



General Assembly

January Session, 2019

Committee Bill No. 48

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:

1 Section 1. (NEW) (*Effective October 1, 2019*) (a) As used in this
2 section: (1) "Eligible product developer" means a person who seeks to
3 develop an application for the approval of a drug under subsections
4 (b) and (j) of section 505 of the federal Food, Drug, and Cosmetic Act
5 or the licensing of a biological product under section 351 of the federal
6 Public Health Service Act, and (2) "wholesale acquisition cost" means
7 the manufacturer's list price for a brand-name drug or a generic drug
8 per person, per year or course of treatment, when sold to wholesalers
9 or direct purchasers in the United States, not including discounts or
10 rebates, for the most recent month for which information is available.

11 (b) A manufacturer or wholesaler registered under chapter 417 of
12 the general statutes shall make a drug distributed in this state available
13 for sale in this state to an eligible product developer for purposes of
14 conducting testing required to support an application for approval of a
15 drug under subsections (b) and (j) of section 505 of the federal Food,

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

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

28 (d) A manufacturer or wholesaler registered under chapter 417 of
 29 the general statutes shall not be liable for injuries alleged to have been
 30 caused by the failure to include adequate safety warnings on a
 31 product's label or by a defect in the product's design if (1) such
 32 manufacturer or wholesaler has made the product distributed in this
 33 state available to an eligible product developer in accordance with the
 34 provisions of this section, and (2) the product was not manufactured or
 35 sold by such manufacturer or wholesaler.

36 (e) A violation of any of the provisions of subsection (b) or (c) of this
 37 section shall be deemed an unfair or deceptive trade practice under
 38 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

GL *Joint Favorable*

JUD *Joint Favorable*

APP *Joint Favorable*

