AMENDED IN SENATE FEBRUARY 22, 2005

SENATE BILL No. 18

Introduced by Senator Ortiz
***(Coauthors: Senators Bowen and Chesbro*)**
(Coauthors: Assembly Members Bermudez, Cohn, Jones, Karnette, Laird, and Lieber)

December 6, 2004

An act to amend Sections 125290.30 and 125290.50 of, ~~and~~ to add Chapter 2 (commencing with Section 125330) and Chapter 3 (commencing with Section 125360) to Part 5.5 of Division 106 of*, and to add and repeal Article 4 (commencing with Section 125292.15) of Chapter 3 of Part 5 of Division 106 of*, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

SB 18, as amended, Ortiz. Reproductive health and research.

The California Stem Cell Research and Cures Act, an initiative measure, establishes 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 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.

Existing law provides that the Political Reform Act shall apply to the institute and to the ICOC, with certain exceptions.

This bill would declare that it is the intent of the Legislature that the ICOC define which positions would be subject to the Political Reform Act and that the requirements for the reporting of economic interest be

commensurate with those required of ~~state agency appointees~~ *certain public officials*.

Existing law establishes various working groups to assist the ICOC in the performance of its duties and requires the ICOC to adopt conflict-of-interest rules for these working groups.

This bill would declare that it is the intent of the Legislature that these rules include certain economic disclosure requirements, and that the state open meeting requirements apply to meetings of the working groups.

Existing law requires that a patient provide informed consent prior to the receiving various medical treatments.

This bill would declare that it is the intent of the Legislature that a physician and surgeon, prior to providing assisted oocyte production, as defined, for purposes of donating eggs for medical research or for fertility treatments, obtain written consent from his or her patient and provide to his or her patient a standardized written summary of health and consumer issues that would be developed by the State Department of Health Services.

Existing law requires a physician and surgeon or other health care provider delivering fertility treatment to provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment.

This bill would declare that it is the intent of the Legislature that a physician and surgeon or other health care provider delivering fertility treatment to provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any oocytes (female eggs or egg cells) remaining following the fertility treatment.

Existing law prohibits a person from knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes.

This bill would declare that it is the intent of the Legislature to prohibit human oocytes or embryos from being acquired, sold, received, or otherwise transferred for valuable consideration, and to prohibit payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

This bill, in addition, would declare that it is the intent of the Legislature that every contract, award, grant, loan, or other

arrangement entered into by a state entity that provides state funding or other resources for biomedical research ensure that, among other things, the arrangement does not result in a gift of public funds and that the state is provided a share of the royalties or revenues derived from the development of clinical treatments, products, or services resulting from the research.

Existing law requires the State Auditor to conduct financial and performance audits as directed by statute. Existing law authorizes the State Auditor to conduct these audits of any state agency, local governmental agency, school, special district, or any publicly created entity.

This bill would require the State Auditor to conduct a performance audit of the institute and the ICOC and to provide the audit report to the Legislature by no later than March 31, 2006.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 125290.30 of the Health and Safety Code is amended to read:

125290.30. Public and Financial Accountability Standards

(a) Annual Public Report

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

(b) Independent Financial Audit for Review by State Controller

The institute shall annually commission an independent financial audit of its activities from a certified public accounting

firm, which shall be provided to the State Controller, who shall review the audit and annually issue a public report of that review.

(c) Citizen's Financial Accountability Oversight Committee

There shall be a Citizen's Financial Accountability Oversight Committee chaired by the State Controller. This committee shall review the annual financial audit, the State Controller's report and evaluation of that audit, and the financial practices of the institute. The State Controller, the State Treasurer, the President pro Tempore of the Senate, the Speaker of the Assembly, and the Chairperson of the ICOC shall each appoint a public member of the committee. Committee members shall have medical backgrounds and knowledge of relevant financial matters. The committee shall provide recommendations on the institute's financial practices and performance. The State Controller shall provide staff support. The committee shall hold a public meeting, with appropriate notice, and with a formal public comment period. The committee shall evaluate public comments and include appropriate summaries in its annual report. The ICOC shall provide funds for the per diem expenses of the committee members and for publication of the annual report.

(d) Public Meeting Laws

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

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

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

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

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

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

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

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

(e) Public Records

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

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

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

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

(C) Prepublication scientific working papers or research data.

(f) Competitive Bidding

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

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

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

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

(g) Conflicts of Interest

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

(B) It is the intent of the Legislature that the ICOC define which positions shall be subject to subparagraph (A) and the scope of the reporting required. It is also the intent of the Legislature that requirements for the reporting of economic interest shall be commensurate with those required of ~~state agency appointees~~ *public officials under Section 87200 of the Government Code*.

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

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

(E) The adoption of standards is not a decision subject to this section.

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

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

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

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

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

The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California 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.

(i) Preference for California Suppliers

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

SEC. 2. Section 125290.50 of the Health and Safety Code is amended to read:

125290.50. Scientific and Medical Working Groups General

(a) The institute shall have, and there is hereby established, three separate scientific and medical working groups as follows:

(1) Scientific and Medical Research Funding Working Group.

(2) Scientific and Medical Accountability Standards Working Group.

(3) Scientific and Medical Research Facilities Working Group.

(b) Working Group Members

Appointments of scientific and medical working group members shall be made by a majority vote of a quorum of the ICOC, within 30 days of the election and appointment of the initial ICOC members. The working group members' terms shall be six years except that, after the first six year terms, the members' terms will be staggered so that one-third of the members shall be elected for a term that expires two years later, one-third of the members shall be elected for a term that expires four years later, and one-third of the members shall be elected for a term that expires six years later. Subsequent terms are for six years. Working group members may serve a maximum of two consecutive terms.

(c) Working Group Meetings

Each scientific and medical working group shall hold at least four meetings per year, one of which shall be designated as its annual meeting.

(d) Working Group Recommendations to the ICOC

Recommendations of each of the working groups may be forwarded to the ICOC only by a vote of a majority of a quorum of the members of each working group. If 35 percent of the members of any working group join together in a minority position, a minority report may be submitted to the ICOC. The ICOC shall consider the recommendations of the working groups in making its decisions on applications for research and facility grants and loan awards and in adopting regulatory standards. Each working group shall recommend to ICOC rules, procedures, and practices for that working group.

(e) Conflict of Interest

(1) The ICOC shall adopt conflict of interest rules, based on standards applicable to members of scientific review committees

of the National Institutes of Health, to govern the participation of non-ICOC working group members. It is the intent of the Legislature that these rules include requirements for disclosure of economic interests and public access to economic interest statements that meet or exceed those required of Category 3 Reviewers by the National Academy of Sciences.

(2) The ICOC shall appoint an ethics officer from among the staff of the institute.

(3) Because the working groups are purely advisory and have no final decisionmaking authority, members of the working groups shall not be considered public officials, employees, or consultants for purposes of the Political Reform Act (Title 9 (commencing with Section 81000) of the Government Code), Sections 1090 and 19990 of the Government Code, and Sections 10516 and 10517 of the Public Contract Code.

(f) Working Group Records

All records of the working groups submitted as part of the working groups' recommendations to the ICOC for approval shall be subject to the Public Records Act. Except as provided in this subdivision, the working groups shall not be subject to the provisions of Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, or Article 1 (commencing with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the Government Code.

(g) It is the intent of the Legislature that the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code) apply to all meetings of the working groups.

SEC. 3. Article 4 (commencing with Section 125292.15) is added to Chapter 3 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 4. State Auditor Review

125292.15. (a) The State Auditor shall conduct an audit of the California Institute for Regenerative Medicine established pursuant to Article XXXV of the California Constitution and the Independent Citizens Oversight Committee (ICOC) created pursuant to Section 125290.15.

(b) The State Auditor shall issue and provide the audit report to the Legislature by no later than March 31, 2006.

(c) The State Auditor shall provide to the Chairs of the Senate Health and Human Services Committee, the Assembly Health Committee, and the Joint Legislative Audit Committee an analysis of the auditee's implementation of the recommendations contained in the audit report no later than December 31, 2006. It is the intent of the Legislature, if the results of the analysis warrant further inquiry, that the Joint Legislative Audit Committee direct the State Auditor to conduct additional audit work, as described in this section, and to issue an additional audit report by June 2007. If circumstances continue to warrant additional work, it is the intent of the Legislature that the Joint Legislative Audit Committee direct the State Auditor to issue a third audit report by June 2008.

(d) The audit reports in subdivisions (a) and (c) shall be performance audits and shall include, but not necessary be limited to, all of the following:

(1) A review of the strategic policies and plans developed by the institute and committee.

(2) A review of contracts and grants executed by the institute and the ICOC.

(3) A review of the policies and procedures put in place by the institute and the ICOC regarding treatment of intellectual property rights associated with research funded or commissioned by the institute.

(4) A review of the decisionmaking procedures and policies adopted by the institute and the ICOC, including procedures for open public meetings and disclosure of conflicts of interest on the part of the ICOC and working group members.

(5) A review of medical and ethical policies and standards adopted by the institute and the ICOC for research funded or commissioned by the institute and the ICOC.

(e) In preparing the audit report, as in the case of any other audit, the State Auditor is subject to Section 8545.1 of the Government Code.

(f) This article shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

~~SEC. 3.~~

SEC. 4. Chapter 2 (commencing with Section 125330) is added to Part 5.5 of Division 106 of the Health and Safety Code, to read:

CHAPTER 2. ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES

125330. The following definitions shall apply to this chapter:

(a) "Assisted oocyte production" or "AOP" means pharmaceutically induced manipulation of oocyte production through the use of injectable, also known as nonoral, stimulation drugs for purposes of donating eggs for medical research or for purposes of fertility treatments.

(b) "Department" means the State Department of Health Services.

(c) "Egg cell donor" or "oocyte donor" means an individual who voluntarily gives her eggs or egg cells to another woman for the purpose of conception or gives her eggs or egg cells to another person for the purpose of research or development of medical therapies.

(d) "Oocyte" means a female egg or egg cell.

125335. It is the intent of the Legislature that:

(a) Prior to providing AOP, a physician and surgeon shall provide to his or her patient the standardized written summary of health and consumer issues described in subdivision (b). The failure to provide to a patient this standardized written summary constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) (1) The department, after consultation with the appropriate national medical specialty societies, shall develop a standardized written summary in laymen's language and in several languages, as necessary, regarding health and consumer issues relating to AOP and oocyte donation. The summary shall be printed and made available by the department to physicians and surgeons. The summary shall include, but not be limited to, disclosures concerning the potential risks of AOP and oocyte donation, including the risk of decreased fertility and the risks associated with using the drugs, medications, and hormones prescribed for ovarian stimulation during the AOP or oocyte donation process.

(2) The department shall utilize existing health and consumer guidelines for assisted reproductive technologies developed by national medical societies as the basis for the information contained within the standardized written summary.

125340. It is the intent of the Legislature that prior to providing AOP, a physician and surgeon shall obtain written consent from his or her patient. The failure to obtain written consent from the patient constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

125345. It is the intent of the Legislature that:

(a) A physician and surgeon or other health care provider delivering fertility treatment shall provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any oocytes remaining following the fertility treatment. The failure to provide to a patient this information constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) Any individual to whom information is provided pursuant to subdivision (a) shall be presented with the option of storing any unused oocytes, donating them to another individual, discarding the oocytes, or donating the remaining oocytes for research. When providing fertility treatment, a physician and surgeon or other health care provider shall provide a form to the individual that sets forth advanced written directives regarding the disposition of oocytes. This form shall indicate the time limit on storage of the oocytes at the clinic or storage facility and shall provide, at a minimum, the following choices for disposition of the oocytes based on the following circumstances:

(1) In the event of the death of the individual, the oocytes shall be disposed of by one of the following actions:

(A) Donation for research purposes.

(B) Thawed with no further action taken.

(C) Donation to another couple or individual.

(D) Other disposition that is clearly stated.

(2) In the event of the individual’s decision to abandon the oocytes by request or a failure to pay storage fees, the oocytes shall be disposed of by one of the following actions:

(A) Donation for research purposes.
(B) Thawed with no further action taken.
(C) Donation to another couple or individual.
(D) Other disposition that is clearly stated.

(c) A physician and surgeon or other health care provider delivering fertility treatment shall obtain written consent from any individual who elects to donate oocytes remaining after fertility treatments for research. For any individual considering donating the oocytes for research, to obtain informed consent, the health care provider shall convey all of the following to the individual:

(1) A statement that the oocytes will be used to derive human pluripotent stem cells for research and that the cells may be used, at some future time, for human transplantation research.

(2) A statement that all identifiers associated with the oocytes will be removed prior to the derivation of human pluripotent stem cells.

(3) A statement that donors will not receive any information about subsequent testing on the oocytes or the derived human pluripotent cells.

(4) A statement that derived cells or cell lines, with all identifiers removed, may be kept for many years.

(5) Disclosure of the possibility that the donated material may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any future commercial development.

(6) A statement that the human pluripotent stem cell research is not intended to provide direct medical benefit to the donor.

(7) A statement that oocytes donated will not be transferred to a woman's uterus, will not survive the human pluripotent stem cell derivation process, and will be handled respectfully, as is appropriate for all human tissue used in research.

125350. It is the intent of the Legislature that no human oocyte or embryo may be acquired, sold, received, or otherwise transferred for valuable consideration. For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of oocytes or embryos.

125355. It is the intent of the Legislature that *no* payment in excess of the amount of reimbursement of expenses may be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

~~SEC. 4.~~

SEC. 5. Chapter 3 (commencing with Section 125360) is added to Part 5.5 of Division 106 of the Health and Safety Code, to read:

Chapter 3. Biomedical Research Funding

125360. (a) It is the intent of the Legislature that every contract, award, grant, loan, or other arrangement entered into by a state entity that provides state funding or other resources for biomedical research ensure all of the following:

(1) The contract, award, grant, loan, or other arrangement does not result in a gift of public funds.

(2) Any clinical treatments, products, or services resulting from the biomedical research are made available at affordable costs to low-income residents, including health care and preventive health programs funded in whole or in part by the state and counties that serve low-income residents.

(3) The terms of any loan, lease, or rental arrangement are consistent with market rates.

(4) The state recoups its legal and administrative costs associated with patenting and licensing activities related to the biomedical research.

(5) The state is provided a share of the royalties or revenues derived from the development of clinical treatments, products, or services resulting from the research that is commensurate with its role in the development of the clinical treatments, products, or services.

(6) Any royalties or licensing revenues are used to repay any costs of issuing bonds associated with the biomedical research being funded.

(b) For purposes of this section, “biomedical research” means research that has as its purpose increasing the understanding of human diseases and conditions and improving treatments for these diseases and conditions.

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