OLR Bill Analysis
SB 48

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.” An “eligible product developer” is 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 drugs available to such developers 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(f)(8) and block or delay an eligible product developer’s application for drug approval (it appears the bill should instead refer to FDCA § 505-1(f)(8)). (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 (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, 2019

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.” This is the manufacturer’s list price for a brand-name or generic drug, per person, per 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 alleged to have been caused by the failure to include adequate safety warnings on product labels or by product design defects, if the subject 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) 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).

**COMMITTEE ACTION**

General Law Committee

Joint Favorable

Yea 11  Nay 5  (03/21/2019)