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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 746 Session of 2013

INTRODUCED BY CUTLER, GINGRICH, BIZZARRO, COHEN, SWANGER, WATSON, PASHINSKI, MILLARD, PETRI, SAYLOR, C. HARRIS, R. BROWN, GROVE, V. BROWN, STERN, ROSS, LAWRENCE, DeLUCA, K. BOYLE, KORTZ, GRELL, ELLIS, HENNESSEY, DiGIROLAMO, BRIGGS, PEIFER, KAMPF AND MILNE, FEBRUARY 14, 2013

REFERRED TO COMMITEE ON HEALTH, FEBRUARY 14, 2013

AN ACT

Amending the act of November 24, 1976 (P.L.1163, No.259), entitled "An act relating to the prescribing and dispensing of generic equivalent drugs," further providing for definitions, for substitutions, for posting requirements, for powers and duties of Department of Health and for immunity of pharmacists under certain circumstances.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2 of the act of November 24, 1976 (P.L.1163, No.259), referred to as the Generic Equivalent Drug Law, is amended by adding definitions to read:

Section 2. As used in this act:

"Biological product" shall have the same meaning as defined in 42 U.S.C. § 262(i) (relating to regulation of biological products).

"Biosimilar" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. § 262(k).

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"Interchangeable biosimilar" means a biosimilar product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. § 262(k)(4).

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Section 2. Section 3(c) and (d) of the act are amended and the section is amended by adding a subsection to read:

Section 3. * * *

(a.1) A pharmacist may substitute a biosimilar product for a prescribed biological product only if:

(1) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed product for the indicated use.

(2) The prescriber does not designate verbally or in writing on the prescription that substitution is prohibited.

(3) The person presenting the prescription provides written consent for such substitution.

(4) The pharmacist notifies the prescriber in writing and as soon as practicable but no later than 72 hours after dispensing.

(5) The pharmacy and the prescriber retain a written record of the biosimilar substitution for a period of no less than five years.

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(c) Any pharmacist substituting a less expensive drug product or interchangeable biosimilar shall charge the purchaser the regular and customary retail price for the generically equivalent drug or interchangeable biosimilar.

(d) Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product or interchangeable biosimilar for a prescribed brand name drug.

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Section 3. Sections 4 and 5(a) and (b) of the act, amended July 11, 1990 (P.L.509, No.121), are amended to read:

Section 4. (a) Every pharmacy shall post in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign which shall read: "Pennsylvania law permits pharmacists to substitute a less expensive generically equivalent drug or interchangeable biosimilar for a brand name drug unless you or your physician direct otherwise."

(b) Every pharmacy shall post in a conspicuous place, easily accessible to the general public, a list of commonly used generically equivalent drugs and interchangeable biosimilars containing the generic names and brand names where applicable.

(c) Each pharmacy shall have available to the public a price listing of brand name and generic equivalent drug products and interchangeable biosimilars available at the pharmacy for selection by the purchaser.

Section 5. (a) The Department of Health shall have the power and its duty shall be to:

(1) Administer and enforce the provisions of this act.

(2) Adopt necessary regulations consistent with this act.

(3) Publicize the provisions of this act.

(4) Publish by notice in the Pennsylvania Bulletin the addition or deletion of generically equivalent drugs and interchangeable biosimilars and any determination by the secretary to not recognize a generically equivalent drug or interchangeable biosimilar in accordance with subsection (b). The department shall also provide notice that a complete list of generically equivalent drugs and interchangeable biosimilars may

be obtained from the United States Food and Drug Administration. This notice shall be published at least every three months.

(b) The secretary, with the advice of the Pennsylvania Drug, Device and Cosmetic Board, may determine that a drug shall not be recognized as a generically equivalent drug or interchangeable biosimilar for purposes of substitution in Pennsylvania and the time after which recognition shall be restored.

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Section 4. Section 6(a) and (b) of the act are amended to read:

Section 6. (a) No pharmacist complying with the provisions of this act shall be liable in any way for the dispensing of a generically equivalent drug or interchangeable biosimilar unless the generically equivalent drug or interchangeable biosimilar was incorrectly substituted.

(b) In no event when a pharmacist substitutes a drug or interchangeable biosimilar shall the prescriber be liable in any action for loss, damage, injury or death or any person occasioned by or arising from the use of the substituted drug or interchangeable biosimilar unless the original drug was incorrectly prescribed.

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Section 5. This act shall take effect in 60 days.