SCA 13 (Ortiz/Runner) Analysis

As of June 1, 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; (3) financial issues related to intellectual property such as return on investment and revenue sharing, and (1) conflict of interest for Independent Citizens' Oversight Committee (ICOC) members, California Institute for Regenerative Medicine ("Institute") employees, and Working Group members.

Process to qualify for ballot: SCA 13 requires a 2/3 vote in both the state Senate and Assembly in order 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.

Status: SCA 13 is currently on the Senate floor. A vote is not expected before Thursday, June 9, 2005.

ICOC position: On May 23, 2005, the Independent Citizens' Oversight Committee unanimously voted to oppose SCA 13 because the measure "will make it extremely difficult if not impossible for scientists to do their jobs, and it will delay critically needed medical therapies."

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, and to adopt all governance, scientific, medical, and regulatory standards, in public meetings. *Since its first regular business meeting on January 6th, the ICOC and its sub-committees has held 32 public meetings.*
- 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, with the exception of compensation, which must be considered in public.
- 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 personnel matters.

- Provides that all ICOC advisory working group recommendations to the ICOC board are subject to open meeting laws, but provides that the technical working sessions of the working groups to the ICOC shall not be subject to the Public Records Act. *This allows for confidential peer review of grant proposals.*

Open Meetings (Provisions in SCA 13 as amended 5/31/05):

SCA 13 would require that meetings and records of the institute, the ICOC, and any working group or advisory group be subject to state open meeting and public records laws, with certain exceptions.

- Any Institute or ICOC working or advisory group charged with reviewing and recommending medical research projects for funding may hold closed sessions "when necessary to conduct or carry out scientific peer review of any research project submitted for funding, or 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."
- Any such working or advisory group must produce a publicly accessible written document summarizing:
  - The reasons why it recommended or did not recommend each project
  - How each project will benefit the residents of California;
- Any such working or advisory group must hold an open session to allow public comment on its decision prior to submitting any recommendation to the ICOC.
- The Institute, the ICOC, and any working or advisory group may also conduct closed sessions as permitted by the Bagley-Keene Open Meeting law.

SCA 13 proposes:
That Section 8 is added to Article XXXV thereof, to read:
SEC. 8.
(c) (1) Except as provided in ~~paragraph (2)~~ *paragraphs (2), (3), and (4)* , 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~~
(2) Notwithstanding paragraph (1), any working or advisory group appointed to assist the institute or its governing body that is charged with reviewing and recommending medical research projects for funding may hold closed sessions when necessary to conduct or carry out scientific peer review of any research project submitted for funding, or for the purpose of considering or discussing matters involving intellectual property or proprietary information and matters involving pre-publication confidential scientific information associated with individual research proposals submitted for funding. *However, any working or advisory group that is charged with*

reviewing and recommending medical research projects for funding shall produce a written summary that shall be a public record of the reasons for recommending or not recommending any project for funding as well as how each project recommended for funding will benefit residents of California. The working or advisory group shall hold an open session to allow public comment on its decision prior to submitting any recommendation to the ICOC.

(3) Notwithstanding paragraph (1), the institute, ICOC, or any body established to govern the institute, and any working group or advisory group, may conduct closed sessions as permitted by 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), or its successor.

(4) Notwithstanding paragraph (1), records containing intellectual property or proprietary information and matters involving prepublication of confidential scientific information shall not be subject to public record laws.

Concerns:

1. Makes public patient information – Although it appears SCA 13 includes an exemption, the measure does not include an exception for the ICOC to consider matters involving confidential intellectual property, patient privacy or prepublication scientific working papers or data. Similarly, the public record provision of SCA 13 does not include an exception for personnel, medical or similar files.

2. Excludes institutional proposals – The current language of SCA 13 authorizes closed sessions for "individual research proposals submitted for funding." While the intent of the new amendments may be that all meetings at which scientific peer review of proposals is conducted can be held in closed session, language to reflect this needs to be included. For example, the initial request for proposal of the Institute is for a research training program; these are institutional, not individual, proposals, and they need to be evaluated confidentially. SCA 13 also lacks confidentially protections for the Grants Working Group advise to the Facilities Working Group on the scientific and medical faculties research record or comparative performance at an applicant institution as compared to another institution that may be competing for facilities funding.

3. Creates bureaucratic hurdles – SCA 13 provisions may introduce cumbersome and redundant requirements that could impede the work of the peer review groups and/or prevent them from participating in what is already a very time-consuming and laborious process. For instance, it is cumbersome and unnecessary to require working groups to conduct open sessions to allow public comment before submitting peer review recommendations to the ICOC. Working group members will be coming from all over country (and from a couple of countries), spending their valuable time to aid in furthering the Institute's mission. Adding a public meeting component will extend time they are required to spend here. Additionally, this step is redundant, since working group recommendations are

already required to be approved by ICOC in an open meeting, where public comments are considered before final votes. Requiring Working Groups to provide a publicly available written summary providing a reason for *not* recommending a particular project is an additional burden and is furthermore not a precedent in any other major grant-making entity, like the NIH or NAS.

4. Risks public humiliation to applicants -- Providing a public summary of each grant review will potentially subject the applicant to public viewing of criticism, sometimes harsh criticism directed at his/her proposal. This is at best an embarrassment and at worst humiliating. In all other reviewing situations, the "summary statement" or written critique belongs solely to the investigator submitting the proposal. Even the institution where he/she works is not provided with this information. Scientists submitting grant applications should not be subjected to a public display of the weaknesses of their ideas and projects. In addition, it would be difficult to avoid reporting on discussions or criticism of parts of the proposal that contain proprietary information, breaking the rule of confidentiality. Finally, knowing that their comments will be read by the public may also inhibit the reviewers from saying or reporting what is really on their minds. Everyone in academia, both reviewers and applicants, is highly sensitive to the confidential nature of the written critiques.

5. Confidentially of individual scores and even identity of individual reviewers preserves the ability of reviewers to "vote their conscience". -- In all cases of peer review, the identity of each reviewer of a particular application, as well as the individual scores, are matters of the greatest confidentiality. Maintaining confidentiality permits those serving as reviewers to provide an unbiased and frank review of their peer's proposal without fear of retaliation when the situation is reversed in some other setting like an NIH study section. If this confidentiality is breeched, the Institute will have great difficulty in recruiting scientists to serve as reviewers and to speak their minds frankly and to vote their consciences. The ICOC is asking some of the best stem cell scientists in America and the world to serve on review panels in order to help California fund the best Californian scientists. Their service is already highly laudable because while they see the opportunities for funding that are available to their Californian colleagues, these same opportunities are not available to them. In other words, they are serving the Institute to help their competitors in the stem cell field get funded for work that they themselves may have great difficulty doing because of lack of opportunity in their home state. Each additional barrier, such as lack of confidentiality of their comments and scores and highly intrusive and onerous conflict of interest reporting of their income and every asset may stretch their generosity of spirit to breaking point, making it difficult if not impossible for Institute to recruit excellent reviewers and ultimately to achieve its goals.

6. Keep confidentiality of applications -- The contents of each proposal is the intellectual property of the applicant. Therefore, except for the abstract, all

proposals must be held in strict confidence. These materials must not be shared in public.

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 – (Section 9 in SCA 13 as amended 5/31/05 – *note: no change in this section from earlier versions of SCA 13.*)

SCA 13 requires that every contract, award, grant, loan, or other arrangement entered into by CIRM or the ICOC shall ensure that:

- Resulting therapies are provided at cost: All clinical treatments, products, or services resulting from the biomedical research are made available at the cost of producing them to California residents eligible to receive assistance through state and county health care and preventive health programs including but not limited to Medi-Cal and Healthy Families.
- The State gets a share of royalties/revenues: The State is to be given a share of royalties or revenues derived from the development of clinical treatments, products and services in an amount sufficient to repay the state's expenses incurred in developing such treatments, to repay the cost of issuing bonds to fund the biomedical research, and to recoup the full amount of the State's legal and administrative costs incurred in patenting and licensing activities related to the funded biomedical research.
- No gift of public funds: The award does not result in the gift of public funds.
- Market rates are used: The terms of any loan, lease or rental arrangement are consistent with or below market rates for rent or interest.

SCA 13 proposes:

Third– 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 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.

(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.

(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.

(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.

(b) Nothing in this section shall be construed to preclude the State from receiving any other benefits to which it would otherwise be entitled under Chapter 3 (commencing with Section 125290.10) of Part 5 of Division 106 of the Health and Safety Code, or its successor.

Concerns:

7. Difficulty to change in the future – The detailed intellectual property provisions of SCA 13 will restrict the Institute's ability to respond to new conditions and tie its hands because these provisions could only be amended by another vote of the people on another constitutional amendment.

8. Opens the door to litigation – SCA 13 imposes six preconditions on the Institute's award of grants, loans, contracts, and awards. Some of these preconditions are simply impossible to meet, while others are so vague and ambiguous that they create opportunities for opponents of stem cell research to try to stop the research in its tracks. For example, SCA 13 requires that each contract, award, grant, or loan ensure that the State receives royalties or license fees sufficient to repay its expenses incurred in developing the treatment. But how, before a grant is even made, could the Institute determine that the research will lead to a therapy or cure that will result in sufficient revenues to repay the State's development costs, especially in the case of orphan diseases? Furthermore, because these provisions are a prerequisite to a grant award, a person who opposes stem cell research could file suit to enjoin the Institute from awarding research grants based on the Institute's failure to comply with these provisions.

9. Litigation concerns, part 2 -- Other preconditions will result in lawsuits. SCA 13 requires each contract, award, grant, or loan to ensure that all clinical treatments, products or services resulting from research funded by CIRM are made available at the "cost of producing" them to Medi-Cal and Health Family participants. Once again, it is impossible for Institute to determine before a grant is made that a future clinical treatment can be economically produced in such a fashion that it

can be made available at cost to low-income Californians. If the Institute cannot make this determination, it cannot award a grant. The State has an opportunity to allocate some of the intellectual property revenue to compassionate care has been suggested by ICOC board members.

10. Litigation concerns, part 3 -- SCA 13 would amend section 6 of article XXXV to add the phrase, "Except as otherwise provided in this article," before "Notwithstanding any other provision of this Constitution or any law, the institute, which is created 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." The drafters of Proposition 71 added this provision to make clear that the Institute was a state agency and could spend state funds in the event of a constitutional challenge based on article XVI, section 3, which prohibits the state from appropriating funds to an institution that is not under the exclusive management and control of the state as a state institution. This is the very basis for the action filed by the Life Legal Defense Foundation on behalf of People's Advocate and the National Tax Limitation Committee. The proposed language in SCA 13 would weaken the exception created by section 6 and the Institute's defense in the pending litigation.

11. Vague and ambiguous language -- SCA 13 requires the Institute to demonstrate that each contract, award, grant, or loan does not result in a gift of public funds in violation of article XVI, section 5. California courts have interpreted this provision to be satisfied if the expenditure of public funds serves a public purpose, regardless of whether an individual or entity receives an incidental personal benefit. Proposition 71, however, declares that funding stem cell research in California serves a *public purpose*. Thus, SCA 13 demands that the Institute has to make a showing above and beyond Proposition 71's declaration of a public purpose, yet it does not explain what that showing must be. If the ICOC were to award a grant to a private non-profit institution, like the Salk Institute, for example, opponents of stem cell research could use this provision in an effort to stymie the Institute from awarding research funding by filing a taxpayer action challenging the Institute's determination. A court would then be left to interpret what showing is required and whether the Institute has met its constitutional burden.

12. 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.

13. Ignores legislative processes – As previously noted, the ICOC is cooperating with the California Council on Science and Technology 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 and ACR 24 (Mullin) this session. This study group is currently meeting and anticipates having a report to the Legislature by July, 2005. SCA 13 ignores the Assembly's thoughtful legislative process of seeking scientific and medical advice and preempts the work of experts in this field.

14. No State patenting costs – Section 9(a)(4) provides that the State will recoup legal and administrative costs related to patents and licensing. This uniform requrest is a problem. These costs will almost always be borne by the grantee institution, not the State. This clause is generally superfluous, but the Institute might incur some of these costs without hope of recovery (for example, for an orphan disease where the therapy is potentially effective but commercially marginal.)

15. 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. This ambiguity could lead to litigation.

16. Economic benefits versus revenues – SCA 13 mistakenly tries to recover 100 percent of the research costs through royalty revenues. Proposition 71 viewed royalty revenue as a small percentage of the state's return. The Proposition 71 economic projections looked dominantly to potential medical savings and new state tax revenues. In striving for public benefit, the hope is for therapies and treatments for chronic diseases. Beyond this goal, the primary economic benefits of the Institute's program are likely to come from the creation and strengthening of California companies, the migration of companies to California, the creation and retention of jobs, and the generation of tax revenues. These benefits are likely to far overshadow any economic return generated from the licensing of intellectual property created from research funded by the Institute.

17. Unintended consequences -- SCA 13 would require that therapies be provided at cost to upwards of 6 or 7 million people. It is difficult to know the effect of such a requirement on other populations (e.g., would drug prices for the working poor or middle class go up significantly?). As of March 2005 there were over 700,000 subscribers to the Healthy Families program, and as of January 2005 Medi-Cal enrollment was over 6.5 million. It is extremely difficult to predict what the effect of this requirement would be, especially given that the cost of yet-to-be-invented therapies is not known. Nor is it known what their medical efficacy or

likely public health benefit. Further analysis is warranted before enacting a constitutional amendment that requires a particular pricing model.

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.
- 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).

Current policies on conflict of interest as passed by the ICOC:

- 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 – (Section 8 in SCA 13 as amended 5/31/05):

- Disclosure Requirements for ICOC members, officers, president, and Institute employees. Would require annual disclosure of income, investments, and interests in real property (via a publicly accessible Form 700).
- Divestment/blind trust requirement for ICOC members, officers, president. ICOC members, the president, chair and vice chair would be required to divest themselves of or place in a blind trust:
    - any financial or real property interest held in an organization that applies for funding from or contracts with the Institute; or
    - any financial or real property interest in any organization with a "substantial interest in stem cell therapy", which is defined to be more than 5 percent of an organization's current annual research budget being allocated to stem cell therapy.
- Disclosure Requirements for members of working groups or advisory groups appointed to assist Institute or the ICOC.

- Would require annual disclosure to the Institute of income, investments, and interests in real property in the same manner as required by Form 700.
- Form 700 filed by Working Group members would be a public document, as there is no specific exemption.
- Would require CIRM to submit these disclosures to the State Auditor.
- Would require the State Auditor to review the disclosures and the voting record of each Working Group member regarding recommendations for applications for awards and for regulatory standards, and to submit an annual report to the Legislature containing findings on whether any such recommendations may constitute a conflict of interest that requires or required recusal from consideration of an application or standard if the member is otherwise required under existing law to recuse himself or herself.

- Definition of "conflict of interest." Would define conflict of interest to mean that a working or advisory group member, or a close relative or professional associate of the member, has a financial or other interest in an application or standard that is known to the member, including a direct benefit in any amount deriving from an application or standard, or a financial benefit of any type from an applicant institution of over five thousand dollars ($5,000) per year, including honoraria, fees, stock, or other benefits. Defines "close relative" and "professional associate" in same way those terms are defined under the NIH Conflict of Interest, Confidentiality, and Non-Disclosure Rules.

SCA 13 proposes:

Section 8 is added to Article XXXV thereof, to read:

SEC. 8.

Second— That 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), *and* 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, *and* the president of the institute ~~,and any member of any working or advisory group appointed to assist 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 ~~organizations~~ *organization's* current annual research budget is allocated to stem cell therapy.

(b) (1) Upon his or her appointment and each year at a time specified by the ICOC, each member of a working or advisory group appointed to assist the institute or its governing body shall disclose to the ICOC his or her income, investments, and interest 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 ICOC shall provide the disclosures to the State Auditor. The State Auditor, or his or her successor, shall review the disclosures, in addition to the voting record of each working or advisory group member regarding recommendations for applications for research and facility grants and loan awards and regulatory standards, and submit an annual report to the Legislature containing findings on whether any of the votes made by these members may constitute, or has constituted, a conflict of interest that requires or required the member to recuse himself or herself from consideration of an application or standard if the member is otherwise required under existing law to recuse himself or herself.

(2) For purposes of this subdivision, "conflict of interest" means the working or advisory group member, or a close relative or professional associate of the member, has 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 five thousand dollars ($5,000) per year, including honoraria, fees, stock, or other benefits. For purposes of this paragraph, "close relative" and "professional associate" shall have the same meaning as those terms are defined under the National Institutes of Health Conflict of Interest, Confidentiality and Non Disclosure Rules.

Concerns:

18. Higher standard than for elected officials – SCA 13 would subject ICOC members 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. This requirement is duplicative of existing law. SCA 13, however, would also require ICOC members to divest, or to put in a blind trust, any financial or real property interest in an applicant for funds. The Political Reform Act defines "financial interest" to include sources of income of $500 or more. This would include salary income of ICOC board members. Therefore, an ICOC board member who is employed by an applicant for funds would have to resign or quit his or her job because it would be impossible to put salary into a blind trust. The divestment/blind trust provision effectively puts a greater onus on ICOC members and the president than is imposed on any other state official, elected or appointed.

19. Negative effect on Working Group retention – The Institute is concerned that anyone who is a member of an ad hoc advisory group would need to meet the same Form 700 disclosure requests as the Governor of the state and disclose without regards to the nature of their work or focus area. This would severely impact their willingness to serve and the Institute's ability to take advantage of volunteer expertise. In addition, the Form 700s required of working group members are public, and this will cause some working group members not to participate.