



M E M O R A N D U M

**TO: MEMBERS OF THE GOVERNING BOARD,
CALIFORNIA INSTITUTE FOR REGENERATIVE
MEDICINE**

FROM: ART TORRES AND DUANE ROTH

SUBJECT: SENATE BILL NO. 1064 (ALQUIST)

DATE: 21 MAY 2010

Based on the Board's direction at the April 28-29, 2010 meeting, we have engaged in negotiations with Senator Elaine Alquist and her staff regarding SB 1064. With the assistance of Senate President pro Tem Darrell Steinberg and the Chair of the Appropriations Committee, Senator Christine Kehoe, and their staffs, we have reached a compromise on the bill.

In brief, the bill would eliminate the 50-employee cap (while requiring CIRM to remain within the 6% cap on administrative expenditures), permit the Board to provide reasonable compensation to the patient advocates for their service on the working groups, and codify certain practices and regulations that are already in effect while maintaining the agency's flexibility to make changes in the future.

In addition, Senator Alquist has agreed to drop her proposed changes to: (1) the terms of the Chair and Vice Chair; (2) codification of CalRX pricing; (3) expansion of the jurisdiction of the Citizens' Financial Accountability Oversight Committee; (4) the duties of the Chair and the President; (5) the pre-application process; and (6) the definition of "administrative costs."

Based on the amendments to which Senator Alquist has agreed, we recommend that the Board support SB 1064. A summary of the bill is set forth below and a full copy of the bill is attached to this memorandum.

SUMMARY OF SB 1064

50-employee cap: SB 1064 would eliminate the 50-employee cap but CIRM would continue to be subject to a 6% cap on administrative expenses.

Compensation for Patient Advocate Member Service on Working Groups: SB 1064 would authorize the Board to set a daily consulting rate for patient advocate members of the Working Groups (other than the Chair and Vice Chair of the Governing Board) for their service on the Working Groups. Currently, patient advocate members of the Working Groups are entitled to a per diem of only \$116 for the many hours of work they perform as members of the Working Groups.

Access/Waiver: SB 1064 would require that CIRM's intellectual property standards include a requirement that grantees and exclusive licensees submit a plan to CIRM to afford access to a drug that is, in whole or in part, the result of research funded by CIRM, to Californians who have no other means to purchase the drug. The plan would have to be consistent with industry standards at the time of commercialization in California, accounting for the size of the market for the drug and the resources of the grantee or exclusive licensee. CIRM would retain the authority to implement this requirement through regulations and to grant a waiver to the access plan requirement if the Board determines that, in the absence of a waiver, development and broad delivery of the drug will be unreasonably hindered or that the waiver will provide benefits that equal or exceed the benefits that would otherwise flow from the access plan. CIRM's regulations currently require that grantees and exclusive licensees submit an access plan. If the bill were enacted, CIRM would have to adopt additional regulations, including definitions and procedures, to implement this provision.

Revenue Sharing: SB 1064 would require that CIRM's intellectual property standards include a requirement that CIRM's grantees share a fraction of the revenues they receive from licensing or self-commercializing an invention or technology that arises from research funded by CIRM and it would codify CIRM's existing revenue sharing formulas. However, the Board would retain the authority to implement this requirement through regulations and to modify the formulas in the future if the Board determines that modification is required in order to ensure that essential medical research, including, but not limited to, therapy development and the broad delivery of therapies to patients, is not unreasonably hindered, or to ensure that the State has an opportunity to benefit from its investment.

15-Scientist Cap: SB 1064 would permit the Grants Working Group to have more than 15 regular scientific members while maintaining the limit of 15 scientists on each peer review panel. Currently, CIRM relies on alternate scientific members, in addition to regular scientific members, to meet its peer review needs.

Performance Audit: SB 1064 would require CIRM to commission an administrative performance audit every three years. This audit would not be required to include a review of scientific performance.

Meeting Minutes: SB 1064 would require CIRM to post vote tallies, including recusals for conflicts, with meeting minutes. The minutes of Board meetings currently include vote tallies along with recusals.

Transition Planning: SB 1064 would require CIRM to engage in transition planning for the eventual expiration of bond funding and to produce a transition report by January 31, 2012. CIRM has already begun to engage in transition planning.

Succession Planning: SB 1064 would require the Board to engage in succession planning to assess leadership needs, outline succession procedures, and develop strategies to ensure the successful transfer of knowledge. The Evaluation Subcommittee has begun to discuss succession issues.

Recommendation: Support the bill, but reserve the right to review for technical proficiency.

cc: Alan O. Trounson, President, CIRM

Attachment