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:

SECTION 1. Section 125292.10 of the Health and Safety Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

(d) "Capitalized interest" means interest funded by bond proceeds.

(e) "Committee" means the California Stem Cell Research and Cures Finance Committee created pursuant to subdivision (a) of Section 125291.40.

(f) "Constitutional officers" means the Governor, Lieutenant Governor, Treasurer, and Controller of California.

(g) "Facilities" means buildings, building leases, or capital equipment.

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

(i) "Fund" means the California Stem Cell Research and Disease Cures Fund created pursuant to Section 125291.25.

(j) "Grant" means a grant, loan, or guarantee.

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

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

(m) "Indirect costs" mean the recipient's costs in the administration, accounting, general overhead, and general support costs for implementing a grant or loan of the institute. NIH

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

(n) "Institute" means the California Institute for Regenerative Medicine.

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

(p) "Life science commercial entity" means a firm or organization, headquartered in California, whose business model includes biomedical or biotechnology product development and commercialization.

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

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

(s) "Progenitor cells" means multipotent or precursor cells that are partially differentiated but retain the ability to divide and give rise to differentiated cells.

(t) "Quorum" means at least 65 percent of the members who are eligible to vote.

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

(v) "Research funding" includes interdisciplinary scientific and medical funding for basic research, therapy development, and the

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

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

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

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

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

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