By the Committee on Civil Justice & Claims and Representatives Warner, Ritter, Flanagan and Thrasher

An act relating to product liability; amending s. 95.031, F.S.; providing a time period for bringing an action for product liability or fraud; providing an exception; creating s. 768.1256, F.S.; providing a government rules defense with respect to certain product

A bill to be entitled

liability actions; providing for a rebuttable presumption; providing requirements with respect to products which are drugs; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 95.031, Florida Statutes, is amended to read:

 95.031 Computation of time.--Except as provided in subsection (2) and in s. 95.051 and elsewhere in these statutes, the time within which an action shall be begun under any statute of limitations runs from the time the cause of action accrues.

(2) Actions for products liability and fraud under s. 95.11(3) must be begun within the period prescribed in this chapter, with the period running from the time the facts giving rise to the cause of action were discovered or should have been discovered with the exercise of due diligence, instead of running from any date prescribed elsewhere in s. 95.11(3), but in no event may an action for product liability or fraud under s. 95.11(3) be commenced unless the complaint is served and filed within 12 years after the date of delivery of the product to its first purchaser or lessee who was not

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engaged in the business of selling or leasing the product or of using the product as a component in the manufacture of another product or any event an action for fraud under s.

95.11(3) must be begun within 12 years after the date of the commission of the alleged fraud, regardless of the date the defect in the product or the fraud was or should have been discovered. However, the 12-year limitation on filing an action for products liability does not apply if the manufacturer knew of a defect in the product and concealed or attempted to conceal this defect.

Section 2. Section 768.1256, Florida Statutes, is created to read:

768.1256 Government rules defense.--

(1) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, the jury shall be instructed that there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a

manufacturer or seller. Evidence of compliance or noncompliance with a regulation or standard not relevant to the event causing the death or injury is not admissible.

- manufacturer or seller, a defendant may raise an affirmative defense that a product that is a drug is not defective or unreasonably dangerous, if the drug was approved for safety and efficacy by the United States Food and Drug Administration and the drug and its labeling were in compliance with the United States Food and Drug Administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States Food and Drug Administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
- (a) Intentionally withholds from or misrepresents to the United States Food and Drug Administration information concerning the drug that is required to be submitted under the Federal Food, Drug and Cosmetic Act, chapter 675, 52 Stat.

  1040, 21 U.S.C. ss. 301 to 321, 331 to 343-2, 344 to 346a,

  347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States

  Food and Drug Administration would have withdrawn approval for, the drug if the information had been accurately submitted; or
- (b) Makes an illegal payment to an official or employee of the United States Food and Drug Administration for the purpose of securing or maintaining approval of the drug.

Section 3. Any action that would not have been barred under s. 95.031(2), Florida Statutes, prior to the amendments to that section by this act may be commenced before June 1, 1998, and, if it is not commenced by that date, and is barred by the amendments to s. 95.031(2), Florida Statutes, by this act, shall be barred. Section 4. This act shall take effect October 1 of the year in which enacted. HOUSE SUMMARY Provides a 12-year statute of repose with respect to actions for product liability or fraud. Provides a government rules defense to a product liability action which provides for a rebuttable presumption against liability under described circumstances. See bill for details.