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)