SENATE BILL **No. 715**

Introduced by Senator Anderson

February 27, 2015

An act to add Article 4.3 (commencing with Section 111547) 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 715, as introduced, Anderson. 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 federal 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department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or the drug or device has been approved pursuant to specified provisions of federal law, including the federal Food, Drug, and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 terminal illnesses, as specified. The bill would authorize, but not require, a health benefit plan, as defined, or governmental agency to provide coverage for any investigational drug, biological product, or device made available pursuant to these provisions or the associated costs. The bill would 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, provided that the recommendation or prescription is consistent with medical standards of care. The bill would prohibit a state agency from altering any recommendation made to the federal Centers for Medicare and Medicaid Services regarding a health care provider's certification to participate in the Medicare or Medicaid program based solely on the recommendation from an individual health care provider that an eligible patient have access to an investigational drug, biological product, or device. The bill would prohibit an official, employee, or agent of the state from blocking an eligible patient's access to the investigational drug, biological product, or device pursuant to the bill's provisions.

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 4.3 (commencing with Section 111547) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 4.3. Right to Try Act

111547. This article shall be known and may be cited as the Right to Try Act.

111547.1. In this article, unless the context otherwise requires, the following definitions shall apply:

(a) "Eligible patient" means a person who meets all of the following conditions:

(1) Has a terminal illness, attested to by the eligible patient's treating physician.

(2) Has considered all other treatment options currently approved by the United States Food and Drug Administration.

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

(4) Has given written, informed consent for the use of the investigational drug, biological product, or device, or if he or she lacks the capacity to consent, his or her legally authorized representative has given written informed consent on his or her behalf.

(5) Has documentation from his or her treating physician attesting that the eligible patient has met the requirements of this subdivision.

(b) "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) "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.

(d) "Physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act.

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

(f) "Terminal illness" means progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even

with theadministration of current United States Food and Drug Administration approved and available treatments, and that, without life-sustaining procedures, will soon result in death.

(g) "Written, informed consent" means a written document that is signed by an eligible patient, parent or legal guardian if the eligible patient is a minor, or his or her legally authorized representative if the eligible patient lacks the capacity to consent, and attested to by the eligible patient's physician and a witness that, at a minimum, does all of the following:

(1) Explains the currently approved products and treatments for the terminal illness from which the eligible patient suffers.

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

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

(4) Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device and provides a realistic description of the most likely outcome. This description shall include the possibility that new, unanticipated, different, or worse symptoms may 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 eligible patient's condition.

(5) States that the eligible patient's health benefit plan or third-party administrator, 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, unless otherwise specifically required to do so by law or contract.

(6) States that the eligible patient's eligibility for hospice care may be withdrawn if the eligible patient begins curative treatment with the investigational drug, biological product, or device and that care may be reinstated if the curative treatment ends and the eligible patient meets hospice eligibility requirements.

(7) States that the eligible 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 eligible patient's estate, except as otherwise provided in the eligible patient's health benefit plan or a contract between the eligible patient and the manufacturer of the drug, biological product, or device.

111547.2. (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 both 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.

(c) (1) This article does not expand or otherwise affect the health care coverage required to be provided by a health benefit plan or governmental agency pursuant to the laws of this state.

(2) This article does not expand or otherwise affect the coverage provided under Sections 1370.4 and 1370.6 of this code, Sections 10145.3 and 10145.4 of the Insurance Code, or Sections 14087.11 and 14132.98 of the Welfare and Institutions Code.

(3) A health benefit plan, third-party administrator, if any, or governmental agency may, but is not required to, provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device under this article.

(4) This article does not require any governmental agency to pay costs associated with the use, care, or treatment of an eligible patient with an investigational drug, biological product, or device.

(5) This article does not require a health facility, as described in Section 1250, to provide new or additional services, unless approved by the health facility.

(d) If an eligible patient dies while being treated by an investigational drug, biological product, or device made available pursuant to this article, the eligible patient's heirs are not liable

for any outstanding debt related to the treatment or lack of insurance for the treatment.

111547.3. (a) Notwithstanding any other law, a state regulatory board shall not revoke, fail to renew, suspend, or take any other disciplinary action against a physician's license based solely on the physician's recommendation to an eligible patient regarding, prescription for, or treatment with, an investigational drug, biological product, or device, provided that the recommendation or prescription is consistent with medical standards of care.

(b) A state agency shall not alter any recommendation made to the federal Centers for Medicare and Medicaid Services regarding a health care provider's certification to participate in the Medicare or Medicaid program based solely on the recommendation from an individual health care provider that an eligible patient have access to an investigational drug, biological product, or device.

(c) An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device pursuant to this article. Counseling, advice, or a recommendation consistent with medical standards of care from an individual licensed under Division 2 (commencing with Section 500) of the Business and Professions Code shall not be considered a violation of this section.

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

111547.4. 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 done to the eligible patient resulting from the investigational drug, biological product, or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this article, unless there was a failure to exercise reasonable care.

O