Senate

General Assembly

File No. 12

January Session, 2021

Substitute Senate Bill No. 262

Senate, March 4, 2021

The Committee on General Law reported through SEN. MARONEY of the 14th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

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, 2021*) (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, 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 manufactured or developed by such manufacturer or wholesaler and 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 by such eligible product developer 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 to such eligible product developer 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 Section 505-1(f)(8) 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 of the eligible product developer 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, 2021*	New section

Statement of Legislative Commissioners:
In line 8, "per" was deleted before "year" for clarity.

GL *Joint Favorable Subst. -LCO*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 22 $	FY 23 $
Consumer Protection, Dept.	GF - Potential Cost	80,071	80,071
State Comptroller - Fringe Benefits[1]	GF - Potential Cost	32,202	32,202

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill results in a potential total cost to the state of $112,273 in FY 22 and FY 23 for one attorney, to the extent the new Connecticut Unfair Trade Practice violation, pursuant to the bill, results in numerous new investigations.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 41.3% of payroll in FY 22 and FY 23.

OLR Bill Analysis

sSB 262

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

SUMMARY

This bill requires state-registered drug manufacturers and wholesalers to make a drug distributed in the state available for sale to an "eligible product developer" for certain purposes at no more than "wholesale acquisition cost." The bill defines an "eligible product developer" as a person that plans to seek drug or biological product approval under certain provisions of the federal Food, Drug, and Cosmetic Act (FDCA) or federal Public Health Service Act (PHSA).

Under the bill, drug manufacturers and wholesalers must make available to these developers the drugs that they manufacture or develop for the purpose of conducting the tests required to support such approval. Manufacturers and wholesalers cannot impose restrictions on these reference sample sales that are inconsistent with FDCA § 505-1(f)(8) and block or delay an eligible product developer's application for drug approval. (For information on these FDCA and PHSA provisions, see BACKGROUND.)

Eligible product developers that obtain drugs at or below wholesale acquisition cost must, when subsequently selling the product that they develop, charge Connecticut consumers the same price or less.

Manufacturers, wholesalers, or eligible product developers that violate the bill's provisions are subject to enforcement action under the Connecticut Unfair Trade Practices Act (CUTPA) (see BACKGROUND). Federal law creates a similar right of action for generic developers that cannot obtain reference samples (see BACKGROUND).

Lastly, the bill specifies that manufacturers and wholesalers that make products available to developers under these provisions are not liable for injuries caused by products they did not manufacture or sell.

EFFECTIVE DATE: October 1, 2021

DUTY TO MAKE AVAILABLE

Under the bill, drug manufacturers and wholesalers must make drugs available to an eligible product developer for the purpose of conducting the tests required to support an application or license under FDCA §§ 505(b) or (j) or PHSA § 351 at no more than the "wholesale acquisition cost." The bill defines this as the manufacturer's list price for a brand-name or generic drug, per person, year, or course of treatment when sold to wholesalers or direct purchasers in the United States, excluding discounts or rebates. The cost calculation is based on the most recent month for which information is available.

LIABILITY

Under the bill, manufacturers and wholesalers that make drugs available to eligible product developers under the bill's provisions are not liable for injuries allegedly caused by the developer's failure to include adequate safety warning labels or by product design defects, if the product was not manufactured or sold by such manufacturer or wholesaler.

BACKGROUND

Connecticut Unfair Trade Practices Act

The law prohibits businesses from engaging in unfair and deceptive acts or practices. CUTPA allows the Department of Consumer Protection commissioner to issue regulations defining what constitutes an unfair trade practice, investigate complaints, issue cease and desist orders, order restitution in cases involving less than $10,000, enter into consent agreements, ask the attorney general to seek injunctive relief, and accept voluntary statements of compliance. It also allows individuals to sue. Courts may issue restraining orders; award actual and punitive damages, costs, and reasonable attorney's fees; and impose

civil penalties of up to $5,000 for willful violations and $25,000 for violation of a restraining order.

FDCA § 505(b) & (j) and PHSA § 351

Sections 505(b) and (j) of FDCA establish abbreviated approval pathways for generic drugs (e.g., by allowing applicants to rely, in part, on data for previously approved drugs). The traditional pathway for new drug approval is also established in § 505(b).

Like FDCA §§ 505(b) and (j), PHSA § 351 includes an abbreviated approval pathway for biologics that are biosimilar to a previously approved biological product.

FDCA § 505-1(f)(8)

Section 505-1(f)(8) prohibits owners of previously approved drugs from imposing certain restrictions on a drug's distribution to block or delay an application submitted pursuant to the abbreviated approval pathways established in FDCA §§ 505(b) and (j).

Federal Private Right of Action to Obtain Reference Samples

In December 2019, a new federal law (P.L. 116-94, § 610) allowed generic drug developers to bring lawsuits in federal court if they cannot obtain brand product (reference) samples needed to support the generic drug application at a price no higher than the drug's wholesale acquisition cost, as defined by federal law.

COMMITTEE ACTION

General Law Committee

Joint Favorable
Yea 16 Nay 3 (02/16/2021)