ADOPTED

NORTH CAROLINA GENERAL ASSEMBLY
AMENDMENT
Senate Bill 648

AMENDMENT NO. A2
(to be filled in by Principal Clerk)

S648-ATG-79 [v.1]

Comm. Sub. [YES]
Amends Title [YES]
Third Edition

Date _____,2014

Senator Barringer

moves to amend the bill on 1, line 3, by adding before the phrase "TO PREVENT" the phrase "TO AMEND THE LAWS GOVERNING PRODUCTS LIABILITY ACTIONS,";

and on page 3, line 47-48, by adding the following between the lines:

"**PART III. AMEND THE LAWS GOVERNING PRODUCTS LIABILITY ACTIONS**

SECTION 3.1 Chapter 99B of the General Statutes is amended by adding a new section to read:

"**§ 99B-13. Regulatory compliance.**

(a) Except as provided in subsection (b) of this section, in any product liability action against a manufacturer of a drug, if the drug that is alleged to have caused the harm was approved for safety and efficacy by the United States Food and Drug Administration, and the drug and its labeling were in compliance with the United States Food and Drug Administration's approval at the time the drug left the control of the manufacturer, there is a rebuttable presumption that the manufacturer did not fail to provide an adequate warning. This presumption may be rebutted by a preponderance of the evidence.

(b) This section does not apply if the claimant proves that the manufacturer, at any time before the event that allegedly caused the harm, did any of the following:

(1) Sold the drug in the United States after the effective date of an order of the United States Food and Drug Administration to remove the drug from the market, to withdraw its approval, or to substantially alter the terms of approval in a manner that would have avoided the claimant's alleged injury.

(2) Intentionally, and in violation of applicable regulations as determined by final agency action, withheld from or misrepresented to the United States Food and Drug Administration information material to the approval or maintaining of approval of the drug, and such information is relevant to the harm which the claimant allegedly suffered.

(3) Made an illegal payment to an official or employee of a government agency for the purpose of securing or maintaining approval of the drug.

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SECTION 3.2. This section applies only to product liability claims alleging that a drug manufacturer failed to provide an adequate warning.

SECTION 3.3. Section 3.1 of this act becomes effective October 1, 2014, and applies to actions commenced on or after that date.".

SIGNED _____
Amendment Sponsor

SIGNED _____
Committee Chair if Senate Committee Amendment

ADOPTED _____ FAILED _____ TABLED _____