HEALTH AND SAFETY CODE - HSC

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406] *(Division 104 added by Stats. 1995, Ch. 415, Sec. 6.)*

PART 4. DRUGS, DEVICES, AND COSMETICS [109250 - 109590] *(Part 4 added by Stats. 1995, Ch. 415, Sec. 6.)*

CHAPTER 4. Treatment of Cancer and Other Serious Diseases [109250 - 109505] *(Chapter 4 added by Stats. 1995, Ch. 415, Sec. 6.)*

ARTICLE 2. Prohibitions and Enforcement [109300 - 109395] *(Article 2 added by Stats. 1995, Ch. 415, Sec. 6.)*

109300. The sale, offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine, compound, or device to be used in the diagnosis, treatment, alleviation, or cure of cancer is unlawful and prohibited unless (1) an application with respect thereto has been approved under Section 505 of the federal Food, Drug and Cosmetic Act, or (2) there has been approved an application filed with the board setting forth:

(a) Full reports of investigations that have been made to show whether or not the drug, medicine, compound, or device is safe for the use, and whether the drug, medicine, compound, or device is effective in the use;

(b) A full list of the articles used as components of the drug, medicine, compound, or device;

(c) A full statement of the composition of the drug, medicine, compound, or device;

(d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug, medicine, or compound or in the case of a device, a full statement of its composition, properties, and construction and the principle or principles of its operation;

(e) Such samples of the drug, medicine, compound, or device and of the articles used as components of the drug, medicine, compound, or device as the board may require; and

(f) Specimens of the labeling and advertising proposed to be used for the drug, medicine, compound, or device.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109305. Within 180 days after the filing of an application provided for in subdivision (2) of Section 109300 or an additional period as may be agreed upon by the board and the applicant, the board shall either:

(a) Approve the application if it finds that none of the grounds for denying approval specified in Section 109315 applies.

(b) Give the applicant notice for an opportunity for a hearing before the board on the question whether the application is approvable. If the applicant elects to accept the opportunity for hearing by written request within 30 days after the notice, the hearing shall commence not more than 90 days after the expiration of the 30 days unless the board and the applicant otherwise agree. Any hearing shall thereafter be conducted on an expedited basis and the board order thereon shall be issued within 90 days after the date fixed by the board for filing final briefs.

Prior to approving the application or giving the applicant notice for an opportunity for a hearing, the board shall have received a written report from the Cancer Advisory Council setting forth its recommendations on the action the board should take. The report shall be signed by a majority of the members of the council.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109310. In the case of any drug, medicine, compound or device for that an approval of an application filed pursuant to this article and Article 1 (commencing with Section 109250) is in effect, the applicant shall establish and maintain the records, and make the reports to the board, of data relating to clinical experience and other data or information, received or otherwise obtained by the applicant with respect to the drug, medicine, compound, or device, as the board may prescribe on the basis of a finding that the records and reports are necessary in order to enable the board to determine, or facilitate a determination, whether there is or may be ground for suspension of the application.

Every person required under this section to maintain records, and every person in charge of custody thereof, shall, upon request of an agent of the board, permit the agent at all reasonable times to have access to and copy and verify the records.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109315. The board shall issue an order refusing to permit the application to become effective, if, after due notice to the applicant and opportunity for a hearing, the board finds any of the following:

(a) The investigations, reports that are required to be submitted to the board pursuant to subdivision (2) of Section 109300 do not include adequate tests by all methods reasonably applicable to show whether or not a drug, medicine, compound, or device is safe for use in the diagnosis, treatment, alleviation, or cure of cancer.

(b) The results of tests specified in subdivision (a) show that a drug, medicine, compound or device is unsafe for use under the conditions specified in subdivision (a) or do not show that the drug, medicine, compound, or device is safe for use under the conditions.

(c) The methods used in, and the facilities and controls used for, the manufacture, processing, and packing of a drug, medicine, compound, or device are inadequate to preserve its identity, strength, quality, and purity and with respect to a device are inadequate to preserve its safety or effectiveness.

(d) Upon the basis of the information submitted to it as part of the application, or upon the basis of any other information before it with respect to a drug, medicine, compound, or device, it has insufficient evidence to determine whether the drug, medicine, compound, or device is safe for use under the conditions specified in subdivision (a).

(e) Evaluated on the basis of the information submitted to it as part of the application and any other information before it with respect to the drug, medicine, compound, or device, there is a reasonable doubt that the drug, medicine, compound, or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling or advertising thereof.

(f) The application contains any untrue statement of a material fact.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109320. (a) The board shall issue an order withdrawing approval of an application concerning any drug, medicine, compound, or device if, after due notice to the applicant and opportunity for a hearing, the board finds any of the following:

(1) That clinical or other experience, tests, or other scientific data show that the drug, medicine, compound, or device is unsafe for use under the conditions of use upon the basis that the application was approved;

(2) That new evidence of clinical experience, not contained in the application or not available to the board until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available to the board when the application was approved, shows that the drug, medicine, compound, or device is not shown to be safe for use under conditions of use upon the basis that the application was approved; or

(3) On the basis of new information with respect to the drug, medicine, compound, or device, evaluated together with the evidence available to the board when the application was approved, that there is a lack of substantial evidence that the drug, medicine, compound, or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or advertising thereof; or

(4) That the application contains any untrue statement of a material fact.

(b) If the board finds that there is an imminent hazard to the public health, it may suspend the approval of the application immediately.

(c) The board may also, after due notice and opportunity for hearing, withdraw the approval of an application with respect to any drug, medicine, compound, or device under this section if the board finds any of the following:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain the records or to make required reports, or the applicant has refused to permit access to, or copying or verification of, the records.

(2) That on the basis of new information before the board, evaluated together with the evidence before it when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, maintenance, processing, and packing of the drug, medicine, compound, or device are inadequate to assure and preserve its identity, strength, quality, and purity

and with respect to a device are inadequate to preserve its safety or effectiveness and were not made adequate within a reasonable time after receipt of written notice from the board specifying the matter complained of.

(3) That on the basis of new information before it, evaluated together with the evidence before it when the application was approved, the labeling of the drug, medicine, compound, or device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the board specifying the matter complained of.

(d) Any order under this section shall state the findings upon which it is based.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109325. This article and Article 1 (commencing with Section 109250) shall not apply to the use of any drug, medicine, compound, or device intended solely for legitimate and bona fide investigational purposes by experts qualified by scientific training and experience to investigate the safety and therapeutic value thereof unless the department shall find that the drug, medicine, compound, or device is being used in diagnosis or treatment for compensation and profit. In order to qualify for an exemption under this section there shall be on file with the federal Department of Health, Education, and Welfare a current and unrevoked investigational new drug application issued pursuant to subdivision (i) of Section 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)), or the following conditions shall be complied with:

(a) The label of the drug, medicine, compound, or device shall bear the statement “Caution: New drug (or medicine or compound or device). Use in the diagnosis, treatment, alleviation, or cure of cancer limited by law to investigational use.”

(b) The drug, medicine, compound, or device has had adequate testing on appropriate experimental animals to demonstrate a lack of toxicity and hazard sufficient to permit its use in or on human beings and to establish with clarity the margins of safety ordinarily recognized by experts qualified by scientific training and experience to investigate the safety and effectiveness of the drugs, substances, or devices.

(c) The drug, medicine, compound, or device is to be used solely for investigational use by, or under the direction of, an expert qualified by scientific training and experience to investigate the safety and effectiveness of the drug, medicine, compound, or device.

(d) A written statement signed by the expert has been filed with the board. The statement shall show what facilities the expert will use for the investigation to be conducted by him or her, and that the drug, medicine, compound, or device will be used solely by him or her or under his or her direction for the investigation. The statement shall contain information identifying any assistant or agent of the expert who uses the drug, medicine, compound, or device under the direction of the expert.

(e) Complete records of the investigation shall be kept by the expert and all records shall be made available by the expert for inspection upon the request of any agent of the board at any reasonable hour as long as the expert desires exemption.

(f) The expert shall inform any persons who participate in the investigation as patients, that the drug, medicine, compound, or device is being used for investigational purposes and shall obtain the consent of the persons or their representatives.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109330. Section 109300 does not apply to any device used within the scope of his or her license privileges by a physician and surgeon or dentist licensed as such in this state.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109335. The failure of any individual, person, firm, association, or other entity representing himself, or itself, as engaged in the diagnosis, treatment, alleviation, or cure of cancer to comply with any of the regulations adopted under this article and Article 1 (commencing with Section 109250) is a misdemeanor. A third, and subsequent violations, of this section is a felony, punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code.

This article and Article 1 (commencing with Section 109250) shall not apply to any person who depends exclusively upon prayer for healing in accordance with the teachings of a bona fide religious sect, denomination, or organization, nor practitioner thereof.

(Amended by Stats. 2011, Ch. 15, Sec. 199. (AB 109) Effective April 4, 2011. Operative October 1, 2011, by Sec. 636 of Ch. 15, as amended by Stats. 2011, Ch. 39, Sec. 68.)

109340. The investigation or testing of any product shall not be deemed to imply or indicate any endorsement of the qualifications or value of any product. No person shall make any representation that investigation or testing hereunder constitutes any approval or endorsement of his or her, or its, activities by the Cancer Advisory Council or the department. The investigation or testing of any product shall not be deemed to imply or indicate that the product is useless or harmful and during testing no person shall make any representation, except to the department or Cancer Advisory Council, that the product under test is discredited or that it has been found useless or harmful.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109345. Following an investigation or testing of the content or composition of any drug, medicine, compound, or device used by any individual, person, firm, association, or other entity in the diagnosis, treatment, alleviation, or cure of cancer, and after hearing as provided in Section 109270, the department, upon recommendation of the Cancer Advisory Council, may direct that any individual, person, firm, association, or other entity shall cease and desist any further prescribing, recommending, or use of any drug, medicine, compound, or device, or any substantially similar drug, medicine, compound, or device, in the diagnosis or treatment of cancer.

In the investigation or testing required by this article and Article 1 (commencing with Section 109250) to determine the value or lack thereof of any drug, medicine, compound or device in the diagnosis, treatment, or cure of cancer, the department shall, as it deems necessary or advisable, utilize the facilities and findings of its own laboratories or other appropriate laboratories, clinics, hospitals, and nonprofit cancer research institutes recognized by the National Cancer Institute, within this State or the facilities and findings of the Federal Government, including the National Cancer Institute. Upon a recommendation by the Cancer Advisory Council, the department shall arrange, by contract, for investigation by and submission to it of findings, conclusions, or opinions of trained scientists in the appropriate departments of universities, medical schools, clinics, hospitals, and nonprofit cancer research institutes recognized by the National Cancer Institute, and the submission to it of findings, conclusions, or opinions of other qualified scientists. Prior to the issuance of a cease and desist order under this section, the Cancer Advisory Council, by the affirmative vote of at least 11 of its members, at least one of whom shall not be a physician and surgeon, shall make a written finding of fact based on the investigation that the drug, medicine, compound, or device so investigated has been found to be either definitely harmful or of no value in the diagnosis, treatment, alleviation, or cure of cancer and the department must be satisfied beyond a reasonable doubt that the written findings of the fact are true.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109350. The department may direct that any individual, person, firm, association, or other entity shall cease and desist any further prescribing, recommending, or use of any drug, medicine, compound, or device for which no application has been approved under this article and Article 1 (commencing with Section 109250) unless its use is exempt under Section 109325 or 109330.

(Amended by Stats. 2006, Ch. 538, Sec. 423. Effective January 1, 2007.)

109355. (a) Any violation of this article and Article 1 (commencing with Section 109250), of the regulations adopted thereunder or of a cease and desist order issued by the department under Section 109345 or 109350 may be enjoined by the superior court in any county, on application of the department.

(b) Proceedings under this section shall be governed by Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109360. Any person against whom an injunction or cease and desist order has been issued, under this article and Article 1 (commencing with Section 109250), may not undertake to use in the diagnosis, treatment, alleviation, or cure of cancer any new, experimental, untested, or secret drug, medicine, compound, or device for which there is no approved application on file or that does not qualify for an exemption, without first submitting an application to the department.

(Amended by Stats. 2006, Ch. 538, Sec. 424. Effective January 1, 2007.)

109365. It is unlawful for any person, with the intent to defraud, to falsely represent and provide for compensation a device, substance, method or treatment as effective to diagnose, arrest, prevent, or cure cancer. Nothing in this section shall abridge the existent rights of the press.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109370. Except as provided in Section 109335, a violation of this article and Article 1 (commencing with Section 109250) is punishable by imprisonment in the county jail for a period not exceeding one year, or in the state prison, or by a fine not exceeding ten thousand dollars ($10,000), or by both the imprisonment and fine.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109375. The director shall investigate possible violations of this article and Article 1 (commencing with Section 109250) and report violations to the appropriate enforcement authority.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109380. County health officers, district attorneys and the Attorney General shall cooperate with the director in the enforcement of this article and Article 1 (commencing with Section 109250).

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109385. The department, upon recommendation of the Cancer Advisory Council, may from time to time publish reports based on its investigation or testing of any drug, medicine, compound, or device prescribed, recommended, or used by any individual, person, firm, association, or other entity, and when, in the opinion of a majority of the members of the Cancer Advisory Council, the use of any drug, medicine, compound, or device in the diagnosis, treatment or cure of cancer constitutes an imminent danger to health or a gross deception of the public, the department may take appropriate steps to publicize the same.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109390. All hearings authorized by this article and Article 1 (commencing with Section 109250) shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1, Division 3, Title 2 of the Government Code.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109395. No provision of this article and Article 1 (commencing with Section 109250) shall preclude reconsideration of an application for use of any drug, medicine, compound or device for the diagnosis, treatment, alleviation or cure of cancer if new evidence or matter is presented to the department and the reconsideration is predicated upon compliance with the applicable sections of the law, and presentation of data developed subsequent to the applicable ruling of the board.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)