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Fifty-sixth
Legislative Assembly
of North Dakota

FIRST ENGROSSMENT

ENGROSSED SENATE BILL NO. 2349

Introduced by

Senators Grindberg, Flakoll

Representative Clark

A BILL for an Act to create and enact a new section to chapter 19-02.1 of the North Dakota Century Code, relating to limitations on punitive 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 punitive damages.

1. Punitive 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.