

AMENDED IN SENATE JULY 2, 2008
AMENDED IN SENATE JUNE 23, 2008
AMENDED IN ASSEMBLY APRIL 3, 2008
AMENDED IN ASSEMBLY MARCH 10, 2008
CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 2381

Introduced by Assembly Member Mullin

February 21, 2008

An act to amend Section 125292.10 of the Health and Safety Code, relating to stem cell research.

LEGISLATIVE COUNSEL'S DIGEST

AB 2381, as amended, Mullin. Stem cell research.

Existing law, the California Stem Cell Research and Cures Act, establishes the Independent Citizen's Oversight Committee (ICOC) and the California Institute for Regenerative Medicine, 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 authorizes the issuance of bonds, not to exceed \$3,000,000,000, for the purpose of funding this research. Existing law requires the ICOC to establish standards that ensure grantees purchase goods and services from California suppliers to the extent possible.

This bill would define "California supplier" for purposes of this act.

The California Stem Cell Research and Cures Act, an initiative measure, provides that the Legislature may amend the non-bond

statutory provisions of that act, to enhance the ability of the California Institute for Regenerative Medicine to further the purposes of the grant and loan programs created by that act, with a 70% vote of each house and compliance with specified procedural requirements.

This bill, which would declare that it enhances the ability of the institute to further the purposes of the grant and loan programs created by that act, would therefore require for passage a 70% vote.

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 125292.10 of the Health and Safety Code
2 is amended to read:

3 125292.10. As used in this chapter and in Article XXXV of
4 the California Constitution, the following terms have the following
5 meanings:

6 (a) “Act” means the California Stem Cell Research and Cures
7 Bond Act constituting Chapter 3 (commencing with Section
8 125290.10) of Part 5 of Division 106 of the Health and Safety
9 Code.

10 (b) “Adult stem cell” means an undifferentiated cell found in a
11 differentiated tissue in an adult organism that can renew itself and
12 may, with certain limitations, differentiate to yield all the
13 specialized cell types of the tissue from which it originated.

14 (c) (1) “California supplier” means any sole proprietorship,
15 partnership, joint venture, corporation, or other business entity that
16 meets any of the following criteria:

17 (A) The owners or policymaking officers are domiciled in
18 California and the permanent, principal office or place of business
19 from which the supplier’s trade is directed or managed is located
20 in California.

21 (B) A business or corporation, including those owned by, or
22 under common control of, a corporation, that meets all of the
23 following criteria:

24 (i) Has owned and operated a manufacturing facility or research
25 facility located in California that researches, develops, builds, or
26 manufactures products for life sciences research, continuously
27 during the five years prior to submitting a bid or proposal to

1 provide supplies to a California Institute of Regenerative Medicine
2 (CIRM) grantee.

3 (ii) Has been licensed by the state on a continuous basis to
4 conduct business within the state during the five years prior to
5 submitting a bid or proposal to provide supplies to a CIRM grantee.

6 (iii) Has continuously employed California residents for work
7 within the state during the five years prior to submitting a bid or
8 proposal to provide supplies to a CIRM grantee.

9 (C) The entity produces, builds, or manufactures a product or
10 products in California and for the specific product or products that
11 are used by CIRM *facilities* grantees.

12 (2) For purposes of qualifying as a California supplier, a
13 distribution or sales management office or facility does not qualify
14 as a manufacturing or research facility.

15 (d) “Capitalized interest” means interest funded by bond
16 proceeds.

17 (e) “Committee” means the California Stem Cell Research and
18 Cures Finance Committee created pursuant to subdivision (a) of
19 Section 125291.40.

20 (f) “Constitutional officers” means the Governor, Lieutenant
21 Governor, Treasurer, and Controller of California.

22 (g) “Facilities” means buildings, building leases, or capital
23 equipment.

24 (h) “Floating-rate bonds” means bonds which do not bear a
25 fixed rate of interest until their final maturity date, including
26 commercial paper notes.

27 (i) “Fund” means the California Stem Cell Research and Disease
28 Cures Fund created pursuant to Section 125291.25.

29 (j) “Grant” means a grant, loan, or guarantee.

30 (k) “Grantee” means a recipient of a grant from the institute.
31 All University of California grantee institutions shall be considered
32 as separate and individual grantee institutions.

33 (l) “Human reproductive cloning” means the practice of creating
34 or attempting to create a human being by transferring the nucleus
35 from a human cell into an egg cell from which the nucleus has
36 been removed for the purpose of implanting the resulting product
37 in a uterus to initiate a pregnancy.

38 (m) “Indirect costs” mean the recipient’s costs in the
39 administration, accounting, general overhead, and general support
40 costs for implementing a grant or loan of the institute. NIH

1 definitions of indirect costs will be utilized as one of the bases by
2 the Scientific and Medical Research Standards Working Group to
3 create a guideline for recipients on this definition, with
4 modifications to reflect guidance by the ICOC and this act.

5 (n) “Institute” means the California Institute for Regenerative
6 Medicine.

7 (o) “Interim standards” means temporary standards that perform
8 the same function as “emergency regulations” under the
9 Administrative Procedure Act (Government Code, Title 2, Division
10 3, Part 1, Chapter 4.5, Sections 11371 et seq.) except that in order
11 to provide greater opportunity for public comment on the
12 permanent regulations, remain in force for 270 days rather than
13 180 days.

14 (p) “Life science commercial entity” means a firm or
15 organization, headquartered in California, whose business model
16 includes biomedical or biotechnology product development and
17 commercialization.

18 (q) “Medical ethicist” means an individual with advanced
19 training in ethics who holds a Ph.D., MA, or equivalent training
20 and who spends or has spent substantial time (1) researching and
21 writing on ethical issues related to medicine, and (2) administering
22 ethical safeguards during the clinical trial process, particularly
23 through service on institutional review boards.

24 (r) “Pluripotent cells” means cells that are capable of
25 self-renewal, and have broad potential to differentiate into multiple
26 adult cell types. Pluripotent stem cells may be derived from somatic
27 cell nuclear transfer or from surplus products of in vitro fertilization
28 treatments when such products are donated under appropriate
29 informed consent procedures. These excess cells from in vitro
30 fertilization treatments would otherwise be intended to be discarded
31 if not utilized for medical research.

32 (s) “Progenitor cells” means multipotent or precursor cells that
33 are partially differentiated but retain the ability to divide and give
34 rise to differentiated cells.

35 (t) “Quorum” means at least 65 percent of the members who
36 are eligible to vote.

37 (u) “Research donor” means a human who donates biological
38 materials for research purposes after full disclosure and consent.

39 (v) “Research funding” includes interdisciplinary scientific and
40 medical funding for basic research, therapy development, and the

1 development of pharmacologies and treatments through clinical
2 trials. When a facility's grant or loan has not been provided to
3 house all elements of the research, therapy development, and/or
4 clinical trials, research funding shall include an allowance for a
5 market lease rate of reimbursement for the facility. In all cases,
6 operating costs of the facility, including, but not limited to, library
7 and communication services, utilities, maintenance, janitorial, and
8 security, shall be included as direct research funding costs. Legal
9 costs of the institute incurred in order to negotiate standards with
10 federal and state governments and research institutions; to
11 implement standards or regulations; to resolve disputes; and/or to
12 carry out all other actions necessary to defend and/or advance the
13 institute's mission shall be considered direct research funding
14 costs.

15 (w) "Research participant" means a human enrolled with full
16 disclosure and consent, and participating in clinical trials.

17 (x) "Revenue positive" means all state tax revenues generated
18 directly and indirectly by the research and facilities of the institute
19 are greater than the debt service on the state bonds actually paid
20 by the General Fund in the same year.

21 (y) "Stem cells" mean nonspecialized cells that have the capacity
22 to divide in culture and to differentiate into more mature cells with
23 specialized functions.

24 (z) "Vital research opportunity" means scientific and medical
25 research and technologies and/or any stem cell research not actually
26 funded by the institute under subparagraph (C) of paragraph (1)
27 of subdivision (c) of Section 125290.60 which provides a
28 substantially superior research opportunity vital to advance medical
29 science as determined by at least a two-thirds vote of a quorum of
30 the members of the Scientific and Medical Research Funding
31 Working Group and recommended as such by that working group
32 to the ICOC. Human reproductive cloning shall not be a vital
33 research opportunity.

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