

Amend CSHB 4 as follows:

On pages 545 and 546 of the packet, strike Sec. 82.009 and substitute a new Sec. 82.009 to read as follows:

Sec. 82.009. COMPLIANCE WITH GOVERNMENT STANDARDS.

(a) In a products liability action brought against a product manufacturer, distributor, or seller, in which the claimant alleges that an injury was caused by some aspect of the formulation, labeling, or design of a product, it is an affirmative defense to the claimant's allegation that the product's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of the manufacture, and that governed the particular product risk alleged by the claimant to have caused harm. Once the product manufacturer, distributor, or seller presents evidence to support this affirmative defense, the claimant may overcome the affirmative defense by establishing by a preponderance of the evidence that:

(1) the mandatory federal safety standards or regulations applicable to the product were inadequate to protect the public from unreasonable risks of injury or damage;

(2) the manufacturer, before or after marketing the product, withheld from or misrepresented to the government or agency information that was relevant to the performance of the product and was causally related to the claimant's injury;

(3) Congress included a "savings" provision, intending to permit state common law to apply to the field being regulated;

(4) with respect to the manufacturer of a motor vehicle, or a component of a motor vehicle, after the product was sold and before the alleged injury occurred, that the manufacturer failed to provide the federal government, or the governing agency of the federal government, with all incidents of which the manufacturer receives actual or constructive notice which involve fatalities or serious injuries which are alleged to have been caused by a possible defect in such manufacturer's motor vehicle or motor vehicle equipment; or

(5) with respect to the manufacture of a tire, that the manufacturer failed to comply with the obligations set forth in the

Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act.

(b) In a products liability action brought against a product manufacturer, distributor, or seller, in which the claimant alleges that an injury was caused by some aspect of the formulation, labeling, or design of a product, it is an affirmative defense to the claimant's allegation that the product was subject to pre-market licensing or approval by the federal government or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that, after full consideration of the product's risk and benefits, was approved or licensed for sale by the government or agency. Once the product manufacturer, distributor, or seller presents evidence to support this affirmative defense, the claimant may overcome the affirmative defense by establishing by a preponderance of the evidence that:

(1) the standards or procedures used in the particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage;

(2) the manufacturer, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government or agency information that was relevant to the performance of the product and was causally related to the claimant's injury;

(3) Congress included a "savings" provision, intending to permit state common law to apply to the field being regulated; or

(4) with respect to the manufacturer of a drug or medical device, after the product was sold and before the alleged injury occurred, that the manufacturer failed to provide the federal government, or the governing agency of the federal government, with all incidents of which the manufacturer receives actual or constructive notice which involve fatalities or serious injuries which are alleged to have been caused by a possible defect in such manufacturer's product.

(c) The affirmative defense created in sections (a) and (b) does not exist if the claimant demonstrates that the product has

been withdrawn from the market.

(d) The affirmative defense created in sections (a) and (b) does not exist if the claimant demonstrates that the product manufacturer acted with gross neglect or malice.

(e) This section does not extend to manufacturing flaws or defects even though the product manufacturer has complied with all quality control and manufacturing practices mandated by the state or federal governments or agencies.