

AMENDED IN SENATE JUNE 4, 2007

AMENDED IN SENATE MAY 15, 2007

SENATE BILL

No. 606

Introduced by Senator Scott

(Coauthor: Senator Kuehl)

(Coauthors: Assembly Members Brownley and Ruskin)

February 22, 2007

An act to add Division 112.6 (commencing with Section 130650) to the Health and Safety Code, relating to pharmaceutical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 606, as amended, Scott. Pharmaceutical information: clinical trial data.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services. Effective July 1, 2007, these duties are transferred to the State Department of Public Health.

This bill would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available the results of every completed clinical trial, except a phase I trial, for that drug and an explanation of noncompletion for any clinical trial, except a phase I trial, that the company initiates or sponsors the initiation of, but does not complete.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Division 112.6 (commencing with Section
2 130650) is added to the Health and Safety Code, to read:

3

4 DIVISION 112.6. PHARMACEUTICAL DRUG
5 INFORMATION AND SAFETY ACT

6

7 130650. This division shall be known, and may be cited as the
8 “Pharmaceutical Drug Information and Safety Act.”

9 130651. For purposes of this division, the following definitions
10 shall apply:

11 (a) “Clinical trial” means a *hypothesis testing* clinical
12 investigation ~~as defined by the federal Food and Drug~~
13 ~~Administration that involves any~~ *that involves any* experiment to
14 test the safety or efficacy of a drug or biological product with one
15 or more human subjects.

16 (b) “Pharmaceutical company” means ~~any entity that is engaged~~
17 ~~in the production, preparation, propagation, compounding,~~
18 ~~conversion, or processing of pharmaceutical drugs, either directly~~
19 ~~or indirectly, by means of chemical synthesis or by a combination~~
20 ~~of extraction and chemical synthesis.~~ “Pharmaceutical company”
21 *a manufacturer of pharmaceutical drugs or biological products.*
22 “*Pharmaceutical company*” also means an entity engaged in the
23 packaging, repackaging, labeling, relabeling, or distribution of
24 pharmaceutical drugs. “Pharmaceutical company” also includes a
25 person who engages in pharmaceutical detailing, promotional
26 activities, or other marketing of a pharmaceutical drug in this state
27 on behalf of a pharmaceutical company.

28 (c) “Pharmaceutical drug” means any drug which is approved
29 by the federal Food and Drug Administration and commercially
30 available in the state.

31 (d) “Phase I trial” means the initial studies designed exclusively
32 to determine the metabolic and pharmacologic actions of drugs in
33 humans, and the side effects associated with increasing doses, and
34 to gain early evidence of effectiveness.

35 130652. Any pharmaceutical company that sells, delivers,
36 offers for sale, or gives away any pharmaceutical drug within this
37 state shall make publicly available, in accordance with Section
38 130654, the results of every completed clinical trial, except for a

1 phase I trial, that the company conducts or sponsors on and after
2 ~~January 1, 1997, October 15, 2002~~, for every pharmaceutical drug
3 that the company sells, delivers, offers for sale, or gives away in
4 this state. The information required to be provided with the results
5 shall include, but not be limited to, all of the following:

- 6 (a) The name of the trial.
- 7 (b) Commercial and chemical name of all pharmaceutical drugs
8 tested, including comparator drugs, if any.
- 9 (c) Initiation and completion dates of the trial.
- 10 (d) Purposes of the trial, including the medical condition or
11 conditions studied.
- 12 (e) Outcomes of the trial including all time points at which
13 outcome data were measured.
- 14 (f) Trial funding sources.
- 15 (g) Number of patients initially enrolled in the trial.
- 16 (h) Number of patients completing the trial.
- 17 (i) A list of all specific characteristics used to include and
18 exclude people as trial participants, such as gender, race, age,
19 preexisting health conditions, and an explanation of ~~why each~~
20 ~~characteristic was used to include or exclude patients.~~ *the suitability*
21 *of the trial participant population for the purposes of the study.*
- 22 (j) Names and contact information for principal sponsors of the
23 trial. Contact information shall include at least a telephone number;
24 ~~mailing address, and e-mail address for public inquiry.~~ *and mailing*
25 *address for public inquiry.*
- 26 (k) Names and contact information for principal researchers of
27 ~~the trial. Contact information shall include at least a telephone~~
28 ~~number, mailing address, and e-mail address for public inquiry.~~
29 *the trial.*
- 30 (l) Frequency, severity, and nature of all adverse events
31 experienced by trial participants, including participants that did
32 not complete the trial, for each drug.
- 33 (m) If the study involved a comparison of two or more
34 pharmaceutical drugs, all information regarding the relative
35 efficacy of each drug and the relative frequency, severity, and
36 nature of all adverse events experienced by trial participants,
37 including participants that did not complete the trial.
- 38 (n) If any of the data from the study were published ~~in any form~~
39 *by a clinical trial investigator in a peer-reviewed medical journal*
40 *that summarizes the safety or efficacy results of the clinical trial,*

1 a complete citation and, if available, a hyperlink for each of these
2 publications.

3 ~~(e) If any of the data from the study were published, the name
4 and employer of each author of the study, including “ghostwriters.”
5 For purposes of this section, “employer” shall mean the employer
6 at the time the trial was conducted and the trial results were
7 prepared and published.~~

8 ~~(p) Any financial interest the principal researchers of the study
9 have in the drugs tested or compared in the trial and in the principal
10 sponsors of the trial. For purposes of this section, “financial
11 interest” shall be considered within the time period between when
12 the trial was conducted and the trial results were prepared and
13 published.~~

14 ~~(q)~~
15 ~~(o) The information contained within the package insert
16 approved by the federal Food and Drug Administration for the
17 drug, including any adverse events to the drug. *drug.*~~

18 130653. Any pharmaceutical company that sells, delivers,
19 offers for sale, or gives away any pharmaceutical drug within this
20 state shall make publicly available, in accordance with Section
21 130654, an explanation of noncompletion for any clinical trial,
22 except a phase I trial, that the pharmaceutical company initiates,
23 or sponsors the initiation of, on and after ~~January 1, 1997, October~~
24 ~~15, 2002~~, but does not complete for every pharmaceutical drug
25 that the company sells, delivers, offers for sale, or gives away in
26 this state. The explanation shall state why the clinical trial was
27 terminated and shall include all available information described
28 ~~in subdivisions (a) to (r), inclusive, of Section 130652. Section~~
29 ~~130652.~~

30 130654. (a) The information required pursuant to Sections
31 130652 and 130653 shall be submitted for inclusion on the Web
32 site administered by the National Institutes of Health or on another
33 publicly accessible Web site, or shall be posted on a publicly
34 accessible Web site directly linked to the pharmaceutical
35 company’s primary corporate Web site. For purposes of this
36 section, a Web site is publicly accessible only if it provides free,
37 nonsubscription access to its contents and clearly indicates the
38 location and instructions for downloading the files or information
39 submitted pursuant to this division.

1 (b) If a drug is sold, delivered, offered for sale, or given away
2 within the state prior to January 1, 2008, and has a trial completion
3 or termination date on or before January 2008, the pharmaceutical
4 company shall submit or post the information pursuant to
5 subdivision (a) by ~~April 1, 2008~~ *January 1, 2009*. If a drug is sold,
6 delivered, offered for sale, or given away within the state prior to
7 January 1, 2008, and has a trial completion or termination date
8 after January 2008, the pharmaceutical company shall submit or
9 post the information pursuant to subdivision (a) within ~~90 days~~ *six*
10 *months* of the completion or termination date of the trial.

11 (c) If a drug is sold, delivered, offered for sale, or given away
12 within the state on or after January 1, 2008, the pharmaceutical
13 company shall submit or post the information pursuant to
14 subdivision (a) within ~~90 days~~ *six months* of the date that the drug
15 is first sold, delivered, offered for sale, or given away within the
16 state or within ~~90 days~~ *six months* of the completion or termination
17 date of the trial, whichever is later.

18 (d) *Notwithstanding subdivisions (b) and (c), a pharmaceutical*
19 *company may extend the deadline requirements of these*
20 *subdivisions by not more than six months if both of the following*
21 *occur:*

22 (1) *The compilation and analysis of the data in the clinical trial*
23 *have not been substantially completed by the appropriate deadline*
24 *described in subdivision (b) or (c).*

25 (2) *The pharmaceutical company submits for inclusion on the*
26 *Web site administered by the National Institutes of Health or on*
27 *another publicly accessible Web site, or posts on a publicly*
28 *accessible Web site directly linked to the pharmaceutical*
29 *company's primary corporate Web site, a statement that the*
30 *availability of the information required by this section has been*
31 *delayed, a statement that provides the reasons for the delay, and*
32 *a statement that provides a date when the information is anticipated*
33 *to be made available.*

34 (e) *Notwithstanding subdivisions (b), (c), and (d), a*
35 *pharmaceutical company may extend the deadline requirements*
36 *of these subdivisions if the company submits the results of the*
37 *clinical trial in a peer-reviewed journal for publication. However,*
38 *the extension of these deadline requirements may not extend beyond*
39 *one year from the applicable deadline described in those*

1 subdivisions or 30 days from the date of publication, whichever
2 is earlier.

3 130655. (a) A pharmaceutical company subject to the
4 requirements of this division that complies with a federal law or
5 regulation that requires public disclosure on a Web site of
6 information that is substantially similar to the information required
7 pursuant to this division shall be deemed to be in compliance with
8 this division.

9 (b) No provision of this division shall be construed to require
10 the public disclosure of a trade secret, as defined in Section 3426.1
11 of the Civil Code.

12 130658. Nothing in this division shall constitute a duty by the
13 State Department of Public Health to enforce the implementation
14 of this division.

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17 CORRECTIONS:

18 Text—Page 2.

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