General Assembly

Committee Bill No. 48

January Session, 2019

LCO No. **6307**

Referred to Committee on GENERAL LAW

Introduced by:
(GL)

AN ACT REQUIRING MANUFACTURERS OF BRAND NAME PRESCRIPTION DRUGS TO PROVIDE SAMPLES OF SUCH DRUGS TO MANUFACTURERS OF GENERIC PRESCRIPTION DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2019*) (a) As used in this section: (1) "Eligible product developer" means a person who seeks to develop an application for the approval of a drug under subsections (b) and (j) of section 505 of the federal Food, Drug, and Cosmetic Act or the licensing of a biological product under section 351 of the federal Public Health Service Act, and (2) "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.

(b) A manufacturer or wholesaler registered under chapter 417 of the general statutes 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 subsections (b) and (j) of section 505 of the federal Food,

Drug, and Cosmetic Act, or the licensing of a biological product under section 351 of the federal Public Health Service Act. Such manufacturer or wholesaler shall make the drug available for sale at a price not greater than the wholesale acquisition cost of the drug and without any restriction that would block or delay the eligible product developer's application in a manner inconsistent with subdivision (8) of subsection (f) of section 505 of the federal Food, Drug, and Cosmetic Act.

(c) An eligible product developer that receives a drug at a price not greater than the wholesale acquisition cost for such drug pursuant to this section shall charge consumers in this state the same price or less for the drug manufactured by such eligible product developer.

(d) A manufacturer or wholesaler registered under chapter 417 of the general statutes shall not be 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) such manufacturer or wholesaler has made the product distributed in this state available to an eligible product developer in accordance with the provisions of this section, and (2) the product was not manufactured or sold by such manufacturer or wholesaler.

(e) A violation of any of the provisions of subsection (b) or (c) of this section shall be deemed an unfair or deceptive trade practice under subsection (a) of section 42-110b of the general statutes.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2019*	New section

Statement of Purpose:

To promote competition in the prescription drug market by allowing developers of generic drugs and biosimilar products to obtain reference samples.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]

Co-Sponsors: SEN. LOONEY, 11th Dist.

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