July 28, 2008

Dear Senator Kuehl:

The Legislative Subcommittee of the Independent Citizens' Oversight Committee (the "ICOC"), the governing board of the California Institute for Regenerative Medicine ("CIRM"), met on Thursday, July 24, 2008, to discuss Senate Bill No. 1565. The Legislative Subcommittee shares 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, but we continue to believe that SB 1565 is premature and unnecessary.

We are mindful of recent remarks attributed to you in the press regarding your general reluctance to make further amendments to SB 1565. Nonetheless, consistent with the conversation you had with us before proceedings began in the Assembly Appropriations Committee during which you asked us to provide specific suggestions to further clarify the proposed language of SB 1565, we offer these amendments for your consideration. The proposed amendments do not cover the full spectrum of issues; rather, the proposals focus on areas that were the subject of past comments indicating that the proposed language may more acutely implement your intent and avoid unintended consequences that might damage the development of new therapies. The Legislative Subcommittee deeply appreciates your willingness to engage in a dialogue regarding these potential amendments.

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

Your recent amendments to subdivision (c)(1) clarify what we understand to be the original intent of SB 1565. We believe that further refinements, however, may sharpen the expression of the Legislature's intent. We understand that you intend SB 1565 to apply only to therapies or drugs purchased in California, by California state or local government funded programs. The current language, however, would appear also to apply to federally funded programs, including programs funded and administered entirely by the federal government without regard to need. Overly broad language could dilute the ability to reduce the costs and increase the subsidies to needs-based programs of state and local governments. We therefore propose the following changes to 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 sell 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)

SB 1565, like CIRM's regulations, requires submission of an access plan to the ICOC "before a drug is placed in commerce." It is possible, however, that a drug could first be commercialized in another part of the world, such as Europe, before the Food and Drug Administration has approved the drug for use in the United States. Given the uncertainties regarding the outcome of the FDA's review, including any restrictions the FDA could place on the use of the drug, it would be premature to require a company to develop an access plan before FDA approval. We therefore propose the following amendment to subdivision (b):

> The ICOC shall require submission of the plan required by subdivision (a) before a drug is placed into commerce ***in the United States***.

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. Some potential CIRM grantees have construed this provision to apply to cases in which CIRM has had minimal involvement, such as drugs developed through the use of re-agents funded by CIRM or cases in which CIRM funding may be a small percentage of the early development costs. CIRM's intent, however, was to apply these provisions only to drugs that result from direct, substantial CIRM funding. We understand that you suggested that the word "substantial" might solve this issue during an informal discussion you had with Sue North and I before the Assembly Appropriations Committee hearing. While CIRM could propose a more involved clarification, 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), meaningfully addresses the problem.

Clarification of "Grantee"

CIRM's intellectual property policies, upon which SB 1565 is based, apply only to the recipients of research grants. (Cal. Code Regs., tit. 17, sections 100301(g), 100400 and 100401(h).) Because CIRM is still in the process of developing its loan program, CIRM regulations do not apply to the recipients of loans. Furthermore, because of the significant differences between grants and loans, there may be good reasons for developing different intellectual property policies for loan recipients. 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. Finally, different diseases may merit different

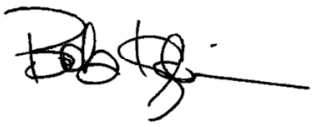
conditions to address the unique challenges specific to bringing that drug to the market The ICOC's Loan Task Force is currently analyzing all of these issues in public hearings as it considers the structure of the loan program. The application of these provisions to loans appears unintended and it would be premature to apply the terms of section 125293 to loan recipients. We therefore propose the following amendment to address this concern:

> ***Section 125293, subdivision (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.***

Conclusion

Thank you for the opportunity to offer these amendments to SB 1565. 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 proposed amendments.

Sincerely,



Robert Klein
Chairman, Governing Board