

AMENDED IN SENATE MAY 1, 2007
AMENDED IN SENATE APRIL 17, 2007

SENATE BILL

No. 771

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

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 amended, 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 *and would authorize the institute to commission an audit of expenditures to ensure appropriate accounting.*

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.

1 The State Controller, the State Treasurer, the President pro
2 Tempore of the Senate, the Speaker of the Assembly, and the
3 Chairperson of the ICOC shall each appoint a public member of
4 the committee. Committee members shall have medical
5 backgrounds and knowledge of relevant financial matters. The
6 committee shall provide recommendations on the institute's
7 financial practices and performance. The State Controller shall
8 provide staff support. The committee shall hold a public meeting,
9 with appropriate notice, and with a formal public comment period.
10 The committee shall evaluate public comments and include
11 appropriate summaries in its annual report. The ICOC shall provide
12 funds for the per diem expenses of the committee members and
13 for publication of the annual report.

14 (d) Public Meeting Laws

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

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

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

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

33 (B) Matters involving confidential intellectual property or work
34 product, whether patentable or not, including, but not limited to,
35 any formula, plan, pattern, process, tool, mechanism, compound,
36 procedure, production data, or compilation of information, which
37 is not patented, which is known only to certain individuals who
38 are using it to fabricate, produce, or compound an article of trade
39 or a service having commercial value and which gives its user an

1 opportunity to obtain a business advantage over competitors who
2 do not know it or use it.

3 (C) Matters involving prepublication, confidential scientific
4 research or data.

5 (D) Matters concerning the appointment, employment,
6 performance, compensation, or dismissal of institute officers and
7 employees. Action on compensation of the institute's officers and
8 employees shall only be taken in open session.

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

12 (e) Public Records

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

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

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

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

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

31 (f) Competitive Bidding

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

37 (2) For all institute contracts, the ICOC shall follow the
38 procedures required of the Regents by Article 1 (commencing with
39 Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public

1 Contract Code with respect to contracts let by the University of
2 California.

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

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

7 (g) Conflicts of Interest

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

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

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

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

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

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

1 (A) The grant, loan, or contract directly relates to services to
2 be provided by any member of the ICOC or the entity the member
3 represents or financially benefits the member or the entity he or
4 she represents.

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

9 (h) Patent Royalties and License Revenues Paid to the State of
10 California

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

18 (2) The standards that the ICOC develops shall do all the
19 following:

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

28 (B) Require every recipient of a grant or loan award for research
29 to grant exclusive licenses involving institute-funded patented
30 inventions relevant to development of therapies, drugs, and
31 diagnostics only to organizations that have plans which the institute
32 determines will provide substantial access to the resultant therapies,
33 drugs, and diagnostics to uninsured Californians. In addition, the
34 licensees shall agree to provide to patients whose therapies, drugs,
35 and diagnostics will be purchased in California with public funds,
36 any drugs at the federal Medicaid price. A licensee shall not be
37 required to establish a new best price for any drugs that the licensee
38 develops with institute funds in order to comply with this
39 subparagraph. Each licensee shall agree to provide any therapies

1 or diagnostics that are not drugs at the best price for which the
2 licensee provides those therapies or diagnostics to any purchaser.

3 (C) Require any recipient of a grant or loan award for research
4 that commercializes any product that it develops using institute
5 funds to agree, as a condition of accepting the funds, to make
6 royalty payments to the state equal to 2 to 5 percent of the revenues
7 over the life of the product, depending on the level of funds
8 provided and contribution of institute-funded patented inventions
9 to the development of the product.

10 (3) *The institute may commission an audit of any institute*
11 *expenditure and all cofunding calculations to ensure appropriate*
12 *accounting.*

13 (i) Preference for California Suppliers

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

18 SEC. 2. The Legislature finds and declares that this act
19 enhances the ability of the California Institute for Regenerative
20 Medicine to further the purposes of the grant and loan programs
21 created by the California Stem Cell Research and Cures Act within
22 the meaning of Section 8 of that act.