CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE



18 February 2010

The Honorable Elaine Kontominas Alquist
Member, California State Senate
Chair, California State Senate Health Committee
State Capitol
Sacramento, Ca 95814

Re: **SB 1064 (Alquist)**

Dear Senator Alquist:

We write to provide important information regarding the California Institute for Regenerative Medicine ("CIRM"), its success in providing jobs for Californians, and its positive impact on the State's general fund. Our full Board has not yet had an opportunity to consider this bill; however, we wish to express our individual concerns regarding the bill's potential economic impact on the state's new tax revenues and new jobs created by CIRM. More importantly, we are concerned about the bill's potential impact on finding treatments and cures for diseases and traumas that Californians struggle with everyday.

**7 Million Votes – $100,000,000 in New State Revenue**

When more than seven million California voters approved Proposition 71, they authorized the sale of $3 billion of general obligation bonds. To ensure that the proceeds of these bonds were used exclusively for stem cell and related research, research facilities, and also the administration of the California Institute for Regenerative Medicine, they continuously appropriated the proceeds of the bonds to CIRM. **In what is a model for all of state government, CIRM operates within a 6% cap on expenses – efficiency unrivaled even in the private sector. CIRM has placed California at the forefront of international breakthroughs in medicine without any net state general fund appropriations or debt service expenditures through December 2009. CIRM continues to serve Californians by advancing research and therapies, creating thousands of jobs, fostering the growth of the biotech industry, and generating over $100 million in new state revenue.**

**California's Most Accountable State Agency**

- CIRM has been audited by the Bureau of State Audits (at the request of the Legilsative Audit Committee) with outstanding results.
- CIRM has been audited and found to have met all accountability standards by the State Controller.
- CIRM has had five years of clean financial audits by independent public accounting firms.
- Each of those independent audits has been reviewed by the Controller's office, giving CIRM an annual stamp of audit approval.
- Annually, the Citizen's Financial Accountability Oversight Committee, created by the voters and chaired by the Controller, has reviewed each financial audit without any exception.
- The voters of California specifically created a governing board to provide accountability and oversight, with twelve patient advocates representing chronic diseases, seven medical school deans, six scientific representatives and four members with biotech therapy development experience to provide the in-depth scientific and medical expertise to review and approve in public meeting every dollar of expenditure.
- There have been over 1100 hours of public meetings held by the governing board to provide the highest degree of transparency, disclosure and public input of any state agency in California.
- The standards, procedures and policies governing the accountability of the agency were all developed in public meetings and now serve as national model.

**Tens of Thousands of Job Years**

CIRM uses the proceeds of the State's general obligation bonds to make contractual commitments to fund multi-year grants and loans. To date, CIRM has committed approximately $1,025 billion. **These commitments, including the matching funds for construction in progress, will generate tens of thousands of job years over their funding term by 2013.**

**Disease Team Awards to Reach Human Trial (IND's)**

For example, CIRM recently awarded approximately $230 million for 14 Disease Research Team awards (thirteen grants and one loan), which will be paid out over four years if the projects meet their milestones. The goal of these awards is to develop new medical therapies from stem cell research to reduce the suffering from chronic disease and injury and to cure these conditions, if possible. The Disease Team grants and loans, specifically, have provided "compelling and reproducible evidence" that "demonstrates that the proposed therapeutic has disease- (or injury-) modifying activity. The project is sufficiently mature, such that there is reasonable expectation that an IND filing" for a Phase 1 human trial "can be achieved within 4 years of the project start date." The initial Disease Team awards focus on the following diseases:

- ALS
- Cancer (solid organs)

- Brain Cancer
- Dry Macular Degeneration (a leading cause of blindness)
- Juvenile Diabetes
- Genetic Skin Disease (Dominant Dystrophic Epidermolysis Bullosa)
- HIV
- Heart Disease
- Leukemia (blood cancer)
- Sickle Cell

Not all of these therapies will be successful in reaching human trials, but one of CIRM's early grants has already successfully completed a Phase I Human Trial – a surprising early milestone of progress.

**$885 Million in Donor and Institutional Matching Funds**

CIRM has also leveraged its funds through its Major Facilities Grants. CIRM awarded $270 million to help build 12 new research facilities in California. This program generated approximately $885 million in institutional and private donor matching funds for a total of $1.155 billion. **This program alone has created over 13,700 job years at a critical time for the construction industry.**

**Legislation Does Not Advance Critical Medical Mission**

**Senate Bill 1064** does not advance the agency's critical medical mission and jeopardizes the agency's successes to date. CIRM's President, Alan Trounson, Governing Board Chairman Robert Klein, and Governing Board Vice-Chairman Art Torres met with Senator Alquist and her staff for several hours recently to discuss why legislation is either duplicative or unnecessary in light of existing provisions in statute, regulation and actions already taken by our management and Board. Our Legislative Subcommittee will convene shortly to review the entire bill before it makes a recommendation to the full CIRM Board for their consideration. We urge you to consider the following points regarding this bill:

1. CIRM is already subject to state audit. Indeed, the Bureau of State Audits (acting at the direction of the Joint Legislative Audit Committee), the Controller, and the Little Hoover Commission have already undertaken extensive audits/reviews of CIRM, in addition to the review of the agencies financial practices performed by the Citizens' Financial Accountability Oversight Committee. If the Legislature believes that another performance review is warranted, it can request that the BSA undertake another review. In addition, CIRM is undertaking an independent external review of its scientific and board's performance, as required by its scientific strategic plan. In short, the Legislature and the Controller already enjoy ample audit authority, and CIRM is supplementing this by commissioning an independent external review. Thus, there is no need for legislation.

2. CIRM has already begun to engage in succession planning, both in terms of the change-over in board Chair and its membership as well as plans for the end of the $3 billion in bond funding. Indeed, CIRM's Loan Program, initiated more than a year ago, is aimed in

part at providing additional funds that can be used to make additional grants and loans. Other initiatives are also under consideration as well. There is no need for legislation to direct CIRM to do something that it has already undertaken.

3. The roles of the Chair and President are addressed in detail in Prop. 71. Furthermore, the Governance Subcommittee, after extensive review, including public input, has developed, and the Governing Board has approved, an internal governance policy that further delineates these roles. Again, there is no need for a bill.

4. Removing the 15-scientist cap on review will not significantly affect the Grant Working Group's (GWG) capacity to review more grant applications or enhance CIRM's ability to make grants and loans . The real limiting factor for review is time. At a review meeting the GWG can only discuss and score about 50 total applications per day for regular research grants and perhaps 15 to 20 for larger proposals such as Disease Teams or Training Grants. Increasing the number of GWG members at a review will not speed up the rate at which each application is reviewed. In fact, it may increase that review time to accommodate discussion by additional members. Thus, regardless of the number of participating GWG members, review of additional applications will require additional meeting days and increased CIRM staff time to manage the reviews and write review summaries. Longer meetings would lead to fewer of the world's leading experts being willing to attend. The current review assignment per panel member is consistent with other funding agencies, such as the NIH.

5. The 50-employee cap poses challenges for CIRM to provide adequate coverage of the science and translational program but the Board is actively exploring other alternatives to address this and remains committed to the 6% cap on administrative expenses.

6. Pre-application review is an important tool employed by CIRM to ensure that it is funding the best scientific and medical proposals. Pre-applications are reviewed by external and internal reviewers against stated criteria. Those proposals determined to be the most promising, competitive and responsive are invited to submit a full application. Applications that are deferred can reapply in subsequent rounds of the RFA or in response to other more suitable RFAs for the proposed research. Staff has undertaken an extensive review of the pre-application process and a subcommittee of the Board will be examining the process to see how it can be improved or whether there are other alternatives to accomplish the same goals. Legislation on this topic is premature and unnecessary.

7. CIRM has already adopted extensive regulations to balance the opportunity for Californians to benefit from their investment in stem cell research while ensuring that the research is not impeded. These regulations include revenue sharing, access plans, and pricing preferences for public entities. CIRM's governing board adopted the regulations after extensive public hearings, a process that John Simpson of Consumer Watchdog has referred to as a model for making policy. For these reasons, the voters expressly delegated the duty to adopt intellectual property regulations to CIRM's Governing Board.

We thank you for your consideration. Please feel free to contact Senator Torres at 415-396-9279, if you wish to discuss this further.

Very truly yours,

Robert Klein
Chairman

Senator Art Torres (Ret.)
Vice-Chairman

Duane Roth
Vice-Chairman

Cc:

Senate President *pro* Tempore Darrell Steinberg
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Members of the Assembly Health Committee