

AMENDED IN SENATE APRIL 16, 2008

SENATE BILL

No. 1565

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

February 22, 2008

An act 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.

Existing provisions of Proposition 71 provide 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 sell drugs at a price that does not exceed any benchmark price in the California Discount Prescription Drug Program.

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 require the commission to conduct a study of the governance structure of the California Stem Cell Research and Cures Act. This bill would, by July 2, 2009, require the commission to 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:

- 1 SECTION 1. Section 125293 is added to the Health and Safety
- 2 Code, to read:
- 3 125293. (a) The intellectual property standards that the ICOC
- 4 develops shall include a requirement that each grantee and the
- 5 licensee of the grantee submit a plan to the California Institute for

1 Regenerative Medicine (CIRM) that will afford uninsured
2 Californians access to any drug that is, in whole or in part, the
3 result of research funded by the CIRM.

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

8 (c) (1) Any plan subject to subdivision (a) shall include a
9 requirement that each grantee and any licensee of the grantee that
10 sells drugs that are, in whole or in part, the result of research funded
11 by CIRM and that are purchased in California with public funds
12 shall sell those drugs at a price that does not exceed any benchmark
13 price in the California Discount Prescription Drug Program
14 (Division 112 (commencing with Section 130500)), as it exists on
15 January 1, 2008.

16 (2) Paragraph (1) shall not preclude any public agency from
17 obtaining prices that are lower than the price determined as
18 described in paragraph (1) through negotiation, bulk purchasing,
19 or any other purchasing arrangement and shall not be construed
20 to conflict with, or preempt, any other provision of state or federal
21 law or regulation that would result in lower drug prices.

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

30 SEC. 2. (a) The *Milton Marks “Little Hoover”* Commission
31 on California State Government Organization and Economy shall
32 conduct a study of the governance structure of the California Stem
33 Cell Research and Cures Act, an initiative measure approved by
34 the voters at the November 2, 2004, statewide general election
35 (Proposition 71), including the membership of the Independent
36 Citizens Oversight Committee and the relative roles of the
37 committee and the California ~~Council of~~ *Institute for* Regenerative
38 Medicine.

39 (b) By July 2 1, 2009, the commission shall submit, to the
40 appropriate committees of each house of the Legislature, a report

1 on the results of the study required by subdivision (a) and
2 recommendations of ways the governance structure of the
3 Independent ~~Citizens~~ *Citizen's* Oversight Committee could better
4 ensure public accountability and reduce conflicts of interest,
5 consistent with the purposes of Proposition 71. The commission
6 shall make the report available to the public.

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