

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

February 23, 2007

An act to amend Section 125290.30 of the Health and Safety Code, relating to stem cell research.

LEGISLATIVE COUNSEL'S DIGEST

SB 771, as introduced, Kuehl. Stem cell research standards: licensing revenues.

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 require all awards be subject to intellectual property agreements.

This bill would require that the intellectual property standards include certain requirements, including, but not limited to, the requirement that every award recipient provide the state with 25% of the associated net licensing revenues.

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 125290.30 of the Health and Safety Code
 2 is amended to read:

3 125290.30. Public and Financial Accountability Standards

4 (a) Annual Public Report

5 The institute shall issue an annual report to the public which sets
 6 forth its activities, grants awarded, grants in progress, research
 7 accomplishments, and future program directions. Each annual
 8 report shall include, but not be limited to, the following: the number
 9 and dollar amounts of research and facilities grants; the grantees
 10 for the prior year; the institute’s administrative expenses; an
 11 assessment of the availability of funding for stem cell research
 12 from sources other than the institute; a summary of research
 13 findings, including promising new research areas; an assessment
 14 of the relationship between the institute’s grants and the overall
 15 strategy of its research program; and a report of the institute’s
 16 strategic research and financial plans.

17 (b) Independent Financial Audit for Review by State Controller

18 The institute shall annually commission an independent financial
 19 audit of its activities from a certified public accounting firm, which
 20 shall be provided to the State Controller, who shall review the
 21 audit and annually issue a public report of that review.

22 (c) Citizen’s Financial Accountability Oversight Committee

23 There shall be a Citizen’s Financial Accountability Oversight
 24 Committee chaired by the State Controller. This committee shall
 25 review the annual financial audit, the State Controller’s report and
 26 evaluation of that audit, and the financial practices of the institute.
 27 The State Controller, the State Treasurer, the President pro
 28 Tempore of the Senate, the Speaker of the Assembly, and the
 29 Chairperson of the ICOC shall each appoint a public member of
 30 the committee. Committee members shall have medical

1 backgrounds and knowledge of relevant financial matters. The
2 committee shall provide recommendations on the institute's
3 financial practices and performance. The State Controller shall
4 provide staff support. The committee shall hold a public meeting,
5 with appropriate notice, and with a formal public comment period.
6 The committee shall evaluate public comments and include
7 appropriate summaries in its annual report. The ICOC shall provide
8 funds for the per diem expenses of the committee members and
9 for publication of the annual report.

10 (d) Public Meeting Laws

11 (1) The ICOC shall hold at least two public meetings per year,
12 one of which will be designated as the institute's annual meeting.
13 The ICOC may hold additional meetings as it determines are
14 necessary or appropriate.

15 (2) The Bagley-Keene Open Meeting Act, Article 9
16 (commencing with Section 11120) of Chapter 1 of Part 1 of
17 Division 3 of Title 2 of the Government Code, shall apply to all
18 meetings of the ICOC, except as otherwise provided in this section.
19 The ICOC shall award all grants, loans, and contracts in public
20 meetings and shall adopt all governance, scientific, medical, and
21 regulatory standards in public meetings.

22 (3) The ICOC may conduct closed sessions as permitted by the
23 Bagley-Keene Open Meeting Act, under Section 11126 of the
24 Government Code. In addition, the ICOC may conduct closed
25 sessions when it meets to consider or discuss:

26 (A) Matters involving information relating to patients or medical
27 subjects, the disclosure of which would constitute an unwarranted
28 invasion of personal privacy.

29 (B) Matters involving confidential intellectual property or work
30 product, whether patentable or not, including, but not limited to,
31 any formula, plan, pattern, process, tool, mechanism, compound,
32 procedure, production data, or compilation of information, which
33 is not patented, which is known only to certain individuals who
34 are using it to fabricate, produce, or compound an article of trade
35 or a service having commercial value and which gives its user an
36 opportunity to obtain a business advantage over competitors who
37 do not know it or use it.

38 (C) Matters involving prepublication, confidential scientific
39 research or data.

1 (D) Matters concerning the appointment, employment,
2 performance, compensation, or dismissal of institute officers and
3 employees. Action on compensation of the institute's officers and
4 employees shall only be taken in open session.

5 (4) The meeting required by paragraph (2) of subdivision (b)
6 of Section 125290.20 shall be deemed to be a special meeting for
7 the purposes of Section 11125.4 of the Government Code.

8 (e) Public Records

9 (1) The California Public Records Act, Article 1 (commencing
10 with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the
11 Government Code, shall apply to all records of the institute, except
12 as otherwise provided in this section.

13 (2) Nothing in this section shall be construed to require
14 disclosure of any records that are any of the following:

15 (A) Personnel, medical, or similar files, the disclosure of which
16 would constitute an unwarranted invasion of personal privacy.

17 (B) Records containing or reflecting confidential intellectual
18 property or work product, whether patentable or not, including,
19 but not limited to, any formula, plan, pattern, process, tool,
20 mechanism, compound, procedure, production data, or compilation
21 of information, which is not patented, which is known only to
22 certain individuals who are using it to fabricate, produce, or
23 compound an article of trade or a service having commercial value
24 and which gives its user an opportunity to obtain a business
25 advantage over competitors who do not know it or use it.

26 (C) Prepublication scientific working papers or research data.

27 (f) Competitive Bidding

28 (1) The institute shall, except as otherwise provided in this
29 section, be governed by the competitive bidding requirements
30 applicable to the University of California, as set forth in Article 1
31 (commencing with Section 10500) of Chapter 2.1 of Part 2 of
32 Division 2 of the Public Contract Code.

33 (2) For all institute contracts, the ICOC shall follow the
34 procedures required of the Regents by Article 1 (commencing with
35 Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public
36 Contract Code with respect to contracts let by the University of
37 California.

38 (3) The requirements of this section shall not be applicable to
39 grants or loans approved by the ICOC.

1 (4) Except as provided in this section, the Public Contract Code
2 shall not apply to contracts let by the institute.

3 (g) Conflicts of Interest

4 (1) The Political Reform Act, Title 9 (commencing with Section
5 81000) of the Government Code, shall apply to the institute and
6 to the ICOC, except as provided in this section and in subdivision
7 (e) of Section 125290.50.

8 (A) No member of the ICOC shall make, participate in making,
9 or in any way attempt to use his or her official position to influence
10 a decision to approve or award a grant, loan, or contract to his or
11 her employer, but a member may participate in a decision to
12 approve or award a grant, loan, or contract to a nonprofit entity in
13 the same field as his or her employer.

14 (B) A member of the ICOC may participate in a decision to
15 approve or award a grant, loan, or contract to an entity for the
16 purpose of research involving a disease from which a member or
17 his or her immediate family suffers or in which the member has
18 an interest as a representative of a disease advocacy organization.

19 (C) The adoption of standards is not a decision subject to this
20 section.

21 (2) Service as a member of the ICOC by a member of the faculty
22 or administration of any system of the University of California
23 shall not, by itself, be deemed to be inconsistent, incompatible, in
24 conflict with, or inimical to the duties of the ICOC member as a
25 member of the faculty or administration of any system of the
26 University of California and shall not result in the automatic
27 vacation of either such office. Service as a member of the ICOC
28 by a representative or employee of a disease advocacy organization,
29 a nonprofit academic and research institution, or a life science
30 commercial entity shall not be deemed to be inconsistent,
31 incompatible, in conflict with, or inimical to the duties of the ICOC
32 member as a representative or employee of that organization,
33 institution, or entity.

34 (3) Section 1090 of the Government Code shall not apply to
35 any grant, loan, or contract made by the ICOC except where both
36 of the following conditions are met:

37 (A) The grant, loan, or contract directly relates to services to
38 be provided by any member of the ICOC or the entity the member
39 represents or financially benefits the member or the entity he or
40 she represents.

1 (B) The member fails to recuse himself or herself from making,
2 participating in making, or in any way attempting to use his or her
3 official position to influence a decision on the grant loan or
4 contract.

5 (h) Patent Royalties and License Revenues Paid to the State of
6 California

7 ~~The~~

8 (1) *The ICOC shall establish standards that require that all grants*
9 *and loan awards be subject to intellectual property agreements that*
10 *balance the opportunity of the State of California to benefit from*
11 *the patents, royalties, and licenses that result from basic research,*
12 *therapy development, and clinical trials with the need to assure*
13 *that essential medical research is not unreasonably hindered by*
14 *the intellectual property agreements.*

15 (2) *The standards that the ICOC develops shall do all the*
16 *following:*

17 (A) *Require every recipient of a grant or loan award for*
18 *research to provide to the state 25 percent of the net licensing*
19 *revenues it receives associated with any institute-funded patented*
20 *invention beyond a reasonable revenue threshold that the ICOC*
21 *may establish. Net licensing revenue shall include all forms of*
22 *financial consideration from licensing and shall be defined as*
23 *gross licensing revenues, less patent expenses and reasonable*
24 *payments to inventors.*

25 (B) *Require every recipient of a grant or loan award for*
26 *research to grant exclusive licenses involving institute-funded*
27 *patented inventions relevant to development of therapies, drugs,*
28 *and diagnostics only to organizations that have plans which the*
29 *institute determines will provide substantial access to the resultant*
30 *therapies, drugs, and diagnostics to uninsured Californians. In*
31 *addition, the licensees shall agree to provide to patients whose*
32 *therapies, drugs, and diagnostics will be purchased in California*
33 *with public funds, the therapies, drugs, and diagnostics at the*
34 *federal Medicaid price.*

35 (C) *Require any recipient of a grant or loan award for research*
36 *that commercializes any product that it develops using institute*
37 *funds to agree, as a condition of accepting the funds, to make*
38 *royalty payments to the state equal to 2 to 5 percent of the revenues*
39 *over the life of the product, depending on the level of funds*

1 *provided and contribution of institute-funded patented inventions*
2 *to the development of the product.*

3 (i) Preference for California Suppliers

4 The ICOC shall establish standards to ensure that grantees
5 purchase goods and services from California suppliers to the extent
6 reasonably possible, in a good faith effort to achieve a goal of more
7 than 50 percent of such purchases from California suppliers.

8 SEC. 2. The Legislature finds and declares that this act the
9 ability of the California Institute for Regenerative Medicine to
10 further the purposes of the grant and loan programs created by the
11 California Stem Cell Research and Cures Act within the meaning
12 of Section 8 of that act.

O