SCA 13 (Ortiz/Runner) Analysis

As of May 20, 2005

Summary: SCA 13 is a proposed California Constitutional amendment, which would change the California Stem Cell Research & Cures Act (Proposition 71) in three key areas: (1) open meetings; and (2) financial issues related to intellectual property like return on investment and revenue sharing, (3) conflict of interest for Independent Citizens' Oversight Committee (ICOC) members, California Institute for Regenerative Medicine (CIRM) employees, and Working Group members.

Process to qualify for ballot: SCA 13 requires a 2/3 vote in both the state Senate and Assembly to appear on the next state ballot that occurs at least 131 days after passage by the Legislature. If the Governor calls a special election for November (the likely date would be November 8), the Legislature would need approval by June 30, unless a bill signed by the Governor extends the qualification date.

Part 1: Open Meetings

Current law on open meetings as provided in Proposition 71:

- Applies the Bagley Keene Open Meeting Act to meetings of the ICOC, with exceptions, and requires the ICOC to award all grants, loans, and contracts in public meetings, as well as all governance, scientific, medical, and regulatory standards. *Since its first regular business meeting on January 6th, 29 public meetings of the ICOC and committees have been held over the last twenty weeks.*
- Allows the ICOC to conduct closed sessions as permitted by the Bagley Keene Act, as well as to consider matters involving information relating to patients or medical subjects, disclosure of which would compromise personal privacy; matters involving confidential intellectual property or work products of various kinds; matters involving pre-publication, confidential scientific research or data; and matters involving personnel matters.
- Provides that the California Public Records Act applies to all records of the ICOC, except as otherwise provided in the Act, with exemptions for records pertaining to patients or medical subjects, disclosure of which would compromise personal privacy; matters involving confidential intellectual property or work products of various kinds; matters involving pre-publication, confidential scientific research or data; and matters involving personnel matters.
- Provides that ICOC advisory working groups are not subject to open meeting laws, but provides that any records the working groups submit as part of their recommendations to the ICOC shall be subject to the Public Records Act. *This allows for confidential peer review of grant proposals.*

Open Meetings – SCA 13 amends the State Constitution to require that records and meetings of the Working Groups be governed by open meeting and public record laws with certain exceptions to protect intellectual property and confidential or proprietary information.

> SCA 13 proposes:
> *(Note: bill language excerpts are based upon unofficial versions reflecting Elections Committee amendments)*
> That Section 8 is added to Article XXXV thereof, to read:
> SEC. 8.
> b) (1) Except as provided in paragraph (2), meetings and records of the institute, the ICOC, or any body established to govern the institute, and any working or advisory group, are subject to California open meeting and public record laws that are applicable to state agencies.
> (2) Notwithstanding paragraph (1), the ICOC, any body established to govern the institute, and any working group or advisory group, may conduct a closed session for the purpose of considering or discussing matters involving intellectual property or proprietary information and matters involving prepublication confidential scientific information associated with individual research proposals submitted for funding.

Concerns:

1. No recognition of necessity for confidential peer review in proposal. While elements of peer review are noted in the exceptions, clear language to protect the confidentiality of the entire grant evaluation process needs to be recognized. The rigor of the scientific review process will be compromised significantly if the Grants and Facilities Working Groups are prevented from reviewing proposals in private meetings. It is the standard and uniform practice of public (e.g., NIH and UC Special Research Program) and private funding agencies (e.g., American Cancer Society, American Heart Association, Juvenile Diabetes Research Foundation, National MS Society), and nearly universally accepted in the scientific community, to conduct scientific peer review of grant applications in private. Requiring such meetings to be conducted in public would compromise and discourage the critical discourse and analysis necessary to ensure rigorous scientific review. This would discourage or widely eliminate applicants from applying for grants where their reputations could be destroyed in a public process of criticism. Such details can make or break a grant proposal. *For example, in analyzing any grant, part of the process is looking at scientific research history and academic reputation of the scientist or physician. Peer reviewers look at the potential grantee's record – whether the scientist or physician achieved what he or she claimed to achieve in previous projects. They will also critically review whether the scientist or physician has the specific technical/scientific knowledge and research staff to accomplish the specific grant proposal. While the scientist or physician may be brilliant in a specific technical sub-area of the science, they may be subject to devastating criticism as to adequacy of their knowledge of the specific scientific specialties required for the grant application under consideration. For scientists or physicians who dedicate their lives to treating*

chronic diseases, being criticized publicly could jeopardize his or her reputation and credibility, permanently damaging their career and ability to carry out future life-saving research in medical therapies. The public and the press cannot be expected to understand the differences between extreme criticism on one proposal and the extraordinary ability of the scientist or physician for break-through research in numerous other scientific specialty areas. If a scientist or physician is criticized as having major deficiencies in a proposed experiment, generally it is believed that they public will conclude that the scientist is incompetent; the public will not research the person's entire career and realize that 95 percent of their work has been an incredible contribution to the advancement of therapies for chronic disease. ***This is why peer review has to be conducted confidentially. The National Institute of Health, the University of California System-statewide, and all major patient funded foundations for medical research, just to name a few organizations, all consistently maintain a confidential peer review process for these reasons.***

2. Negatively impact Working Group membership. We will not be able to get candid and critical review to invest the public's money in the best research. We will not get the best proposal submitted, and we will not get the best review in a public environment. We believe a public meeting requirement for scientific peer review meetings of Working Groups will discourage potential reviewers from joining the Working Groups.

Part 2: Intellectual Property

Current law on intellectual property as provided in Proposition 71:

- Requires the ICOC to establish standards that require all Proposition 71 grants and loans to be subject to intellectual property agreements that **balance the opportunity of the state to benefit from the licenses, patents, and royalties that result from basic research, therapy development, and clinical trials with the need to ensure that essential medical research is not unreasonably hindered by the intellectual property agreements.**

Intellectual Property and treatment access – SCA 13 amends the California Constitution to require that contracts, awards, grants, or loans entered into by any state entity that provides state funding for research funded by the Institute comply with specified criteria, including that they do not result in a gift of public funds; that any clinical treatments, products, or services resulting from funded research are made available at affordable costs to low-income residents; that the State recoup legal and administrative costs associated with patenting and licensing agreements; and that the State receives a share of royalties or revenues commensurate with its role in the development of the clinical treatments, products, or services.

SCA 13 proposes:
First – That Section 6 of Article XXXV thereof is amended to read, to read:

> SEC. 6. Except as otherwise provided in this article, notwithstanding any other provision of this Constitution or any law, the institute, which is established in state government, may utilize state issued tax-exempt and taxable bonds to fund its operations, medical and scientific research, including therapy development through clinical trials, and facilities.

Concerns:

3. Likely legal challenges – The phrase "except as otherwise provided" in Section 6 opens an avenue for legal challenges based upon procedural arguments that will disrupt the financing of meritorious research. SCA 13 is being advanced with ambiguous language and no serious implementation plan. Proposition 71 was carefully written with the involvement of three separate law firms and based upon case law research to avoid the constant litigation that would be likely should SCA 13 become law as written. The legal battles could paralyze the Institute's mission for years to come.

> SCA 13 proposes:
> That Section 9 is added to Article XXXV thereof, to read:
> SEC. 9.
> (a) Every contract, award, grant, loan, or other arrangement entered into by the institute or the Independent Citizen's Oversight Committee that provides state funding or other resources, shall ensure all of the following:
> (1) Notwithstanding Section 6, the contract, award, grant, loan, or other arrangement does not result in a gift of public funds within the meaning of Section 6 of Article XVI.
> (2) All clinical treatments, products, or services resulting from the biomedical research are made available at the costs of producing them to California residents who are eligible to receive assistance through state and county health care and preventive health programs including, but not limited to, the Medi-Cal and Healthy Families programs.

Concerns:

4. Discourages private sector involvement – While well-intentioned, these provisions could have a host of unfortunate and unintended consequences, including discouraging industry from involvement with the Institute. Private industry is a critical partner in developing scientific discoveries into safe and effective drugs and treatments that benefit the public. If an affordable drug-pricing requirement or a revenue sharing requirement were to discourage industry from participating in technology transfer, it would be to the detriment of the public health and well being.
5. Ignores legislative processes – As previously noted, the ICOC is cooperating with the California Council on Science and Technology (CCST) to study how the state should treat intellectual property made under state contracts, grants, and agreements, as requested by ACR 252 (Mullin) in the 2003-04 session. This study group is currently meeting and anticipates having a report to the Legislature by

July, 2005. SCA 13 ignores the legislative and scientific process initiated by the State Assembly and preempts the work of experts in this field. At the inaugural meeting of the ICOC on December 17, 2004, the Chairman announced that the ICOC would work in full cooperation with the CCST and two members from the ICOC are participating with the work group.

6. Gifting prohibition – The prohibition on gifting may affect the Institute's ability to provide training grants to post-doctorate fellows and post-doctorate clinical fellows at California's leading nonprofit educational and research institutions.
7. Small population diseases – With its one-size-fits-all approach, this provision does not recognize the distinction between large population diseases, like heart disease, and small population diseases, like ALS or MS. The potential market for therapies is significantly different and costs for development would vary. Imposing the same intellectual property policies on large population diseases and small population diseases could result in destroying the feasibility of developing medical therapies for these tragic small disease populations.

> SCA 13 proposes:
> (3) The terms of any loan, lease, or rental arrangement are consistent with, or below, market rates for rent or interest.
> (4) The State recoups the full amount of its legal and administrative costs incurred with respect to patenting and licensing activities related to the biomedical research.

Concerns:

8. No State patenting costs – Section 9(a)(4) provides that the State will recoup legal and administrative costs related to patents and licensing. These costs are borne by the grantee institution, not the State. This clause is superfluous, as the State will not incur these administrative and legal costs.

> SCA 13 proposes:
> (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 sufficient to repay its expenses incurred in developing the clinical treatments, products, or services.

Concerns:

9. Lack of clarity in language -- The provision stating "The State is provided a share or the royalties or revenues, derived from the development or treatment of clinical treatments, products, or services resulting from the research, that is sufficient to repay its expenses incurred in developing the clinical treatments, products or services" is problematic. The word "develop" has a specific meaning in the biotech and pharma industry and the State will not likely be engaging in these activities because they are both expensive and risky, which raises the question of what this provision even means and thus how it would be implemented. Furthermore, calculating intellectual property formulas for shares of revenue does not belong in the Constitution.

SCA 13 proposes:

(6) In addition to royalties or licensing revenues described in paragraph (5), royalties or licensing revenues are transmitted to the State in an amount sufficient to repay any costs of issuing bonds incurred by the State in funding the biomedical research.

Concerns:

10. Revenue levels – It is not clear how agreements would be structured so that the State received royalties sufficient to repay costs associated with issuing the bonds. While it is reasonable to ask that an intellectual property agreement is part of any Institute grant, it is naïve to believe that a level can be set for those revenue streams and may actually decrease the amount the state would get in the long run. A typical structure for sharing revenue streams is to require a certain percentage.
11. Effect on tax exempt status on bonds – If the State has a right to share in royalties, even if it is only in an amount that recovers the State's costs, the transfers to the research entities will not be treated as grants, resulting in tax-exempt questions.
12. True return is healthcare savings – The contribution from intellectual property are expected to occur after the 14th year of the program at relatively small amounts. Historically, never has it been feasible for intellectual property – on a portfolio wide basis – to recoup 100 percent of cost of research. The major economic benefit of Proposition 71 was in major healthcare savings, not IP revenues.

Part 3: Conflict of Interest

Current law on conflict as interest as provided in Proposition 71:

- Applies the Political Reform Act to the Institute staff and members of the ICOC, with certain modifications. *This means that all board members and staff must file a statement of economic interests (Form 700).*
- Allows a member of the ICOC to participate in a decision to approve or award a grant, loan, or contract to a **non-profit entity** in the same field as his or her employer. *This would permit an ICOC member working for USC – for example – to vote for a grant to another non-profit institution in the same field. A separate section of Proposition 71 prohibits anyone from serving on the ICOC while working for a private company developing stem cell therapies.*
- Allows an ICOC member to participate in awarding a grant, loan, or contract for purposes of research involving a disease from which the member or an immediate family member suffers from or which the member has an interest in as a representative of a disease advocacy organization.
- Provides that service as a member of the ICOC shall not be deemed incompatible with service as a faculty member or administrator of the University of California, representative or employee of a disease advocacy organization, a nonprofit academic research institution, or a life science commercial entity.
- Provides that ICOC working group members are not subject to the Political Reform Act and instead, subjects them to conflict of interest rules to be adopted by the ICOC, which shall be based on standards applicable to members of

scientific review committees of the National Institutes of Health (NIH). *The ICOC has adopted strong conflict of interest policies for the ICOC, employees, and working group members. All policies are accessible to the public on* www.cirm.ca.gov.

Conflict of Interest – SCA 13 requires two levels of compliance with conflict of interest – financial disclosure and divestment or blind trust depending upon role with the work of the Institute. The chair and vice chair and any appointed member of the Independent Citizen's Oversight Committee (ICOC), the Institute president, and any member of any working or advisory group appointed to assist the Institute or its governing body must *disclose* his or her income, investments, and interests in real property. The chair and vice chair and ICOC members, the Institute president must divest of or place into a blind trust, any financial or real property interest held in any organization that applies for funding from, or contracts with, the Institute or in any organization with a substantial interest in stem cell therapy. An organization with a substantial interest in stem cell therapy is defined as one that has more than five percent of the organization's current annual research budget is allocated to stem cell therapy, based upon publicly available information.

SCA 13 proposes:
Section 8 is added to Article XXXV thereof, to read:
SEC. 8.
(a) The chair and vice chair and any appointed member of the Independent Citizen's Oversight Committee (ICOC), the president and each employee of the institute, and any member of any working or advisory group appointed to assist the institute or its governing body shall disclose his or her income, investments, and interests in real property in the manner set forth in Chapter 7 (commencing with Section 87100) of Title 9 of the Government Code, or its successor. The chair and vice chair and any appointed member of the ICOC, the president of the institute or its governing body shall divest themselves of or place into a blind trust, any financial or real property interest held by that person in any organization that applies for funding from, or contracts with, the institute or in any organization with a substantial interest in stem cell therapy. An organization with a substantial interest in stem cell therapy is one for which, based upon publicly available information, more than five percent of the organization's current annual research budget is allocated to stem cell therapy.

Concerns:

13. This amendment would subject members of the Working Groups to the Political Reform Act's conflict of interest provisions, including disclosure of investments, income, gifts, travel payments and real property through the filing of Form 700. This information would be subject to public disclosure. The divestment provision puts a greater onus on ICOC members and the president than is imposed on any other state official. CIRM Working Groups are *advisory*, not decision-making bodies and Working Group members are *not employees* of CIRM. COI policies

for Working Group members should recognize this important but limited role. This provision would negatively impact the Institute's ability to recruit and retain leading scientists and clinicians for the ICOC and the Working Groups. We are concerned that anyone who is a member of an ad hoc advisory group would need to disclosure without regards to the nature of their work or focus area. This may impede the Institute from taking advantage of volunteer expertise.

14. Duplication – What SCA 13 is trying to accomplish has already been accomplished in the conflict of interest policies passed by the ICOC. In those policies, NIH conflict policies for peer reviewers were the model for the Grant Working Group conflict of interest policy that require disclosure of any conflicts within the Working Group and recusal from participation in the review.