.2946 and 600.5827), section 2946 as amended by 1995 PA 249, and by adding section 5828.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 2946. (1) It shall be IS admissible as evidence in a product liability action that the production of the product was in accordance with the generally recognized and prevailing nongovernmental standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the initial purchaser or user.

7 (2) In a product liability action brought against a
8 manufacturer or seller for harm allegedly caused by a production
9 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 avail-7 able that would have prevented the harm without significantly 8 impairing the usefulness or desirability of the product to users 9 and without creating equal or greater risk of harm to others. An 10 alternative production practice is practical and feasible only if 11 the technical, medical, or scientific knowledge relating to pro-12 duction of the product, at the time the specific unit of the pro-13 duct left the control of the manufacturer or seller, was devel-14 oped, available, and capable of use in the production of the pro-15 duct and was economically feasible for use by the manufacturer. 16 Technical, medical, or scientific knowledge is not economically 17 feasible for use by the manufacturer if use of that knowledge in 18 production of the product would significantly compromise the 19 product's usefulness or desirability.

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(3) With regard to the production of a product that is the
subject of a product liability action, evidence of a philosophy,
theory, knowledge, technique, or procedure that is learned,
placed in use, or discontinued after the event resulting in the
death of the person or injury to the person or property, which if
learned, placed in use, or discontinued before the event would
have made the event less likely to occur, is admissible only for

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the purpose of proving the feasibility of precautions, if
 controverted, or for impeachment.

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(4) In a product liability action brought against a manufac-3 4 turer or seller for harm allegedly caused by a product, there is 5 a rebuttable presumption that the manufacturer or seller is not 6 liable if, at the time the specific unit of the product was sold 7 or delivered to the initial purchaser or user, the aspect of the 8 product that allegedly caused the harm was in compliance with 9 standards relevant to the event causing the death or injury set 10 forth in a federal or state statute or was approved by, or was in 11 compliance with regulations or standards relevant to the event 12 causing the death or injury promulgated by, a federal or state 13 agency responsible for reviewing the safety of the product. 14 Noncompliance with a standard relevant to the event causing the 15 death or injury set forth in a federal or state statute or lack 16 of approval by, or noncompliance with regulations or standards 17 relevant to the event causing the death or injury promulgated by, 18 a federal or state agency does not raise a presumption of negli-19 gence on the part of a manufacturer or seller. Evidence of com-20 pliance or noncompliance with a regulation or standard not rele-21 vant to the event causing the death or injury is 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 26 food and drug administration, and the drug and its labeling were

27 in compliance with the United States food and drug

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1 administration's approval at the time the drug left the control 2 of the manufacturer or seller. However, this subsection does not 3 apply to a drug that is sold in the United States after the 4 effective date of an order of the United States food and drug 5 administration to remove the drug from the market or to withdraw 6 its approval. This subsection does not apply if the defendant at 7 any time before the event that allegedly caused the injury does 8 any of the following:

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9 (a) Intentionally withholds from or misrepresents to the 10 United States food and drug administration information concerning 11 the drug that is required to be submitted under the federal food, 12 drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 13 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 14 360b to 376, and 378 to 395, and the drug would not have been 15 approved, or the United States food and drug administration would 16 have withdrawn approval for the drug if the information were 17 accurately submitted.

18 (b) Makes an illegal payment to an official or employee of
19 the United States food and drug administration for the purpose of
20 securing or maintaining approval of the drug.

Sec. 5827. Except as otherwise expressly provided, the period of limitations runs from the time the claim accrues. The claim accrues at the time provided in sections - 5829 to 5838-5828 TO 5838A, and in cases not covered by these sections the claim accrues at the time the wrong upon which the claim is based was done regardless of the time when damage results.

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SEC. 5828. IN A PHARMACEUTICAL PRODUCT LIABILITY ACTION, 1 2 THE CLAIM ACCRUES AT THE TIME THE INJURED PARTY KNOWS OF THE 3 INJURY AND KNOWS OF THE CAUSAL CONNECTION BETWEEN THE INJURY AND 4 ITS CAUSE.

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