Amend the bill by striking out the title and substituting the following:

'An Act To Amend the Law Pertaining to Defective or Unreasonably Dangerous Implantable Medical Devices and Pharmaceuticals'

Amend the bill by striking out everything after the enacting clause and before the summary and inserting the following:

'**Sec. 1. 14 MRSA §221,** as enacted by PL 1973, c. 466, §1, is amended to read:

§ 221.Defective or unreasonably dangerous goods

One who sells any goods or products in a defective condition unreasonably dangerous to the user or consumer or to ~~his~~the user's or consumer's property is subject to liability for physical harm ~~thereby~~ caused to a person whom the manufacturer, seller or supplier might reasonably have expected to use, consume or be affected by the goods, or to ~~his~~the user's or consumer's property, if the seller is engaged in the business of selling such a product and it is expected to and does reach the user or consumer without significant change in the condition in which it is sold. This section applies although the seller has exercised all possible care in the preparation and sale of ~~his~~the product and the user or consumer has not bought the product from or entered into any ~~contractural~~contractual relation with the seller. A civil action to enforce this section against a seller of a pharmaceutical or implantable medical device must be commenced within 6 years after the date that both that injury and its cause are known or should have been known by the exercise of reasonable diligence.

As used in this section, the following terms have the following meanings.

1. Implantable medical device. "Implantable medical device" means a medical device that is intended to be surgically or medically introduced into the human body and is intended to remain in the human body after the surgical or medical procedure.

2. Medical device. "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory.

3. Pharmaceutical. "Pharmaceutical" means:

A. Articles recognized as drugs in the official United States Pharmacopeia and National Formulary or other drug compendiums or any supplement to any of them;

B. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;

C. Articles, other than food, intended to affect the structure or any function of the body of humans or other animals; and

D. Articles intended for use as a component of any articles specified in paragraphs A to C.'

SUMMARY

The bill requires a user or consumer who has been injured by defective or unreasonably dangerous goods or products to bring a civil action within 6 years after the date that both that injury and its cause are known or should have been known by the exercise of reasonable diligence. This amendment, which is the majority report of the committee, limits the type of civil actions subject to the 6-year limitation to actions against sellers of pharmaceuticals or implantable medical devices and provides definitions of those terms.