



Bill Draft 2011-TG-14A: Reg. Compliance/Product Liability Defense.

2011-2012 General Assembly

Committee: Senate Judiciary I

Introduced by:

Analysis of: 2011-TG-14A

Date: February 20, 2012

Prepared by: Bill Patterson

Committee Counsel

SUMMARY: *Draft bill 2011-TG-14A is identical to 2011-TG-14, except that it adds an additional exception under which the defense based on FDA approval would not be available if the drug was advertised or marketed for off-label use and the injury was the result of the drug being used as so advertised or marketed.*

CURRENT LAW AND BILL ANALYSIS:

Current Law: Same as stated in summary for draft bill 2011-TG-14.

Bill Analysis: Draft bill 2011-TG-14A makes one change to 2011-TG-14: it adds new subsection 99B-12(d), which makes the FDA approval defense unavailable if the claimant establishes by a preponderance of the evidence all of the following:

- the manufacturer or seller recommended, promoted, or advertised the drug for an indication not approved by the United States Food and Drug Administration
- the drug was used as recommended, promoted, or advertised
- the recommended, promoted, or advertised use of the drug was the proximate cause of the claimant's injury

EFFECTIVE DATE: The act is effective October 1, 2012, and applicable to actions commenced on or after that date.

2011-TG-14A-SMTG-74 v4