August 5, 2008

Mr. Robert Klein
Chairman, Independent Citizen's Oversight Committee
210 King Street
San Francisco, CA 94107

Dear Mr. Klein:

Thank you for your letter of July 28, 2008, detailing your proposed amendments to SB 1565. We appreciate your perspective on the measure and the time you've taken to outline your remaining concerns.

In response to your specific suggestions for amendments, we can agree with the suggestions outlined in your first and second amendments, as stated below:

- **Proposed Amendment to Section 125293, subdivision (c)(1)**

  (c)(1) Any plan subject to subdivision (a) shall include a requirement that each grantee and any licensee of the grantee that sells drugs that are, in whole or in part, the result of research funded by CIRM shall provide those drugs ***in California*** to ~~**publicly**~~ ***California state and local government*** funded programs ~~***in California***~~ at one of the three benchmark prices in the California Discount Prescription Drug Program (Division 112 (commencing with Section 130500)), as it exists on January 1, 2008.

- **Proposed Amendment to Section 125293, subdivisions (b)**

  (b) The ICOC shall require submission of the plan required by subdivision (a) before a drug is placed into commerce ***in the United States***. The plan shall be subject to the approval of the CIRM, after a public hearing and opportunity for public comment.

With regard to your third and fourth proposed amendments, we cannot accept those specific amendments for the following reasons:

- **Proposed Amendment to Section 125293, subdivisions (a), (c)(1), (e)**

  The addition of the word "substantial" before "part," so that the phrase reads "in whole or in substantial part" where it appears in subdivisions (a), (c)(1), and (e).

The proposed language is overly broad and, we fear, may result in no drug qualifying for the Cal-Rx pricing benchmarks, given the considerable costs of drug development. Additionally, determining whether the Cal-Rx pricing benchmarks should apply should depend on whether the funding is key to the drug's development, not whether it is minimal or substantial. In the case of a grant that is considered minimal, CIRM funding will either be minimal and key, or not needed, in which case it will be clear that there is opportunity for the drug to be developed solely with private or other public funds. We believe this is in keeping with Prop 71's goals, which created the bond mechanism not to be in competition with other sources of funding, but to ensure that promising research opportunities did not go unfunded. Finally, CIRM's own regulations include the language "in whole or in part," and CIRM has taken no formal action to rescind this language.

- **Proposed Amendment to Section 125293, new subdivision (f)**

  (f) As used in this section, the term "grantee" means the recipient of a CIRM research grant. "Grantee" does not include the recipient of a CIRM loan.

Your letter states that CIRM regulations do not apply to the recipients of loans, and that CIRM is in the process of developing its loan program. Your letter further states that "First, we expect that CIRM will require loan recipients to supply matching funds. It is entirely possible that these matching funds could come from a variety of sources, including institutions that might agree to participate in a clinical trial in exchange for a discount in the price of the drug that is being tested. Second, under the loan program, a loan recipient would have an obligation to repay the loan and provide warrant coverage (a right to subscribe to stock at a specified time and price), provided as an interest rate risk premium. Thus, CIRM's mission will enjoy a major benefit that is not available from grants."

While the scenario you describe may occur, it is also reasonable to believe that these benefits will not come to fruition, given the considerable risks involved in these endeavors. Additionally, because the bill applies to grantees, and CIRM has underlying authority under Proposition 71 to make grants and loans, we don't believe the measure would prohibit CIRM from developing its loan program. For these reasons, we do not believe the proposed amendment is necessary.

As you know, we substantially amended on the bill on July 14, 2008, in response to your desire for greater flexibility on the pricing provisions. The current standards in CalRx provide a great deal of flexibility, and the latest amendments give CIRM and its grantees even more

flexibility in meeting the Cal-Rx pricing benchmarks. Because grantees would be able to pick one of these prices, at which to sell stem cell therapies, one of which is the lowest price they sell them to commercial payers, there is already considerable flexibility on pricing in the bill.

As we've communicated with you in past discussions, our intent is to establish minimum requirements in statute to guide policy in this area. We believe that guaranteeing the state's ability to buy CIRM-funded therapies at the lowest prices at which drug manufacturers offer them to nonpublic entities is appropriate and consistent with the interests of the taxpayers who have funded this initiative. This will ensure that low-income populations will have access to therapies, and will also alleviate pressure on the General Fund in future years in paying for these therapies.

We have worked constructively with you and your staff for several months on amendments to SB 1565. The bill has benefited from this dialogue, and we appreciate your commitment to improving the bill so that important stem cell therapies are developed and the state's residents broadly have an opportunity to benefit from the state's investment in the research.

Sincerely,

SHEILA J. KUEHL
23rd District

GEORGE RUNNER
17th District

cc: Members of the ICOC