L.D. 1280

Date: (Filing No. S-)

LABOR, COMMERCE, RESEARCH AND ECONOMIC DEVELOPMENT

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STATE OF MAINE

SENATE

128TH LEGISLATURE

FIRST REGULAR SESSION

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

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

'An Act To Require Drug Manufacturers To Comply with Federal Law'

Amend the bill in section 4 in subsection 4 in the last line (page 1, line 18 in L.D.) by inserting after the following: "E." the following: 'If the Attorney General prevails in an action under this subsection, the court must order the person to reimburse the State for the Attorney General's costs of prosecuting the action, including reasonable attorney's fees.'

Amend the bill by striking out all of section 5 and inserting the following:

'**Sec. 5. 32 MRSA §13800** is enacted to read:

§13800. Access to distributed drugs

A manufacturer or wholesaler licensed under section 13758 shall make a drug distributed in this State available for sale in this State to an eligible product developer for purposes of conducting testing required to support an application for approval of a drug under the Federal Food, Drug, and Cosmetic Act, Section 505(b) or 505(j) or the licensing of a biological product under the federal Public Health Service Act, Section 351.

The manufacturer or wholesaler licensed under section 13758 shall make the drug available for sale at fair market price and without any restriction that would block or delay the eligible product developer's application in a manner inconsistent with Section 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code, Section 355-1(f)(8) (2016).'

SUMMARY

This amendment, which is the majority report of the committee, clarifies that the bill's requirement that a drug distributed in this State be made available for sale to an eligible

product developer applies only to manufacturers and wholesalers of drugs licensed in this State under the Maine Pharmacy Act. The amendment further requires sale of a drug distributed in this State to eligible product developers at a fair market price for purposes of supporting the eligible product developer's application for approval of a drug under the Federal Food, Drug, and Cosmetic Act, Section 505(b) or 505(j) or the licensing of a biological product under the federal Public Health Service Act, Section 351. The licensed manufacturer or wholesaler may not impose any restriction on the sale that would block or delay the eligible product developer's application in a manner inconsistent with Section 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code, Section 355-1(f)(8) (2016).

The amendment ensures increased competition in the market for drugs and biological products, which will lower the cost of prescription drugs for Maine residents and for the State. Developers of low-cost generic drugs and biosimilar biological products must have access to approved drugs distributed in this State by licensed wholesalers and manufacturers to engage in bioequivalence and biosimilarity testing prior to receiving approval from the Food and Drug Administration, or FDA, for sale of their generic drugs and biosimilar biological products. Federal laws and regulations governing bioequivalence and biosimilarity testing are designed to ensure availability of generic drugs and biosimilar biological products in a timely manner without risking patient safety, even in cases where an FDA-approved drug is subject to risk evaluation and mitigation strategies and elements to assure safe use, or REMS with ETASU, under Section 505-1 of the Federal Food, Drug, and Cosmetic Act, 21 United States Code, Section 355-1 (2016). Wholesalers and manufacturers of FDA-approved drugs have used REMS with ETASU programs imposed by the FDA as excuses for refusing to sell their drugs and biological products to eligible product developers, despite the prohibition in Section 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code, Section 355-1(f)(8) against such use of REMS with ETASU requirements "to block or delay approval" of a new generic drug or biosimilar biological product.