

AMENDED IN SENATE MAY 2, 2006

SENATE BILL

No. 1683

Introduced by Senator Scott

(Coauthors: Senators Chesbro and Ortiz)

*(Coauthors: Assembly Members Frommer, Laird, Lieber, Koretz,
Oropeza, and Pavley)*

February 24, 2006

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 1683, 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.

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 every ~~new initiated and ongoing~~ *on-going* clinical trial *except a phase I trial*, the results of every completed clinical trial, *except a phase I trial*, and an explanation of noncompletion for any uncompleted clinical trial, *except a phase I trial*, that the company conducts or sponsors. The bill would authorize the Director of Health Services to adopt additional reporting requirements and would require each subject company to submit an annual report to the Attorney General that certifies that the company is in compliance with the provisions of the bill. The bill would make violation of its provisions subject to a civil penalty of \$_____.

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

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

1 SECTION 1. (a) The Legislature finds and declares all of the
2 following:

3 (1) Recent scandals involving Vioxx, Celebrex, Paxil, and
4 other medications have demonstrated a need for the state to better
5 protect California consumers taking pharmaceutical products.

6 (2) In some of these scandals, including Vioxx and Paxil, the
7 manufacturers of the drugs had access to clinical trial data
8 demonstrating serious potential adverse side effects or lack of
9 effectiveness, but the manufacturers did not share the data with
10 the general public.

11 (3) The absence of this information hurts consumers both
12 financially and physically. Research by the federal Food and
13 Drug Administration estimates that Vioxx alone may have
14 caused up to 140,000 cases of coronary heart disease in the
15 United States.

16 (4) Articles and editorials in leading medical journals and
17 newspapers have highlighted problems with clinical trial
18 reporting beyond outright data suppression, including: the use of
19 a comparison drug at a dosage that is too low to be effective,
20 making the study drug appear superior; the choice of a
21 comparison drug dosage that is too high, making the study drug
22 appear less toxic; the publication of data only from preferential
23 endpoints; the publication of the same data in multiple articles to
24 increase the data's impact; and the use of ghostwriters paid
25 indirectly or directly by the study sponsor to give the sponsor
26 control over the publication's message.

27 (5) By making sure that all clinical studies on pharmaceutical
28 drugs see the light of day and that the information necessary to
29 understand and critique the studies is available, doctors and other
30 medical professionals will be better equipped to make sound
31 decisions about medicines and patients will be better informed
32 about potential dangers of certain medicines.

33 (b) It is the intent of the Legislature in enacting this act to
34 require pharmaceutical drug companies to make public the

1 results of all clinical trials conducted on their drugs if those drugs
2 are made available to California consumers.

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

5
6 DIVISION 112.6. PHARMACEUTICAL DRUG
7 RIGHT-TO-KNOW ACT
8

9 130650. This division shall be known, and may be cited as
10 the “Pharmaceutical Drug Right-to-Know Act.”

11 130651. For purposes of this chapter, the following
12 definitions shall apply:

13 (a) “Adverse events” means any negative health outcome
14 occurring in a clinical trial subject during the course of the
15 clinical trial.

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

20 (c) “Comparator drug” means an investigational or marketed
21 drug or placebo against which a new drug is being tested and
22 compared.

23 (d) “Completion date” means the date of the last patient visit
24 necessary for completion of the trial or the date of the first
25 publication of any data from the clinical trial, whichever is first.

26 (e) “Initiation date” means date of enrollment for the first
27 patient in a clinical trial.

28 (f) “Pharmaceutical company” means any entity that is
29 engaged in the production, preparation, propagation,
30 compounding, conversion, or processing of pharmaceutical
31 drugs, either directly or indirectly, by means of chemical
32 synthesis or by a combination of extraction and chemical
33 synthesis. “Pharmaceutical company” also means an entity
34 engaged in the packaging, repackaging, labeling, relabeling, or
35 distribution of pharmaceutical drugs. “Pharmaceutical company”
36 also includes a person who engages in pharmaceutical detailing,
37 promotional activities, or other marketing of a pharmaceutical
38 drug in this state on behalf of a pharmaceutical company.

1 (g) “Pharmaceutical drug” means any drug which is approved
2 by the federal Food and Drug Administration and commercially
3 available in the state.

4 (h) *“Phase I trial” means the initial studies designed*
5 *exclusively to determine the metabolism and pharmacologic*
6 *actions of drugs in humans, and the side effects associated with*
7 *increasing doses, and to gain early evidence of effectiveness.*

8 ~~(h)~~

9 (i) “Principal sponsors” means the entity ultimately
10 responsible for funding the trial, the entity ultimately responsible
11 for designing the trial protocol, and the entity who owns the data
12 generated by the trial.

13 ~~(i)~~

14 (j) “Purposes of the trial” means the hypotheses that the trial is
15 testing, including, but not limited to, all of the following:

16 (1) The drug’s effectiveness in treating a specific illness or
17 condition. In this case, the illness or condition shall be named,
18 and what type of effect is being sought shall be specified.

19 (2) The drug’s safety when used to treat a specific illness or
20 condition. In this case, the illness or condition shall be named.

21 (3) The relative effectiveness or relative safety of the drug in
22 treating a specific illness or condition as compared to another
23 drug. In this case, the illness or condition shall be named, and the
24 effect or adverse events to be compared shall be specified.

25 ~~(j)~~

26 (k) “Outcomes of the trial” means the specific measurements
27 that were taken to evaluate the effects the drug and any
28 comparator drug had on trial participants.

29 ~~(k)~~

30 (l) “Outcomes to be tested” means the specific measurements
31 that will be taken to evaluate the effects the drug and any
32 comparator drug have on trial participants.

33 ~~(l)~~

34 (m) “Trial funding sources” means the name of and financial
35 contribution amount for each organization, corporation,
36 individual, or other entity that provides any funding for the
37 clinical trial.

38 130652. Any pharmaceutical company that sells, delivers,
39 offers for sale, or gives away any pharmaceutical drug within this
40 state shall make publicly available, in accordance with Section

1 130655, every ~~new and ongoing clinical trial~~ *initiated and*
2 *on-going clinical trial, except a phase I trial*, that the company
3 conducts or sponsors for every pharmaceutical drug that the
4 company sells, delivers, offers for sale, or gives away in this
5 state. Information required for registration shall include, but not
6 be limited to, all of the following:

- 7 (a) The name of the trial.
- 8 (b) Commercial and chemical name of all pharmaceutical
9 drugs to be tested, including comparator drugs, if any.
- 10 (c) Dosages to be tested for each drug, including dosages of
11 comparator drugs, if any.
- 12 (d) Initiation date and expected completion date of the trial.
- 13 (e) Purposes of the trial, including the medical condition or
14 conditions to be studied.
- 15 (f) Outcomes to be tested, including all time points at which
16 outcome data will be measured.
- 17 (g) Trial funding sources.
- 18 (h) Number of participants to be enrolled *in the trial*.
- 19 (i) A list of all specific characteristics used to include and
20 exclude people as trial participants, such as gender, race, age,
21 preexisting health conditions, and an explanation of why each
22 characteristic was used to include or exclude patients.
- 23 (j) Names and contact information for principal sponsors of
24 the trial. Contact information shall include at least a telephone
25 number, mailing address, and e-mail 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 (l) Any other information required for clinical trial registration
30 by section 113 of the federal Food and Drug Administration
31 Modernization Act of 1997.

32 130653. Any pharmaceutical company that sells, delivers,
33 offers for sale, or gives away any pharmaceutical drug within this
34 state shall make publicly available, in accordance with Section
35 130655, the results of every completed clinical trial, *except a*
36 *phase I trial*, that the company has conducted or sponsored for
37 every pharmaceutical drug that the company sells, delivers,
38 offers for sale, or gives away in this state. Information necessary
39 to meet this requirement shall include, but not be limited to, all of
40 the following:

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

1 (q) Any financial interest the principal researchers of the study
2 have in the drugs tested or compared in the trial and in the
3 principal sponsors of the trial. *For purposes of this section,*
4 *“financial interest” shall be considered within the time period*
5 *between when the trial was conducted and the trials results were*
6 *prepared and published.*

7 (r) How the information regarding adverse events to the study
8 drug is reflected in the package insert for the drug, including
9 direct quotations from the package insert.

10 130654. Any pharmaceutical company that sells, delivers,
11 offers for sale, or gives away any pharmaceutical drug within this
12 state shall make publicly available, in accordance with Section
13 130655, an explanation of noncompletion for any clinical ~~trial~~,
14 *except a phase I trial*, that the manufacturer initiates but does not
15 complete for every pharmaceutical drug that the company sells,
16 delivers, offers for sale, or gives away in this state. Information
17 required for an explanation of noncompletion shall include, but
18 not be limited to, all of the following:

19 (a) The name of the trial.

20 (b) Commercial and chemical name of all pharmaceutical
21 drugs tested, including comparator drugs, *if any*.

22 (c) Dosages tested for each drug including dosages of
23 comparator drugs, if any.

24 (d) Initiation and termination dates of the trial.

25 (e) Purposes of the trial, including the medical condition or
26 conditions studied.

27 (f) Reasons for termination of the trial.

28 (g) Trial funding sources.

29 (h) Number of patients initially enrolled in the trial.

30 (i) Number of patients enrolled in the trial on the termination
31 date.

32 (j) A list of all specific characteristics used to include and
33 exclude people as trial participants, such as gender race, age, and
34 preexisting health conditions and an explanation of why each
35 characteristic was used to include or exclude patients.

36 (k) Names and contact information for principal sponsors of
37 the trial. Contact information shall include at least a telephone
38 number, mailing address, and ~~email~~ *e-mail* address for public
39 inquiry.

1 (l) Names and contact information for principal researchers of
2 the trial. Contact information shall include at least a telephone
3 number, mailing address, and e-mail address for public inquiry.

4 (m) Frequency, severity, and nature of all adverse events
5 experienced by trial participants, *including participants that*
6 *dropped out of the trial for any reason, prior to the termination*
7 *date.*

8 (n) If the study involved a comparison of two or more
9 pharmaceutical drugs, all information regarding the relative
10 efficacy of each drug and the relative frequency, severity and
11 nature of all adverse events experienced by trial participants,
12 including participants that did not complete the trial *prior to the*
13 *termination date*, for each drug.

14 (o) How the information regarding adverse events to the study
15 drug is reflected in the package insert for the drug, including
16 direct quotations from the package insert.

17 130655. The information required pursuant to Sections
18 130652, 130653, and 130654 shall be submitted for inclusion on
19 www.clinicaltrials.gov, the Web site administered by the
20 National Institutes of Health pursuant to section 113 of the
21 federal Food and Drug Administration Modernization Act of
22 1997, or its successor Web site—~~subject,~~ *subject* to all of the
23 following conditions:

24 (a) For clinical trials with a trial initiation date on or after
25 January 1, 2007, the sponsor of the trial shall submit the
26 information required pursuant to Section 130652 to
27 www.clinicaltrials.gov no later than 21 days after the trial's
28 initiation. For ongoing clinical trials with a trial initiation date
29 before January 1, 2007, the sponsor of the trial shall submit the
30 information required pursuant to Section 130652 to
31 www.clinicaltrials.gov on or before January 22, 2007.

32 ~~(b) For clinical trials with a trial completion date on or after~~
33 ~~January 1, 2007, the sponsor of the trial shall submit the~~
34 ~~information required pursuant to Section 130653 to~~
35 ~~www.clinicaltrials.gov on or before 90 days from when the~~
36 ~~pharmaceutical drug is first sold, delivered, or offered for sale, or~~
37 ~~given away in the state.~~

38 (b) *For clinical trials with a trial completion date on or after*
39 *January 1, 2007, the sponsor of the trial shall submit the*
40 *information required pursuant to Section 130653 to*

1 *www.clinicaltrials.gov or its successor Web site no later than 90*
2 *days after the trial's completion. For clinical trials with a*
3 *completion date before January 1, 2007, the sponsor of the trial*
4 *shall submit the information required pursuant to Section 130653*
5 *to www.clinicaltrials.gov or its successor Web site on or before*
6 *April 1, 2007. The publication information required in*
7 *subdivisions (o) and (p) of Section 130653 shall be updated*
8 *promptly no later than 21 calendar days from publication,*
9 *whenever data from the trial have been included in a new*
10 *publication. If the trial was registered when it was initiated, any*
11 *differences between the information reported at that time and the*
12 *information being submitted upon completion shall be*
13 *highlighted and explained.*

14 (c) For clinical trials with a noncompletion date on or after
15 January 1, 2007, the sponsor of the trial shall submit the
16 information required by Section 130654 to
17 *www.clinicaltrials.gov* no later than 21 days after the trial's
18 noncompletion. For clinical trials with a trial noncompletion date
19 before January 1, 2007, the sponsor of the trial shall submit the
20 required information to *www.clinicaltrials.gov* on or before
21 January 22, 2007.

22 130657. All information submitted pursuant to this division
23 shall be in plain English to the maximum extent possible, with
24 the goal of being readily understandable by a person who is not a
25 medical professional.

26 130658. The Director of Health Services may adopt
27 additional reporting requirements and rules for the
28 implementation of this division.

29 130659. On or before February 1 of each year beginning
30 February 1, 2008, each company subject to this division shall
31 submit a report to the Attorney General certifying that it is in
32 compliance with this section and that the information submitted
33 is accurate and complete.

34 130660. Failure by a pharmaceutical company to meet all of
35 the requirements of this division shall be deemed a violation of
36 the law and the pharmaceutical company shall be liable for a civil
37 penalty of ____ dollars (\$____) per violation. Each clinical trial
38 registration required by, and each clinical trial results disclosure
39 required that does not fully comply with, this division shall be
40 considered a separate violation for which the pharmaceutical

- 1 company is liable. Additionally, each day of each violation shall
- 2 be considered a separate violation for which the pharmaceutical
- 3 company is liable.

O