



# Senate

General Assembly

**File No. 214**

February Session, 2022

Senate Bill No. 188

*Senate, March 30, 2022*

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 bill ought to pass.

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

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

1 Section 1. (NEW) (*Effective October 1, 2022*) (a) As used in this section:

2 (1) "Eligible product developer" means a person who seeks to develop  
3 an application for the approval of a drug under Subsections (b) and (j)  
4 of Section 505 of the federal Food, Drug and Cosmetic Act or the  
5 licensing of a biological product under Section 351 of the federal Public  
6 Health Service Act; and

7 (2) "Wholesale acquisition cost" means the manufacturer's list price  
8 for a brand-name drug or a generic drug per person, year or course of  
9 treatment, when sold to wholesalers or direct purchasers in the United  
10 States, not including discounts or rebates, for the most recent month for  
11 which information is available.

12 (b) A manufacturer or wholesaler registered under chapter 417 of the

13 general statutes shall make a drug manufactured or developed by such  
14 manufacturer or wholesaler and distributed in this state available for  
15 sale in this state to an eligible product developer for purposes of  
16 conducting testing required to support an application by such eligible  
17 product developer for approval of a drug under Subsections (b) and (j)  
18 of Section 505 of the federal Food, Drug and Cosmetic Act, or the  
19 licensing of a biological product under Section 351 of the federal Public  
20 Health Service Act. Such manufacturer or wholesaler shall make the  
21 drug available for sale to such eligible product developer at a price not  
22 greater than the wholesale acquisition cost of the drug and without any  
23 restriction that would block or delay the eligible product developer's  
24 application in a manner inconsistent with Section 505-1(f)(8) of the  
25 federal Food, Drug and Cosmetic Act.

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

30 (d) A manufacturer or wholesaler registered under chapter 417 of the  
31 general statutes shall not be liable for injuries alleged to have been  
32 caused by the failure of the eligible product developer to include  
33 adequate safety warnings on a product's label or by a defect in the  
34 product's design if:

35 (1) Such manufacturer or wholesaler has made the product  
36 distributed in this state available to an eligible product developer in  
37 accordance with the provisions of this section; and

38 (2) The product was not manufactured or sold by such manufacturer  
39 or wholesaler.

40 (e) A violation of any of the provisions of subsection (b) or (c) of this  
41 section shall be deemed an unfair or deceptive trade practice under  
42 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	<i>October 1, 2022</i>	New section

**GL**      *Joint Favorable*

*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 23 \$	FY 24 \$
Consumer Protection, Dept.	GF - Potential Cost	80,071	77,971
State Comptroller - Fringe Benefits <sup>1</sup>	GF - Potential Cost	31,602	31,602

Note: GF=General Fund

**Municipal Impact:** None

**Explanation**

The bill creates a new Connecticut Unfair Trade Practice violation and to the extent this results in numerous new investigations there is a potential total cost to the state of \$111,673 in FY 23 and \$109,573 FY 24 for the Department of Consumer Protection to hire one attorney.

**The Out Years**

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

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<sup>1</sup>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 40.53% of payroll in FY 23.

**OLR Bill Analysis****SB 188*****AN ACT REQUIRING BRAND NAME PRESCRIPTION DRUG MANUFACTURERS TO PROVIDE SAMPLES OF BRAND NAME DRUGS TO GENERIC PRESCRIPTION DRUG MANUFACTURERS.*****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 the drugs that they manufacture or develop available to these developers to conduct the tests required to support these approvals. 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 (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, 2022

### **DUTY TO MAKE AVAILABLE**

Under the bill, drug manufacturers and wholesalers must make drugs available to an eligible product developer to conduct 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 the 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**

A 2019 federal law (P.L. 116-94, § 610) allows 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 11    Nay 7    (03/15/2022)