SENATE BILL No. 343

Introduced by Senator Alquist

February 25, 2009

An act to add Section 125293 to the Health and Safety Code, relating to stem cells.

LEGISLATIVE COUNSEL'S DIGEST

SB 343, as introduced, Alquist. Stem cell research: intellectual property standards.

The California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 2, 2004, statewide general election as Proposition 71, establishes the California Institute for Regenerative Medicine (CIRM), the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC) composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute, including, but not limited to, establishing standards applicable to research funded by the institute. Existing law prohibits amendment of Proposition 71 by the Legislature unless the amendment is approved by the voters, or the amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses, and only if the amendment enhances the ability of the institute to further the purposes of the grant and loan programs.

The act provides that the ICOC shall establish standards that require that all grants and loan awards under the act shall be subject to intellectual property agreements that balance the opportunity of the

state to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to ensure that essential medical research is not unreasonably hindered by the intellectual property agreements.

This bill would require that intellectual property standards that the ICOC develops shall include a requirement that each grantee and the licensees of the grantee submit to the CIRM for approval a plan that will afford uninsured Californians access to any drug that is, in whole or in part, the result of research funded by the CIRM, and would require that the plan shall require that the grantees and licensees thereof provide drugs to California state and local government funded programs at one of the three benchmark prices in the California Discount Prescription Drug Program, except when the ICOC adopts a waiver, as specified.

Vote: 70%. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Section 125293 is added to the Health and Safety Code, to read:

125293. (a) The intellectual property standards that the ICOC develops shall include a requirement that each grantee and the licensee of the grantee submit a plan to the California Institute for Regenerative Medicine (CIRM) that will afford uninsured Californians access to any drug that is, in whole or in part, the result of research funded by the CIRM.

(b) The ICOC shall require submission of the plan required by subdivision (a) before a drug is placed into commerce within the United States. The plan shall be subject to the approval of the CIRM, after a public hearing and opportunity for public comment.

(c) (1) Any plan permitted pursuant to subdivision (a) shall require each grantee and any licensee of the grantee that sells drugs that are, in whole or in part, the result of research funded by CIRM to provide those drugs to California state and local government funded programs at one of the three benchmark prices in the California Discount Prescription Drug Program (Division 112 (commencing with Section 130500)), as it exists on January 1, 2008.

(2) Paragraph (1) shall not preclude any public agency from obtaining prices that are lower than the price determined as

described in paragraph (1) through negotiation, bulk purchasing, or any other purchasing arrangement and shall not be construed to conflict with, or preempt, any other provision of state or federal law or regulation that would result in lower drug prices.

(d) For purposes of this section, "drug" includes any article recognized in the United States Pharmacopeia or supplement thereof, the National Formulary, or any supplement thereof, and any article intended for the diagnosis, cure, mitigation, or prevention of disease in humans or animals, or any article intended for use as a component thereof, and shall include therapeutic products, including, but not limited to, blood, blood products, cells, and cell therapies.

(e) Notwithstanding subdivision (c), the ICOC may waive the requirement that grantees and licensees of the grantee provide drugs that are, in whole or in part, the result of research funded by CIRM at one of the three benchmark prices in the California Discount Prescription Drug Program (Division 112 (commencing with Section 130500)), as it exists on January 1, 2008, only when both of the following conditions are met:

(1) Either of the following conditions is met:

(A) The drug shall be used for the diagnosis, cure, mitigation, or prevention of a rare disease or condition, as recognized by the federal Food and Drug Administration under Section 360bb of Title 21 of the United States Code, by individuals who would not otherwise have access to the drug through private insurance or public programs, the number of individuals who will have increased access to the drug represent a significant proportion of the individuals in California who have that rare disease or condition, and the ICOC has made a determination that, in the absence of the waiver, development of the drug will be impeded.

(B) The grantee commits, in writing, to provide expanded access to a drug under its access plan to a class of patients who would not otherwise receive access to the drug, including working uninsured individuals who do not qualify for any public program or private health plan or policy that provides coverage of the drug and the ICOC anticipates that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise accrue to the state through the pricing requirements set forth in subdivision (c).

(2) The ICOC has conducted a public hearing prior to adopting any waiver pursuant to this subdivision.

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