By: Blanco H.B. No. 4027

A BILL TO BE ENTITLED

AN ACT

relating to products liability action related to a pharmaceutical product.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 82.007, Civil Practice and Remedies Code, is amended to read as follows:

Sec. 82.007. MEDICINES. (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, such as a failure of the manufacturer to place notice to the United States Food and Drug Administration of a potential safety signal, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:

(1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended; or

(2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed

without an approved new drug application.

(b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:

(1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration relevant [~~required~~] information that was material [~~and relevant~~] to the performance of the product and was causally related to the claimant's injury;

(2) the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the United States Food and Drug Administration to remove the product from the market or to withdraw its approval of the product;

(3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;

(B) the product was used as recommended, promoted, or advertised; and

(C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;

(4)(A) the defendant prescribed the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;

(B) the product was used as prescribed; and

(C) the claimant's injury was causally related to the prescribed use of the product; or

(5) the defendant, before or after pre-market approval

or licensing of the product, engaged in conduct that would constitute a violation of 18 U.S.C. Section 201 and that conduct caused the warnings or instructions approved for the product by the United States Food and Drug Administration to be inadequate.

(6) the defendant, before or after pre-market approval or licensing of the product, failed to report any adverse event (or adverse experience), adverse drug reaction or unexpected adverse drug reaction for the product as defined by the United States Food and Drug Administration.

(7) the United States Food and Drug Administration adds or amends a boxed warning as defined by USC §201.57(c)(1).

(c) The claimant is entitled to reasonable discovery on any rebuttable presumption before a dispositive motion under (a).

SECTION 2. This Act takes effect September 1, 2015.