

STATE OF MAINE

—  
IN THE YEAR OF OUR LORD  
TWO THOUSAND AND EIGHTEEN

—  
S.P. 432 - L.D. 1280

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

Be it enacted by the People of the State of Maine as follows:

**Sec. 1.** 32 MRSA §13702-A, sub-§12-A is enacted to read:

**12-A. Eligible product developer.** "Eligible product developer" means a person that seeks to develop an application for the 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.

**Sec. 2.** 32 MRSA §13742-A, sub-§1, ¶¶C and D, as enacted by PL 2007, c. 402, Pt. DD, §19, are amended to read:

C. Engaging in unprofessional conduct by violating any standard of professional behavior, including but not limited to a breach of confidentiality of health care information pursuant to state law, that has been established in the practice for which the licensee is licensed; or

D. Engaging in false, misleading or deceptive advertising; or

**Sec. 3.** 32 MRSA §13742-A, sub-§1, ¶E is enacted to read:

E. Failing to comply with section 13800.

**Sec. 4.** 32 MRSA §13742-A, sub-§4 is enacted to read:

**4. Injunction.** Notwithstanding any other provision of law, the Attorney General may seek injunctive relief against a person who violates subsection 1, paragraph E. 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.

**Sec. 5.** 32 MRSA §§13800 and 13800-A are 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 a price no greater than the wholesale acquisition cost 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).

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.

#### **§13800-A. Liability for product of another; exemption**

A manufacturer or wholesaler licensed under section 13758 is not liable for injuries alleged to have been caused by the failure to include adequate safety warnings on a product's label or by a defect in the product's design if:

**1. Access to distributed drugs.** The manufacturer or wholesaler has made the product distributed in this State available to an eligible product developer in accordance with section 13800; and

**2. Manufactured or sold by another.** The product was not manufactured or sold by that manufacturer or wholesaler.

**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.