**GENERAL ASSEMBLY OF NORTH CAROLINA**
**SESSION 2011**

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**BILL DRAFT 2011-TG-14A [v.1] (02/17)**

**(THIS IS A DRAFT AND IS NOT READY FOR INTRODUCTION)**
**2/17/2012 10:25:27 AM**

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| Short Title: | Reg. Compliance/Product Liability Defense. | (Public) |
| Sponsors: | Senator. | |
| Referred to: | | |

A BILL TO BE ENTITLED AN ACT TO ESTABLISH A PRODUCT LIABILITY DEFENSE BASED ON FDA REGULATORY COMPLIANCE BY DRUG MANUFACTURERS AND SELLERS.

The General Assembly of North Carolina enacts:

**SECTION 1.** G.S. 99B-1 reads as rewritten:

"**§ 99B-1. Definitions.**

When used in this Chapter, unless the context otherwise requires:

(1) "Claimant" means a person or other entity asserting a claim and, if said claim is asserted on behalf of an estate, an incompetent or a minor, "claimant" includes plaintiff's decedent, guardian, or guardian ad litem.

(1a) "Government agency" means this State or the United States, or any agency of this State or the United States, or any entity vested with the authority of this State or of the United States to issue rules, regulations, orders, or standards concerning the design, manufacture, packaging, labeling, or advertising of a product or provision of a service.

(2) "Manufacturer" means a person or entity who designs, assembles, fabricates, produces, constructs or otherwise prepares a product or component part of a product prior to its sale to a user or consumer, including a seller owned in whole or significant part by the manufacturer or a seller owning the manufacturer in whole or significant part.

(3) "Product liability action" includes any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product.

(4) "Seller" includes a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sale is for resale or for use or consumption. "Seller" also includes a lessor or bailor engaged in the business of leasing or bailment of a product."

**SECTION 2.2.** Chapter 99B of the General Statutes is amended by adding the following new section to read:

"**§ 99B-12. Regulatory compliance.**

(a) Except as provided in subsection (b), (c), or (d) of this section, in any product liability action against a manufacturer or seller 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 or seller, there is a rebuttable presumption that the drug was safe and effective for its approved use, and the manufacturer or seller is not liable. This presumption may be rebutted only by clear and convincing evidence.

(b) This section does not apply if the claimant proves by a preponderance of the evidence 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.

(d) This section does not apply if the claimant establishes by a preponderance of the evidence all of the following:

(1) The manufacturer or seller recommended, promoted, or advertised the drug for an indication not approved by the United States Food and Drug Administration.

(2) The drug was used as recommended, promoted, or advertised.

(3) The recommended, promoted, or advertised use of the drug was the proximate cause of the claimant's injury.".

**SECTION 2.** This becomes effective October 1, 2012, and applies to actions commenced on or after that date.