

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 339 Session of
2007

INTRODUCED BY BROWNE, BOSCOLA, ORIE, RHOADES, COSTA, ERICKSON,
VANCE, FERLO AND WASHINGTON, MARCH 12, 2007

REFERRED TO PUBLIC HEALTH AND WELFARE, MARCH 12, 2007

AN ACT

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

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

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

20 Section 2. Definitions.--* * *

21 (b) As used in this act:

22 * * *

23 "Clinical trial" means a clinical investigation as defined by

1 the United States Food and Drug Administration that involves any
2 experiment to test the safety or efficacy of a drug or
3 biological product with one or more human subjects.

4 * * *

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

8 * * *

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

10 Section 6.1. Drug Manufacturer Clinical Trials Reporting.--

11 (a) A manufacturer of a pharmaceutical drug that sells,
12 delivers, offers for sale or gives away any pharmaceutical drug
13 for use within this Commonwealth shall post on a publicly
14 accessible clinical trials registry, including the clinical
15 trials database established pursuant to section 402(i) of the
16 Social Security Act (49 Stat. 620, 42 U.S.C. § 282(i)) and
17 developed by the National Library of Medicine, the following
18 information regarding all clinical trials that the manufacturer
19 has conducted or sponsored on each pharmaceutical drug that it
20 sells, delivers, offers for sale or gives away for use within
21 this Commonwealth:

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

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

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

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

29 (b) A manufacturer of a pharmaceutical drug that sells,
30 delivers, offers for sale or gives away any pharmaceutical drug

1 for use within this Commonwealth that conducts or sponsors a
2 clinical trial shall register the clinical trial at or before
3 the onset of patient enrollment by providing information
4 necessary for publication in the clinical trials databank
5 established pursuant to 42 U.S.C. § 282(i) and in a manner as
6 required by regulations or other guidance established by the
7 United States National Library of Medicine or the United States
8 Secretary of Health and Human Services.

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

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

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

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

27 * * *

28 (39) The failure by a manufacturer of a pharmaceutical drug
29 to submit the results of all clinical trials that have been
30 conducted on each pharmaceutical drug that it sells, delivers,

1 offers for sale or gives away for use within this Commonwealth.

2 * * *

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

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

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