COMMENTS ON JUNE 8, 2005 VERSION OF SCA 13

General Comment: SCA 13 represents an extraordinarily high risk of damaging or paralyzing Proposition 71; the Independent Citizen's Oversight Committee is unanimously opposed.

The Independent Citizens' Oversight Committee is composed of highly qualified scientists, physicians, patient advocates, and business leaders, including a Nobel Laureate and two former commissioners of the Food and Drug Administration. Californians have entrusted members of the ICOC to run medical schools and universities, including the University of California, Berkeley, and in adopting Proposition 71, they entrusted the Board to oversee the establishment of an innovative and urgently-needed research program. The Board, in turn, has demonstrated its high standards by enacting strict conflict of interest rules; conducting 30 public hearings of the Board and its subcommittees in the last 22 weeks; clearly implementing the requirement that all grants, loans and standards be adopted in open public sessions of the Board; and opening the meetings of two of its three advisory working groups to the public. After discussions with members of the Senate, Senator Perata's staff, and Senator Ortiz and her staff, the Chair of the ICOC, the President of the CIRM, and counsel for the CIRM have recommended that the Board proactively adopt a number of additional policies to address the concerns raised by the Legislature. Given the Board's credibility and the good faith it has demonstrated by responding to the Legislature's concerns, a constitutional amendment is unnecessary and would contravene Proposition 71, which was intended to give the Board an opportunity to jump start this vital program before the introduction of legislative amendments. The risk that the detailed provisions of SCA 13 could lead to unintended consequences that could paralyze the CIRM with litigation as early as January 2006, without a remedy, combined with the risk that ambiguous provisions and provisions that are impossible to implement could lay a foundation for further litigation, are simply too great to countenance.

Conflicts of Interest

ICOC Members and CIRM Staff: Section 8(a) requires ICOC members and all employees of the CIRM to disclose their financial interests pursuant to the Political Reform Act.

- This language is not necessary because Proposition 71 already requires board members and designated CIRM employees to disclose their financial interests pursuant to the Political Reform Act.

Members of Working and Advisory Groups: Section 8(b)(1) requires all members of any working or advisory group to disclose income and investments in any entity that has sought funding from the CIRM or that is engaged in biomedical research.

- The ICOC has already adopted strict conflict of interest rules pursuant to which members of the Grants and Facilities Working Groups have to file, under penalty

of perjury, pre- and post-certification disclosures to ensure that they have not participated in a decision in which they have a financial interest.

- Requiring members of a working or advisory group that is not involved in making funding recommendations to disclose their financial interests serves no purpose and there are strong indications that it would dissuade qualified individuals from serving on such groups, including the Standards Working Group, whose sole function is to recommend medical and ethical standards to the Board. The historical practices of the NIH, public medical foundations, and the University of California system demonstrate that these requirements are not necessary to the extent that they go beyond the NIH and National Academy internal disclosure provisions.

- While it is important for members of the Grants and Facilities Working Groups to disclose whether or not they have a significant financial interest ($5,000 or more) in an applicant for funds or in a company that is engaged in biomedical research, it is irrelevant whether an individual has a $5,000 interest or a $100,000 interest, because under the conflict of interest standards *already* adopted by the ICOC, the member would have to recuse himself or herself under either scenario.

- There are strong indications that the public disclosure of these statements could dissuade a large number of the nationally-known scientists and physician-scientists who have agreed to serve on the working groups from serving.

Review by State Auditor: Section 8(b)(1) requires the State Auditor to review the disclosure forms to determine whether any members of the working groups participated in decisions in which they have a conflict of interest.

- A "conflict of interest" is defined to include an interest held by a member, as well as a close relative of a member or a professional associate of the member. This would require a member to be aware not only of his or her immediate family's investments, but also investments held by professional colleagues.

- "Professional associate" and "close relative" are defined based on National Institutes of Health rules, but SCA 13 does not identify the date of those rules. The NIH is currently reconsidering its new conflict rules after receiving harsh criticism from Congress for overreaching and extreme provisions. The NIH rules were not intended to be applied to the provisions proposed in California.

- While it is sensible to authorize the State Auditor to review the CIRM's process for ensuring that working group members do not participate in decisions in which they have a financial interest, a report on the actions of individual members, whether intentional or inadvertent, could dissuade individuals from participating in the working groups. The report should focus on whether the process worked, and if it did not, what corrective actions the CIRM took to prevent future

occurrences. The report could also be the basis for the immediate removal of individuals who have violated the conflict provisions.

- The report could lead to the invalidation of standards or facilities that have been in progress for a year, which could give rise to litigation concerning those standards or facilities. The NIH and National Academies have complex procedures for dealing with these issues, and an overly simplistic approach could create major secondary problems, including substantial litigation.

Open Meetings: Section 8(c)(2) would impose the Bagley-Keene Open Meeting Act on the working groups and require the Grants and Facilities Working Groups to produce a written summary of the reasons why applications were not funded.

- The ICOC adopted open meeting policies for the Standards Working Group in April

- The ICOC adopted open meeting policies for the Facilities Working Groups in May.

- The Chair has recommended that the Board require the Grants Working Group to meet in public when considering medical and scientific criteria and standards for grants.

- The public disclosure of this information on losing proposals would dissuade scientists from submitting proposals for cutting edge science and it would chill the full and frank evaluation of such proposals. Furthermore, disclosing the geographic region of rejected applications would encourage review of applications based on geography rather than scientific merit.

- The disclosure of cutting edge ideas could lead to the misappropriation of those ideas while the original applicant works to refine and resubmit the proposal.

Public Records: Section 8(c)(4) would impose the Public Records Act on the records of the working groups:

- SCA 13 does not create an exception for applications, for scientific evaluations of applications, and for the disclosure forms filed by members of the working groups. Under Proposition 71, these records are not subject to the Public Records Act. Public disclosure of this information would: (1) dissuade scientists from submitting applications, particularly for cutting-edge science; (2) dissuade working group members from conducting a full and frank evaluation of applications; and (3) dissuade working group members of the working groups from serving.

Intellectual Property: Section 9 would require that the ICOC "seek to ensure" that treatments and therapies resulting from research funded by the CIRM are made available at affordable prices to low income Californians.

- As board members stated at the ICOC meeting on Monday, they share Senator Ortiz's goal, but a constitutional amendment is not the best way to achieve it. The proposed language does not explain how the ICOC can satisfy this standard, and by enshrining the language in the Constitution, it opens the door to litigants to argue that the ICOC has not met its burden. SCA 13 offers no standard for resolving such a claim and leaves the ICOC at the mercy of a court's interpretation.

- The ICOC's mission is to fund research to find therapies and cures for diseases. Its mission is not to make healthcare affordable and it does not have the resources to do so. While the ICOC would be amenable to adopting a policy pursuant to which it will consider as one preference criterion whether an applicant agrees to make therapies available at affordable prices, this issue is too complex to enshrine in the Constitution.