2005 California Stem Cell Research-Related Bill Update

Active measures of August 1, 2005

Assembly Concurrent Resolution (ACR) 1 (Negrete McLeod)

Conflict-of-interest and open meetings

- Urges the Independent Citizens' Oversight Committee (ICOC) to adopt robust conflict-of-interest standards for itself and for members of the working groups prior to the award of loans, grants and contracts. These standards should include:
  (1) Requirements that working group members disclose to the ICOC their income and investments in any entity that has sought funding from the institute or that is engaged in biomedical research;
  (2) Requirements that the ICOC provide the disclosures to the State Auditor, who shall be requested to review them and report to the Legislature on whether any of the votes made by these members constituted a conflict of interest that should have required the member to recuse themselves from consideration of an application or standard;
  (3) Requirements that the definition of a "conflict of interest" be defined to include a financial or other interest in an application or standard that is known to the member, including a direct benefit of any amount deriving from an application or standard, or a financial benefit of any type from an applicant institution of over $5,000 per year.
- Strongly urges the ICOC that the these conflict-of-interest standards, open meeting and public record policies, and intellectual property policies, and subsequent standards developed for stem cell research and for the award of bond funds, be developed in compliance with standards set forth in the Bagley-Keene Open Meeting Act and the California Public Records Act.
- Strongly urges the committee to develop policies that provide that the institute, and any working or advisory group appointed to assist the institute is subject to California open meeting and public record laws that are applicable to state agencies, with exceptions to allow for scientific evaluation of any application for research, training, or facility grants, loans, or contracts and consideration of matters relating to patient or medical privacy, intellectual property or work product, prepublication, confidential scientific information, and personnel matters;
- Urges that any working or advisory group that is charged with reviewing and recommending applications for research, training, or facility grants, loans, or contracts shall produce a written summary that shall be a public record of the reasons for recommending or not recommending any application for funding.
- Strongly urges the committee to additionally adopt a policy committing itself, when negotiating or overseeing intellectual property agreements associated with technologies or inventions derived from grants awarded pursuant to the California Stem Cell Research and Cures Act, to seek to ensure that treatments, therapies,

products, and services resulting from or utilizing these technologies and inventions are accessible and affordable to low-income residents, including those residents eligible for state and county-funded health care programs.
- Asks for a report to the Legislature on or before July 15, 2005 regarding implementation of this resolution.

Status: Passed Assembly; passed Senate Health 6/29/05 with amendments; in Senate Appropriations 8/15/05.

Assembly Concurrent Resolution (ACR) 24 (Mullin)
California Council on Science and Technology and ACR 252

- Requests the California Council on Science and Technology to expand the scope of the study approved in ACR 252 in the 2003-04 session to establish a study group to develop recommendations to the Governor and the Legislature on how the state should treat intellectual property made under state contracts, grants, and agreements, to include in the scope of the study contracts, grants, and agreements developed under Proposition 71 and to study how the commercialization of technology developed with taxpayer dollars could generate a public financial benefit.
- Requests the study group to study how the commercialization of technology developed with the investment of taxpayer dollars in the form of contracts and grants could generate some public benefit, including, but not limited to, state revenues, favorable pricing, revenue sharing, and reinvestment into research.
- Requests that the study group develop general guidelines or criteria to define how the state can achieve maximum public benefit from research funded under Proposition 71.
- Requests that the options and recommendations identified by the study for Proposition 71-funded research reflect the constraints posed by the use of tax-exempt bonds for research and represent options and recommendations that are consistent with the goal and intent of using tax-exempt bonds to fund the research, including options and recommendations for achieving accessibility and affordability of treatments, products, and therapies resulting from Proposition 71-funded research.
- Requests that CCST establish a review group to include representatives of bond counsel firms, the Legislative Analyst, the Treasurer, consumer and public interest groups, and foundations engaged in funding biomedical research, to review and comment on the study and options and recommendations for generating public benefit from commercialization of technology developed with Proposition 71 funds prior to their release and compile those comments in the report.
- Requests that the CCST complete its study by November 1, 2005, and report its options and recommendations for generating public benefits from commercialization of technology developed with Proposition 71 funds to the

health committees of the Senate and Assembly no later than January 1, 2006 for consideration in developing further policies in this area.

Status: Passed Assembly; passed Senate Government Modernization, Efficiency & Accountability Committee. Passed Senate Health with amendments 7/13/05; note the final language of the amendments is not yet public.

Senate Bill (SB) 18 (Ortiz)

Conflicts-of-interest rules, reproductive health and research, and state audit

- Requires the State Auditor to conduct an audit of the CIRM and the ICOC and to provide the audit report to the Legislature by June 30, 2006. Expresses legislative intent that if the results of the analysis warrant further inquiry the Joint Legislative Audit Committee shall direct the State Auditor to conduct additional audits. The audits to be conducted by the State Auditor shall include a review of policies and procedures established by the ICOC to determine whether the ICOC has established a suitable structure for administering the California Institute for Regenerative Medicine, whether those policies and procedures comply with relevant laws and regulations and best practices, and, whether the institute is complying with those policies and procedures. The audit shall include, but not be necessarily limited to:
    (1) The strategic policies and plans developed by the institute and the ICOC.
    (2) Policies and procedures for issuance of contracts and grants and a review of a sample of contracts and grants executed by the institute and the ICOC.
    (3) Policies and procedures relating to protection or treatment of intellectual property rights associated with research funded or commissioned by the institute.
- Requires that the State Auditor provide to the Legislature an analysis of the Institute's implementation of the recommendations contained in the audit report by October 2007, June 2008, and December 2009.
- Requires that prior to providing assisted oocyte production for research or development of medical therapies, a physician to provide to his or her patient a standardized written summary of health and consumer issues associated with assisted oocyte production. The summary shall include, but not be limited to, disclosures concerning the potential risks of assisted oocyte production and oocyte donation.
- Requires the Department of Health Services to print and make available to physicians the the patient guide published and updated by the American Society for Reproductive Medicine entitled, "Assisted Reproductive Technology: A Guide for Patients."
- Requires the physician to obtain written consent from his or her patient prior to providing assisted oocyte production for research.

- Provides that no human oocyte or embryo may be acquired, sold, received, or otherwise transferred for valuable consideration for the purposes of medical research or development of medical therapies, excluding reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of oocytes or embryos.
- Prohibits payments in excess of the amount of reimbursement of expenses to any research subject to encourage her to produce human oocytes for the purposes of medical research.
- Encourages the ICOC to review existing studies concerning the health risks and benefits of ovarian stimulation drugs used for assisted oocyte production, identify gaps in existing knowledge concerning health risks and benefits, and undertake further research as necessary to characterize the risks and benefits of those drugs.

Status: Passed Senate; passed Assembly Health; on suspense in Assembly Appropriations.

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