Fifty-sixth Legislative Assembly, State of North Dakota, begun in the Capitol in the City of Bismarck, on Tuesday, the fifth day of January, one thousand nine hundred and ninety-nine

SENATE BILL NO. 2349 (Senators Grindberg, Flakoll) (Representative Clark)

AN ACT to create and enact a new section to chapter 19-02.1 of the North Dakota Century Code, relating to limitations on exemplary damages.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new section to chapter 19-02.1 of the North Dakota Century Code is created and enacted as follows:

Limitation on exemplary damages.

- 1. Exemplary damages may not be awarded against the manufacturer or seller of a product or device that caused the harm claimed by the plaintiff if:
 - a. The product or device was subject to approval under 21 United States Code 355 or premarket approval under 21 United States Code 360e by the food and drug administration with respect to the safety of formulation or performance of the aspect of the product or device that caused the harm, or by the adequacy of the packaging or labeling of the product or device; or
 - b. The product or device was approved by the food and drug administration.
- 2. Subsection 1 does not apply in a case in which it is determined on the basis of clear and convincing evidence that the defendant:
 - a. Withheld from or misrepresented to the food and drug administration information concerning the product or device which is required to be submitted under the federal Act which is material and relevant to the harm suffered by the claimant;
 - b. Made an illegal payment to an official of the food and drug administration for the purpose of securing approval of the product or device;
 - c. Failed to use reasonable care to comply with the food and drug administration regulations concerning the manufacture of, or the investigation and correction of defects in design or manufacture of, a medical device, and the failure to comply has caused the harm suffered by the plaintiff;
 - d. Made a significant or knowing departure from official food and drug administration requirements; or
 - e. Acted with conscious disregard for human safety.

President of the Senate

Speaker of the House

Secretary of the Senate

Chief Clerk of the House

This certifies that the within bill originated in the Senate of the Fifty-sixth Legislative Assembly of North Dakota and is known on the records of that body as Senate Bill No. 2349.

Senate Vote:Yeas45Nays0Absent4House Vote:Yeas90Nays7Absent1

Secretary of the Senate

Received by the Govern	nor at M. on	, 1999.
Approved at	M. on	, 1999.

Governor

Filed in this o	office this		day of		, 1999,
at	o'clock	М.			

Secretary of State