AMENDED IN ASSEMBLY JULY 13, 2015

AMENDED IN SENATE MAY 5, 2015

AMENDED IN SENATE APRIL 14, 2015

SENATE BILL No. 149

Introduced by Senator Stone
(Coauthor: Senator Anderson)

January 29, 2015

An act to add Article 4.1 (commencing with Section 111546) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs and devices.

LEGISLATIVE COUNSEL'S DIGEST

SB 149, as amended, Stone. Investigational drugs, biological products, or devices: right to try.

Existing law, the Federal Food, Drug, and Cosmetic Act, prohibits a person from introducing into interstate commerce any new drug unless the drug has been approved by the United States Food and Drug Administration (FDA). Existing law requires the sponsor of a new drug to submit to the FDA an investigational new drug application and to then conduct a series of clinical trials to establish the safety and efficacy of the drug in human populations and submit the results to the FDA in a new drug application.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of drugs and devices and is administered by the State Department of Public Health. A violation of that law is a crime. The Sherman Food, Drug, and Cosmetic Law prohibits, among other things, the sale, delivery, or giving away of a new drug or new device unless either the department has approved a

new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the Federal Food, Drug, and Cosmetic Act.

The Medical Practice Act provides for the licensure and regulation of physicians and surgeons by the Medical Board of California and requires the board to take action against a licensee who is charged with unprofessional conduct. The Osteopathic Act provides for the licensure and regulation of osteopathic physicians and surgeons by the Osteopathic Medical Board of California and requires the board to enforce the Medical Practice Act with respect to its licensees.

This bill, among other things, would permit a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with ~~a terminal disease,~~ *an immediately life-threatening disease or condition,* as specified. ~~The bill would require a manufacturer that provides an investigational drug, biological product, or device to an eligible patient to report specified data to the State Department of Public Health.~~ The bill would provide that the act does not require a health benefit plan, as defined, or governmental agency to provide coverage for the cost of any investigational drug, biological product, or device made available pursuant to these provisions, but would authorize a health benefit plan to provide coverage for an investigational drug, biological product, or device. The bill would also prohibit the Medical Board of California and the Osteopathic Medical Board of California from taking any disciplinary action against the license of a physician based solely on the physician's recommendation to an eligible patient regarding, or prescription for, or treatment with, an investigational drug, biological product, or ~~device.~~ *device if the recommendation or prescription is consistent with protocol approved by the physician's institutional review board or an accredited institutional review board, and would require the institutional review board to biannually report specified information to the State Department of Public Health, among others.*

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

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

SECTION 1. Article 4.1 (commencing with Section 111546) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 4.1. Right to Try Act

111546. This article shall be known and may be cited as the Right to Try Act.

111546.1. In this article, unless the context otherwise requires, the following definitions shall apply:

(a) "Consulting physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act who performs all of the following:

(1) Examines the qualified individual and his or her relevant medical records.

(2) Confirms, in writing, the physician's diagnosis and prognosis.

(3) Verifies, in the opinion of the consulting physician, that the eligible patient is competent, acting voluntarily, and has made an informed decision.

~~(a)~~

(b) "Eligible patient" means a person to whom all of the following conditions apply:

(1) He or she has ~~a terminal disease as determined by that person's physician and a consulting physician.~~ *an immediately life-threatening disease or condition.*

(2) His or her physician has determined that the person has no comparable or satisfactory United States Food and Drug Administration approved treatment options available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug, biological product, or device is not greater than the probable risk from the disease or condition.

(3) He or she has received a prescription or recommendation from his or her physician for an investigational drug, biological product, or device.

(4) He or she has given written informed consent for the use of the investigational drug, biological product, or device, or if he or she is a minor or lacks the capacity to provide informed consent, his or her parent, legal guardian, or legally authorized representative has given written informed consent on his or her behalf.

(5) He or she has documentation from his or her physician that the patient has met the requirements of this subdivision.

~~(b)~~

(c) "Health benefit plan" means any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of this code, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer.

~~(c)~~

(d) "Health facility" has the same meaning as in Section 1250.

(e) "Immediately life-threatening disease or condition" means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months.

~~(d)~~

(f) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial approved by the United States Food and Drug Administration, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

~~(e)~~

(g) "Physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act, and who is providing medical care or treatment to the eligible patient for the ~~terminal illness,~~ *immediately life-threatening disease or condition,* but does not include a primary care physician.

~~(f)~~

(h) "State regulatory board" means the Medical Board of California or the Osteopathic Medical Board of California.

~~(g) "Terminal disease" means an incurable and irreversible disease that has been medically confirmed and will, according to reasonable medical judgment, result in death within six months of diagnosis.~~

(i) (1) "Written, informed consent" means a written document that has been approved by the physician's institutional review board or an accredited independent institutional review board, is signed by an eligible patient, or his or her legally authorized representative when the patient lacks the capacity to consent, and is attested to by the patient's physician and a witness that, at a minimum, does all of the following:

(A) Explains the currently approved products and treatments for the immediately life-threatening disease or condition from which the patient suffers.

(B) Attests to the fact that the patient, or his or her legally authorized representative when the patient lacks the capacity to consent, concurs with the patient's physician in believing that all existing approved and conventionally recognized treatments are unlikely to prolong the patient's life.

(C) Clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

(D) Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device and describes the most likely outcome. This description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(E) Clearly states that the patient's health benefit plan, if any, and health care provider are not obligated to pay for the investigational drug, biological product, or device or any care or treatments consequent to use of the investigational drug, biological product, or device.

(F) Clearly states that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.

(G) Clearly states that in-home health care may be denied if treatment begins.

(H) States that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device, and that this liability extends to the patient's estate, except as otherwise provided in the patient's health benefit plan or a contract between the patient and the manufacturer of the drug, biological product, or device.

(2) Written, informed consent for purposes of this article shall be consistent with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

111546.2. (a) Notwithstanding Section 110280, 111520, or 111550, a manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to an eligible patient pursuant to this article. This article does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may do any of the following:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(2) Require an eligible patient to pay the costs of or associated with the manufacture of the investigational drug, biological product, or device.

(3) Require an eligible patient to participate in data collection relating to the use of the investigational drug, biological product, or device.

(c) (1) Except as otherwise required by law, this article does not require a health benefit plan or any state agency to provide coverage for the cost of any investigational drug, biological product, or device.

(2) A health benefit plan may provide coverage for an investigational drug, biological product, or device.

(d) If the clinical trial for an investigational drug, biological product, or device is closed due to the lack of efficacy or for toxicity, the investigational drug, biological product, or device shall not be offered. If notice of closure of a clinical trial is given for an investigational drug, biological product, or device taken by an eligible patient outside of a clinical trial, the manufacturer and the patient's physician shall notify the patient of the information from the safety committee of the clinical trial.

111546.3. (a) Notwithstanding any other law, a state regulatory board shall not revoke, fail to renew, or take any other disciplinary action against a physician's license based solely on the physician's recommendation to an eligible patient regarding, or prescription for, or treatment with, an investigational drug, biological product, or device ~~pursuant to this article.~~ *if the recommendation or prescription is consistent with protocol approved by the physician's institutional review board or an accredited independent institutional review board.*

(b) Notwithstanding any other law, a state agency shall not take any action against a health facility's license based solely on the facility's participation in the treatment by or use of an investigational drug, biological product, or device pursuant to this article.

(c) A violation of this article shall not be subject to Chapter 8 (commencing with Section 111825).

(d) This article does not create a private cause of action against a manufacturer of an investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, for any harm to the eligible patient resulting from the investigational drug, biological product, or device so long as the manufacturer or other person or entity complies in good faith with the terms of this article and exercises reasonable care.

111546.4. (a) ~~A manufacturer that provides an investigational drug, biological product, or device to an eligible patient pursuant to Section 111546.2 shall~~ *A physician's institutional review board or an accredited institutional review board shall biannually* report all of the following information to the State Department of Public ~~Health:~~ *Health, the Medical Board of California, and the Osteopathic Medical Board of California:*

(1) The number of requests made for an investigational drug, biological product, or device.

(2) The number of requests that were approved.

(3) The duration of treatments.

(4) The success or failure of the investigational drug, biological product, or device in treating the ~~terminal disease~~ *immediately life-threatening disease or condition* with which the eligible patient was diagnosed.

(5) Any adverse event for each investigational drug, biological product, or device.

(6) Costs paid by each eligible patient for each investigational drug.

(7) The *physician and* consulting physician's diagnosis and prognosis, and verification that the eligible patient is competent, acting voluntarily, and has made an informed decision, or that the consulting physician has determined that the person is not an eligible patient.

(b) The information collected shall be confidential and shall be collected in a manner that protects the privacy of the patient, the patient's family, and any medical provider or pharmacist involved with the patient under the provisions of this part.

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