CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

August 6, 2008

The Honorable Sheila Kuehl
CA State Senate
State Capitol
Sacramento, CA 95814

The Honorable George Runner
CA State Senate
State Capitol
Sacramento, CA 95814

Dear Senators Kuehl and Runner:

Thank you for your letter of August 5, 2008. We appreciate your willingness to make two of the four amendments we requested to Senate Bill No. 1565 in our letter dated July 28, 2008. Since we sent our last letter, we have had several productive discussions with your staff, Lark Park and Peter Hansel, including conference calls with Tom Okarma, the Chief Executive Officer of Geron, and Martin McGlynn, the Chief Executive Officer of Stem Cells, Inc., who shared some of the private sector's concerns regarding SB 1565's impact in discouraging or diverting critical future capital that is essential for human clinical trials and therapy development. We strongly share your goal of ensuring that California state and local government purchasers have access, at the lowest possible price, to the therapies and drugs derived from CIRM-funded research, and in that spirit, we offer additional proposed amendments in an effort to accomplish that goal while attempting to reduce some of the obstacles to therapy development presented by SB 1565. However, we must restate our strong opposition to Section 1 of the bill, which would remove the two-thirds vote requirement for funding "vital research opportunities" **This proposed amendment would undermine the very purpose for which California voters approved Proposition 71 – to fill the gap in funding resulting from federal**

restrictions on funding for human embryonic stem cell research – by eliminating the priority in Proposition 71 for funding human embryonic stem cell research.

Clarification Regarding Grantee

Based on our discussions with Lark Park and Peter Hansel, we understand that it is your intent to apply the terms of SB 1565 to the recipients of CIRM grants and to licensees of CIRM grants. Consistent with that intent, SB 1565 refers only to grantees. Under Health and Safety Code section 125292.10(i), however, the term "grant" includes a loan. As a result, the term "grantee" includes a recipient of a loan. (Health & Saf. Code, § 125292.10(j).) We therefore propose clarifying the original intent of SB 1565 as follows:

> ***Section 125293, subdivision (f). Notwithstanding section 125292.10, subdivisions (i) and (j), the term "grantee," as used in this section, does not include the recipient of a loan.***

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

SB 1565, like CIRM's regulations, imposes its access and pricing policies on any drugs that are, "in whole or in part," the result of CIRM-funded research. As we discussed with Ms. Park and Mr. Hansel, some potential CIRM grantees have construed this provision to apply to cases in which CIRM has had only indirect involvement, such as drugs developed through the use of re-agents or basic stem cell lines funded by CIRM. It appears, however, from the discussion with your staff that we share the intent to apply these provisions only to drugs that result directly from CIRM funding. We therefore propose adding the word "direct" before "result" so that the phrase reads "that sells drugs that are, in whole or in part, the *direct* result of research funded by CIRM" where it appears in subdivisions (a), (c)(1), and (e). Permitting vague, indirect references of applicability could predictably generate litigation and confusion that would delay the development of critical therapies for patients.

Proposed Addition of Subdivision (f) to Section 125293

We also discussed the possibility that CIRM funding will be made available to some grantees after the grantees have expended significant private funding in the development of a therapy and the need to treat early funders differently from a second generation funder like CIRM, under those circumstances. To ensure that new therapies reach the market, it is critical that CIRM have the ability to negotiate with

grantees regarding the application of CIRM's intellectual property regulations under these conditions. We therefore propose that you add a new subdivision to section 125293 as follows:

> ***Subdivision (f). To the extent that CIRM funds are made available to a grantee only after the grantee has expended significant resources in the development of a therapy, CIRM may negotiate modifications to the requirements set forth in this section to the extent that CIRM determines they are necessary to ensure that the therapy is commercialized.***

Conclusion

Although we believe statutory language will eliminate the flexibility to respond to material opportunities that could significantly advance critical medical therapies, we appreciate your support of CIRM and your willingness to consider these amendments. We believe that the clarifications we have proposed are critical to our ability to implement SB 1565, if it were to be enacted, in a manner that is consistent with your intent and that permits us to advance medical research.

As we have previously discussed, however, section 1 of SB 1565 creates a major obstacle to our support this bill for the reasons outlined in our letter dated July 10, 2008, and we therefore remain opposed to SB 1565.

Sincerely,



Robert Klein	Ed Penhoet	Alan Trounson
Chairman, ICOC	Vice-Chairman, ICOC	President, CIRM