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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 421 Session of 2009

INTRODUCED BY BROWNE, WASHINGTON, BOSCOLA, ERICKSON, O'PAKE, COSTA, VANCE, RAFFERTY AND FERLO, FEBRUARY 20, 2009

REFERRED TO PUBLIC HEALTH AND WELFARE, FEBRUARY 20, 2009

AN ACT

Amending the act of April 14, 1972 (P.L.233, No.64), entitled "An act relating to the manufacture, sale and possession of controlled substances, other drugs, devices and cosmetics; conferring powers on the courts and the secretary and Department of Health, and a newly created Pennsylvania Drug, Device and Cosmetic Board; establishing schedules of controlled substances; providing penalties; requiring registration of persons engaged in the drug trade and for the revocation or suspension of certain licenses and registrations; and repealing an act," providing for the definitions of "clinical trial" and "pharmaceutical drug" and for drug manufacturer clinical trials reporting; and further providing for prohibited acts and penalties.

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

Section 1. Section 2(b) of the act of April 14, 1972 (P.L. 233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, is amended by adding definitions to read:

Section 2. Definitions.--* * *

(b) As used in this act:

* * *

"Clinical trial" means a clinical investigation as defined by the United States Food and Drug Administration that involves any

experiment to test the safety or efficacy of a drug or biological product with one or more human subjects.

* * *

"Pharmaceutical drug" means any drug which is approved by the United States Food and Drug Administration and commercially available for dispensing with a prescription.

* * *

Section 2. The act is amended by adding a section to read:

Section 6.1. Drug Manufacturer Clinical Trials Reporting.--(a) A manufacturer of a pharmaceutical drug that sells, delivers, offers for sale or gives away any pharmaceutical drug for use within this Commonwealth shall post on a publicly accessible clinical trials registry, including the clinical trials data bank established pursuant to section 402(i) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 282(i)) and developed by the National Library of Medicine, the following information regarding all clinical trials that the manufacturer has conducted or sponsored on each pharmaceutical drug that it sells, delivers, offers for sale or gives away for use within this Commonwealth:

(1) The name of the entity that conducted or is conducting the clinical trial.

(2) A summary of the purposes of the clinical trial.

(3) The dates during which the trial has taken place.

(4) Information concerning the results of the clinical trial, including potential or actual diverse effects of the drug.

(b) A manufacturer of a pharmaceutical drug that sells, delivers, offers for sale or gives away any pharmaceutical drug for use within this Commonwealth that conducts or sponsors a

clinical trial shall register the clinical trial at or before the onset of patient enrollment by providing information necessary for publication in the clinical trials data bank established pursuant to 42 U.S.C. § 282(i) and in a manner as required by regulations or other guidance established by the United States National Library of Medicine or the United States Secretary of Health and Human Services.

(c) Upon annual registration or filing with the secretary under section 6, each manufacturer subject to this section shall submit a report to the secretary certifying that it is in compliance with this section, together with a filing fee of one thousand dollars ($1,000). Fees collected under this subsection shall be used to cover the cost of overseeing the implementation of this section, including maintaining links to publicly accessible Internet websites to which manufacturers are posting clinical trial information under this section and other relevant sites.

(d) The department may adopt rules or regulations to implement this section.

Section 3. Section 13(a) of the act is amended by adding a clause and the section is amended by adding a subsection to read:

Section 13. Prohibited Acts; Penalties.--(a) The following acts and the causing thereof within the Commonwealth are hereby prohibited:

* * *

(39) The failure by a manufacturer of a pharmaceutical drug to submit the results of all clinical trials that have been conducted on each pharmaceutical drug that it sells, delivers, offers for sale or gives away for use within this Commonwealth.

* * *

(g) (1) The Attorney General may bring a civil action to enforce the requirements of section 6.1.

(2) A manufacturer that violates subsection (a)(39) shall be liable for civil penalties of not more than twenty-five thousand dollars ($25,000) per violation.

Section 4. This act shall take effect in 180 days.