

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To protect generic drug manufacturers from being sued for label language over which they have no control.

**IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.**

**S. 369**

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. CORNYN

Viz:

1 At the appropriate place, insert the following:  
2 **SEC. \_\_\_\_ . PREVENTING STATE TORT LAWSUITS AGAINST**  
3 **GENERICS FOR MANDATORY WARNING**  
4 **LABEL LANGUAGE.**

5 Notwithstanding any other provision of State or Fed-  
6 eral law, a person who manufacturers a generic drug ap-  
7 proved under an abbreviated new drug application shall  
8 not be liable because the label did not warn against an  
9 adverse reaction, unless the Food and Drug Administra-  
10 tion required a change to the label to provide such warn-  
11 ings and the manufacturer failed to comply with such re-

1 quirement, or the manufacturer failed to provide to the  
2 Food and Drug Administration health and safety informa-  
3 tion otherwise required to be provided under regulations  
4 issued by the Secretary for Health and Human Services  
5 regarding such drug.