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

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

H542-ATG-89 [v.4]

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

Date 6/1, 2011

Representative Rhyne

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

3 "(a) Except as provided in subsection (b) or (c) of this section, no manufacturer  
4 or seller of a product that is a drug shall be held liable in any product liability action if the drug  
5 alleged to have caused the harm was approved for safety and efficacy by the United States  
6 Food and Drug Administration and the drug and its labeling were in compliance with the  
7 United States Food and Drug Administration's approval at the time the drug left the control of  
8 the manufacturer or seller.

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

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

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

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

25 (c) This section shall not bar an action brought pursuant to Article 51 of Chapter  
26 1 of the General Statutes, if the action is not based upon allegations that the product was not  
27 safe or effective or that the manufacturer failed to provide an adequate warning."

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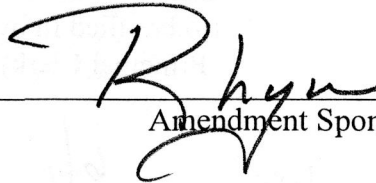


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SIGNED   
Amendment Sponsor

SIGNED \_\_\_\_\_  
Committee Chair if Senate Committee Amendment

ADOPTED 112-0 ev FAILED \_\_\_\_\_ TABLED \_\_\_\_\_

JUN 01 2011  


**ADOPTED**