ADOPTED

**NORTH CAROLINA GENERAL ASSEMBLY**
**AMENDMENT**
House Bill 542

AMENDMENT NO. 2
(to be filled in by Principal Clerk)

H542-ATG-89 [v.4]



Comm. Sub. [NO]
Amends Title [NO]
Second Edition

Date 6/1 ,2011

Representative Rhyne

moves to amend the bill on page 2, line 47, through page 3, line 13, by rewriting those lines to read:

"(a) Except as provided in subsection (b) or (c) of this section, no manufacturer or seller of a product that is a drug shall be held liable in any product liability action if the drug 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 or seller.

(b) This section does not apply if the claimant proves that the manufacturer or seller, 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.

(c) This section shall not bar an action brought pursuant to Article 51 of Chapter 1 of the General Statutes, if the action is not based upon allegations that the product was not safe or effective or that the manufacturer failed to provide an adequate warning.".

**NORTH CAROLINA GENERAL ASSEMBLY**
**AMENDMENT**
House Bill 542

AMENDMENT NO. 2
(to be filled in by Principal Clerk)

H542-ATG-89 [v.4]



SIGNED _____
Amendment Sponsor

SIGNED _____
Committee Chair if Senate Committee Amendment

ADOPTED 112-0 EV FAILED _____ TABLED _____

JUN 01 2011

ADOPTED