

AMENDED IN SENATE MAY 15, 2007

SENATE BILL

No. 606

Introduced by Senator Scott

(Coauthor: Senator Kuehl)

(Coauthor: ~~Assembly Member Ruskin~~ 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~~ *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 ~~chapter~~ *division*, the following
10 definitions shall apply:

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

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

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

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

33 130652. Any pharmaceutical company that sells, delivers,
34 offers for sale, or gives away any pharmaceutical drug within this
35 state shall make publicly available, in accordance with Section
36 130654, the results of every completed clinical trial, except for a
37 phase I trial, that the company conducts or sponsors *on and after*
38 *January 1, 1997*, for every pharmaceutical drug that the company

1 sells, delivers, offers for sale, or gives away in this state. The
2 information required to be provided with the results shall include,
3 but not be limited to, all of the following:

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

1 (m) If the study involved a comparison of two or more
2 pharmaceutical drugs, all information regarding the relative
3 efficacy of each drug and the relative frequency, severity, and
4 nature of all adverse events experienced by trial participants,
5 including participants that did not complete the trial.

6 ~~(n)~~

7 (n) If any of the data from the study were published in any form,
8 a complete citation and, if available, a hyperlink for each of these
9 publications.

10 ~~(o)~~

11 (o) If any of the data from the study were published, the name
12 and employer of each author of the study, including “ghostwriters.”
13 For purposes of this section, “employer” shall mean the employer
14 at the time the trial was conducted and the trial results were
15 prepared and published.

16 ~~(p)~~

17 (p) Any financial interest the principal researchers of the study
18 have in the drugs tested or compared in the trial and in the principal
19 sponsors of the trial. For purposes of this section, “financial
20 interest” shall be considered within the time period between when
21 the trial was conducted and the trial results were prepared and
22 published.

23 ~~(r) A copy of the package insert for the drug that includes any~~

24 ~~(q) The information contained within the package insert~~
25 ~~approved by the federal Food and Drug Administration for the~~
26 ~~drug, including any adverse events to the drug.~~

27 130653. Any pharmaceutical company that sells, delivers,
28 offers for sale, or gives away any pharmaceutical drug within this
29 state shall make publicly available, in accordance with Section
30 130654, an explanation of noncompletion for any clinical trial,
31 except a phase I trial, that the pharmaceutical company initiates,
32 or sponsors the initiation of, *on and after January 1, 1997*, but
33 does not complete for every pharmaceutical drug that the company
34 sells, delivers, offers for sale, or gives away in this state. The
35 explanation shall state why the clinical trial was terminated and
36 shall include all available information described in subdivisions
37 (a) to (r), inclusive, of Section 130652.

38 130654. (a) The information required pursuant to Sections
39 130652 and 130653 shall be submitted for inclusion on the Web
40 site administered by the National Institutes of Health or on another

1 publicly accessible Web site, or shall be posted on a publicly
2 accessible Web site directly linked to the pharmaceutical
3 company's primary corporate Web site. For purposes of this
4 section, a Web site is publicly accessible only if it provides free,
5 nonsubscription access to its contents and clearly indicates the
6 location and instructions for downloading the files or information
7 submitted pursuant to this division.

8 (b) If a drug is sold, delivered, offered for sale, or given away
9 within the state prior to January 1, 2008, and has a trial completion
10 or termination date on or before January 2008, the pharmaceutical
11 company shall submit or post the information pursuant to
12 subdivision (a) by April 1, 2008. If a drug is sold, delivered, offered
13 for sale, or given away within the state prior to January 1, 2008,
14 and has a trial completion or termination date after January 2008,
15 the pharmaceutical company shall submit or post the information
16 pursuant to subdivision (a) within 90 days of the completion or
17 termination date of the trial.

18 (c) If a drug is sold, delivered, offered for sale, or given away
19 within the state on or after January 1, 2008, the pharmaceutical
20 company shall submit or post the information pursuant to
21 subdivision (a) within 90 days of the date that the drug is first sold,
22 delivered, offered for sale, or given away within the state or within
23 90 days of the completion or termination date of the trial,
24 whichever is later.

25 130658. Nothing in this division shall constitute a duty by the
26 State Department of Public Health to enforce the implementation
27 of this division.