AMENDED IN ASSEMBLY AUGUST 7, 2008

AMENDED IN ASSEMBLY JULY 14, 2008

AMENDED IN ASSEMBLY JUNE 9, 2008

AMENDED IN SENATE APRIL 16, 2008

SENATE BILL No. 1565

Introduced by Senators Kuehl and Runner
(Coauthor: Senator Wiggins)
(Coauthor: Assembly Member Jones)

February 22, 2008

An act to amend Section 125290.60 of, and to add Section 125293 to, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1565, as amended, Kuehl. California Stem Cell Research and Cures Act.

The California Stem Cell Research and Cures Act (the 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 assure 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 any plan subject to that approval shall require that the grantees and licensees thereof provide drugs to ~~publicly~~ *California state and local government* funded programs ~~in California~~ at one of the three benchmark prices in the California Discount Prescription Drug Program, except when the ICOC adopts a waiver, as specified.

The act provides that the CIRM shall have 3 separate scientific and medical working groups, including the Scientific and Medical Research Funding Working Group, which, among other things, shall make grant and loan award recommendations to the ICOC.

Existing law provides that, in order to ensure CIRM funding does not duplicate or supplant existing funding, certain research categories shall not be funded by the CIRM, except when at least ⅔ of a quorum of the members of the Scientific and Medical Research Funding Working Group recommend to the ICOC that such a research proposal is a vital research opportunity.

This bill would, instead, only require a simple majority of a quorum of the members of the Scientific and Medical Research Funding Working Group to recommend to the ICOC that a particular research proposal is a vital research opportunity.

Existing law establishes the Milton Marks “Little Hoover” Commission on California State Government Organization and Economy, a multimember body appointed by the Governor and the Legislature with various duties that include making recommendations

to the Governor and the Legislature to promote efficiency in government operations.

This bill would request the commission to conduct a study of the governance structure of the California Stem Cell Research and Cures Act. This bill would provide that if the commission conducts the study, it shall, by July 1, 2009, submit, to the appropriate committees of each house of the Legislature, a report on the results of the study and recommendations of ways the governance structure of the ICOC could better ensure public accountability and reduce conflicts of interest, consistent with the purposes of Proposition 71, and would require the commission to make the report available to the public.

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 125290.60 of the Health and Safety Code is amended to read:

125290.60. Scientific and Medical Research Funding Working Group

(a) Membership

The Scientific and Medical Research Funding Working Group shall have 23 members as follows:

(1) Seven ICOC members from the 10 disease advocacy group members described in paragraphs (3), (4), and (5) of subdivision (a) of Section 125290.20.

(2) Fifteen scientists nationally recognized in the field of stem cell research.

(3) The Chairperson of the ICOC.

(b) Functions

The Scientific and Medical Research Funding Working Group shall perform the following functions:

(1) Recommend to the ICOC interim and final criteria, standards, and requirements for considering funding applications and for awarding research grants and loans.

(2) Recommend to the ICOC standards for the scientific and medical oversight of awards.

(3) Recommend to the ICOC any modifications of the criteria, standards, and requirements described in paragraphs (1) and (2) above as needed.

(4) Review grant and loan applications based on the criteria, requirements, and standards adopted by the ICOC and make recommendations to the ICOC for the award of research, therapy development, and clinical trial grants and loans.

(5) Conduct peer group progress oversight reviews of grantees to ensure compliance with the terms of the award, and report to the ICOC any recommendations for subsequent action.

(6) Recommend to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. These standards shall mandate periodic reporting by grantees and shall authorize the Scientific and Medical Research Funding Working Group to audit a grantee and forward any recommendations for action to the ICOC.

(7) Recommend its first grant awards within 60 days of the issuance of the interim standards.

(c) Recommendations for Awards

Award recommendations shall be based upon a competitive evaluation as follows:

(1) Only the 15 scientist members of the Scientific and Medical Research Funding Working Group shall score grant and loan award applications for scientific merit. This scoring shall be based on scientific merit in three separate classifications—research, therapy development, and clinical trials, on criteria including the following:

(A) A demonstrated record of achievement in the areas of pluripotent stem cell and progenitor cell biology and medicine, unless the research is determined to be a vital research opportunity.

(B) The quality of the research proposal, the potential for achieving significant research, or clinical results, the timetable for realizing such significant results, the importance of the research objectives, and the innovativeness of the proposed research.

(C) In order to ensure that institute funding does not duplicate or supplant existing funding, a high priority shall be placed on funding pluripotent stem cell and progenitor cell research that cannot, or is unlikely to, receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. In this regard, other research categories funded by the National Institutes of Health shall not be funded by the institute.

(D) Notwithstanding subparagraph (C), other scientific and medical research and technologies and/or any stem cell research proposal not actually funded by the institute under subparagraph

(C) may be funded by the institute if at least a simple majority of a quorum of the members of the Scientific and Medical Research Funding Working Group recommend to the ICOC that the research proposal is a vital research opportunity.

(E) By making the changes to subparagraph (D) by the act adding this subparagraph, the Legislature affirms that the underlying purpose of the ICOC and the institute is to give priority to stem cell research that has the greatest potential for development of therapies and cures.

SEC. 2. 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 subject to subdivision (a) shall include a requirement that 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 shall provide those drugs to ~~publicly~~ *California state and local government* funded programs ~~in California~~ 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 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 has made a determination, before granting a waiver and based on the number of individuals who will have access to the drug and the likely costs of the drug, 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. The ICOC shall provide findings and declarations and documentation to the Legislature substantiating the need for, and the benefits of, a waiver adopted pursuant to this subdivision at least 30 days prior to the public hearing and shall post these documents on its Internet Web site at the time of submission to the Legislature and provide notice to the public that these documents have been posted.

SEC. 3. (a) The Legislature hereby requests the Milton Marks "Little Hoover" Commission on California State Government Organization and Economy to conduct a study of the governance structure of the California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 2, 2004, statewide general election (Proposition 71), including the membership of the Independent Citizen's Oversight Committee and the relative roles of the committee and the California Institute for Regenerative Medicine.

(b) If the commission conducts the study described in subdivision (a), the commission shall, by July 1, 2009, submit to the appropriate committees of each house of the Legislature, a report on the results of the study requested by subdivision (a) and recommendations of ways the governance structure of the Independent Citizen's Oversight Committee could better ensure public accountability and reduce conflicts of interest, consistent with the purposes of Proposition 71. The commission shall make the report available to the public.

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