L.D. 1280

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STATE OF MAINE

SENATE

128TH LEGISLATURE

FIRST REGULAR SESSION

SENATE AMENDMENT " " to COMMITTEE AMENDMENT "A" to S.P. 432, L.D. 1280, Bill, "An Act Regarding Generic Drug Pricing"

Amend the amendment in section 5 in §13800 in the 2nd paragraph in the 2nd line (page 1, line 27 in amendment) by striking out the following: "fair market price" and inserting the following: 'a price no greater than the wholesale acquisition cost'

Amend the amendment in section 5 in §13800 by inserting after the 2nd paragraph 2 new paragraphs to read:

'An eligible product developer that receives a drug at a price no greater than the wholesale acquisition cost for that drug pursuant to this section shall charge consumers in this State the same price or less for the drug manufactured by that eligible product developer.

As used in this section, "wholesale acquisition cost" means the manufacturer's list price for a brand-name drug or a generic drug per person per year or course of treatment when sold to wholesalers or direct purchasers in the United States, not including discounts or rebates, for the most recent month for which information is available.'

Amend the amendment by inserting after section 5 the following:

'**Sec. 6. Intent.** The costs of health care in this State are making health care coverage unaffordable for many consumers, increasing health care costs for the State and contributing to a health care crisis in this State. Increased competition in the market for drugs and biological products lowers prescription drug costs for patients and taxpayers. In order for there to be competition in the prescription drug market, developers of generic drugs and biosimilar biological products must be able to obtain quantities of the reference listed drug or biological product with which the generic drug or biosimilar biological product is intended to compete, referred to in this section as "reference samples," for purposes of supporting an application for approval by the United States Food and Drug Administration. Closed distribution systems are impeding generic and biosimilar product developers from obtaining reference samples to conduct necessary testing and otherwise meet requirements for approval of generic and biosimilar drugs and subjecting residents of this State to monopoly drug prices. This Act promotes competition in the market for drugs and biological products by facilitating access to reference samples. Developers of generic drugs and biosimilar biological products are required to act in accordance with

applicable federal law and regulations in the testing of reference samples. The increased sales of reference samples in this State will generate revenue for the State.'

SUMMARY

This amendment requires a drug manufacturer or wholesaler to make a drug available for sale at a price no greater than the wholesale acquisition cost rather than at the fair market price as provided in Committee Amendment "A" and limits the price charged to customers for the drug obtained pursuant to this requirement to no more than the wholesale acquisition cost. This amendment also adds an intent section.

SPONSORED BY: _____

(Senator JACKSON)

COUNTY: Aroostook