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June 8, 2009

David Schwarz
Little Hoover Commission
925 L Street, Suite 805
Sacramento, CA 95814

Dear Commissioner Schwarz,

On behalf of the Governing Board of the California Institute for Regenerative Medicine, we would like to thank you for your invitation to Bob Klein, the Chairman of the CIRM Board, to speak with staff of the Little Hoover Commission about the Commission's draft report on CIRM.

We strongly believe that a collaborative effort between the Little Hoover Commission and CIRM is the best way to achieve our common goals of maintaining public confidence in CIRM and ensuring CIRM's success. **In order to accomplish this, we believe it is imperative that the Chairman and the President of CIRM have an opportunity to discuss the proposed recommendations with members of the Commission.** We would also welcome the opportunity to discuss proposals which CIRM could implement to enhance public confidence and CIRM's effectiveness.

To facilitate your staff's call with Chairman Klein, we thought it would be helpful to describe our preliminary, overarching concerns regarding the draft recommendations. As we discuss in greater detail below, the proposed recommendations would drastically restructure CIRM's governance by reducing the size of the board and the terms of board members, concentrating appointment power in a single constitutional officer, and transferring virtually all of the Chair's statutory duties to the President – changes that could only be accomplished by another ballot measure. Furthermore, the proposed recommendations, if implemented, would undermine public confidence in CIRM by causing disruption and significant delay.

CIRM's Progress to Date

CIRM's goal is to find therapies and cures for chronic disease and injury as quickly as possible. In the short period of time in which CIRM

has had the capacity to award research funding, we have made significant progress towards this goal. Examples of this progress include:

- CIRM grantees have published nearly 300 papers in scientific journals. Each of these scientific discoveries contributes incrementally to the advancement of medical therapies. As a result, California is leading the world in scientific and technological advances in stem cell medicine.
- Most importantly, the first human clinical trial arising, in part, from CIRM-funded research began a year ago. The phase I trial of a JAK2 inhibitor for myelofibrosis, an acquired blood disease which leads to leukemia and strokes, shows considerable promise for patients who previously had very few viable treatment options. The patients who participated in the trial have been removed from bone marrow transplant lists and appear to have avoided the need for a high risk medical procedure with a cost of over \$120,000. An investigator at the University of California, San Diego led the research and is now working in collaboration with TargeGen, a San Diego biotech company, which is sponsoring the trial.
- CIRM's major facilities program, which involves an investment of \$270 million of Proposition 71 funding in the construction of 12 new stem cell research facilities across the State, generated approximately \$885 million in matching funds, for total funding of \$1.15 billion, to carry out an express direction in Proposition 71 to seek "leverage" to benefit California taxpayers and patients.
- By October, CIRM will have approved approximately \$1 billion in funding and attracted more than \$1 billion in matching funds. These matching funds include funding from five other nations (Canada, Spain, Victoria (Australia), the United Kingdom, and Japan) that have entered into bilateral agreements with CIRM to provide California researchers with scientific leverage as well as financial leverage and to bring the best global scientific advances to California. CIRM has made substantial progress towards its goals of completing agreements with the world's ten most influential nations in the science of regenerative medicine.
- CIRM's medical and ethical standards have served as a model for other states, including Illinois, which adopted CIRM's medical and ethical standards in their entirety. CIRM's staff has earned national respect. For example, CIRM's President serves on the international board of the International Society for Stem Cell Research, the leading stem cell research organization in the world, and CIRM's Scientific and Medical Standards Officer serves as the co-chair of the Interstate Alliance for Stem Cell Research.
- Pursuant to its strategic plan, CIRM is creating a broad portfolio of translational research that will bring the private sector into a significant number of research projects dedicated to advancing therapies to Phase I human trials. (In fiscal year 2010/2011, this collaboration with the private sector will seek both Phase I and Phase II human clinical trial proposals.) In September 2009, CIRM's Grants Working Group will review submissions by disease teams that have preliminary evidence that must rise to the level of convincing proof that the team can reach a Phase I human trial application to the Food and Drug Administration within 48 months. Some 32 teams will compete, based on this criterion, for an award before our international peer review panel and Board. Nearly half of these teams include private companies as participants.

Many of the Proposals Would Require Another Ballot Measure

Many of the proposals would require another ballot measure. Pursuant to Proposition 71, the Legislature may only amend the law “to enhance the ability of the institute to further the purposes of the grant and loan programs created by the measure.” (Prop. 71, § 8.) As the California Supreme Court has recognized, the voters’ power to decide whether the Legislature may amend or repeal initiative statutes “is absolute and includes the power to enable legislative amendment *subject to conditions attached by the voters.*” (*Amwest Surety Ins. Co v. Wilson* (1995) 11 Cal.4th 1243, 1251, emphasis in original.) Furthermore, “[a]ny doubts should be resolved in favor of the initiative and referendum power, and amendments which *may* conflict with the subject matter of initiative measures must be accomplished by popular vote, as opposed to legislatively enacted ordinance, where the original initiative does not provide otherwise.” (*In re Estate of Claeysens* (2008) 161 Cal.App.4th 465, 470, citations omitted, emphasis in original.)

LHC Staff Would Drastically Restructure the Board

The Commission’s staff proposes a drastic restructuring of the Board and CIRM. They would reduce the size of the Board from 29 to 15 members, reduce board member terms, and concentrate appointment authority in the Governor (eliminating the appointment authority of the Controller, the Treasurer and the Lieutenant Governor). This proposal rests on the false premise that the Board is too large and unwieldy and lacks truly independent voices, and it flies in the face of the voters’ intent. The size of the Board, which is similar to both the UC Regents (26 members) and the Judicial Council (28 members), has been a great advantage to CIRM, offering not only the breadth of expertise necessary to encompass the entire scientific and medical research pipeline from discovery to clinical application, but also a diversity of viewpoints that have enriched debates and improved outcomes. The notion that there are no truly independent voices on the Board is not only wrong, it is extraordinarily misleading. All of us have taken an oath to represent the citizens of the State of California, an oath we take very seriously. Furthermore, many of us have no affiliation with applicants for CIRM funding, and those who do have an interest recuse themselves from participating in even the discussion of decisions in which they may have an interest. As the Court of Appeal noted, “by approving Proposition 71 the voters have determined that the advantages of permitting particularly knowledgeable persons to decide which research projects to fund outweigh any concerns that these decisions may be influenced by the personal or professional interests of those members, so long as the members do not participate in any decision to award grants to themselves or their employer.” The proposal to reshape the Board puts at risk the quality of debate and decisions. It would reduce the expertise and diversity of viewpoints on the Board and it is at odds with the voters’ express intent.

LHC Staff Would Reduce Board Member Terms and Shift Appointment Authority

The same is true of the proposal to reduce board members’ terms and eliminate the power of the Lieutenant Governor, the Controller, and the Treasurer to make appointments. As its name implies, the Board was designed to be “independent.” By providing for 6 and 8 year terms and by dispersing the appointment authority among four constitutional officers, the Legislature,

and the Chancellors of the UC campuses with medical schools, as specified in Proposition 71, the voters sought to protect the Board's scientific mission by distributing and balancing the appointment authority among the legislative and executive officers and UC Chancellors. Like the proposal to reduce the size of the Board, the proposal to reduce terms and concentrate the power of appointment in a single constitutional officer would not further the intent of the voters; indeed, it would frustrate the voters' intent.

LHC Staff Would Shift the Bulk of the Chair's Duties to the President

By the plain language of Proposition 71, the voters also intended to create an executive chair who would provide financial leadership and a president who would provide scientific leadership. Under the financial leadership of Chairman Klein and the scientific leadership of President Trownson, CIRM has made accelerated progress by utilizing their respective expertise collaboratively. The staff's draft report would shift nearly all of the Chair's authority to the President, and strip the Chair of a salary. As President Trownson testified, he does not have the strategic financial expertise of Chairman Klein. Far from enhancing CIRM's ability to carry out its mission, this proposal would undermine the agency and the voters' intent.

As the Commission's staff conceded, even if the Legislature were to approve these recommendations, notwithstanding CIRM's legal and policy concerns, the result would almost certainly be litigation over whether the changes enhance CIRM's ability to further the purposes of the grant and loan program. This would be yet another distraction from the critical work that the voters have entrusted us with and a financial drain for the agency and the State's court system.

The Voters' Clear Expression of Intent

Finally, the voters' recent rejection of any effort to amend popularly enacted ballot measures suggests that the voters jealously guard their right to initiative. The voters unanimously rejected attempts to amend Propositions 10 and 63, which had been enacted by 50.1% and 53.8% of the voters, respectively – substantially less popular support than Proposition 71, which garnered 59% of the vote or more than 7 million California voters.

The Proposals, if Adopted, Would Cause Delay and Disruption

As you know, the voters have entrusted CIRM with an important mission and a short timeframe within which to complete it. Implementation of the recommendations in the draft report would cause major disruption and delay that would impede CIRM's mission. The Board has adopted an ambitious scientific strategic plan (currently under an update review) pursuant to which CIRM plans to complete its commitment of the agency's \$3 billion in bond proceeds sometime between 2016 and 2017. In the absence of additional funding, therefore, CIRM has only eight to nine years to accomplish its goals.

Successful Resolution of Litigation at Cost of Two Years of Research

Although CIRM has made remarkable progress, its path has not been smooth. Immediately after the voters' approval of Proposition 71, opponents of stem cell research filed lawsuits challenging CIRM's existence. The trial court, the appellate court, and the state Supreme Court reviewed the agency structure in depth and resolved the challenge in favor of the agency. Since CIRM's inception, it has confronted, and prevailed in, four separate lawsuits. The mere fact of the litigation, however, prevented the State from issuing bonds on CIRM's behalf, thereby delaying CIRM's progress by almost two years.

High Marks from Audits but at a Substantial Cost in Time and Resources

CIRM has also been subject to numerous audits, including thorough audits of its policies and procedures conducted by the Bureau of State Audits and the Controller. CIRM passed both audits with flying colors and adopted many of the audit recommendations, strengthening its grants management, travel, and compensation policies. Although CIRM benefited from these reviews, they have had a cost, consuming time and resources that could have been devoted to the pursuit of CIRM's mission.

Staff Recommendations Would Disrupt Research Funding

The vast majority of the recommendations in the draft report go much further than anything proposed by the BSA or the Controller. Indeed, the draft report would effectively rewrite Proposition 71 by fundamentally altering the structure of the Board and CIRM. These proposed changes come at a critical time for CIRM. The agency is in the midst of updating its scientific strategic plan to reflect new developments in stem cell science and new opportunities created by President Obama's reversal of President Bush's executive order, which imposed strict limits on federal funding of human embryonic stem cell research. CIRM staff and board members have participated in several public hearings regarding the plan and CIRM staff intend to present an update to the Board this summer. Similarly, as discussed above, the Board recently approved its first translational research awards, and in October, the Board will consider Disease Team Awards, an ambitious program designed to fund research that results in the filing of an Investigational New Drug application with the Food and Drug Administration within 48 months.

If the Little Hoover Commission staff's proposed recommendations were adopted, they would disrupt CIRM's plans, once again delaying its progress during the months of ensuing reorganization. All of the members of the Board would be termed out and would be precluded from being reappointed. The Board would lose not only the expertise of its members, but also their institutional history and their demonstrated ability to work effectively together.

One of the key objectives of Proposition 71 was to provide stability and predictability to a scientific funding program. The current program has earned the trust and respect of the scientific community in California and across the nation. (CIRM's 2008 Annual Report identifies more than 150 leading researchers who fly from around the United States and the world to participate in CIRM's peer review process. The extraordinary commitment of these individuals to California's mission and the trust of California scientists in the objective, scientific process of review would be severely undermined if the seasoned and experienced Board that is in place were to be restructured out of existence and if the appointment power were to be

concentrated in a single constitutional officer who, in the future, could be an individual who is opposed to stem cell research.

The transfer of most of the Chair's duties to the President would also present significant challenges to the agency. As President Trounson testified, he and Chairman Klein work well with one another and understand their respective roles. It is no exaggeration to say that the drastic restructuring and new appointments that would be required by the proposal would likely set the agency back by two years or more (if confidence could be restored). The voters expected CIRM to move quickly to find therapies and cures. The upheaval and delay that would ensue from the implementation of these proposals would serve only to undercut the voter's confidence in CIRM. We simply cannot afford any further delay in our pursuit of CIRM's mission – a mission the voters expressly entrusted to CIRM's 29-member governing board.

Conclusion

We are concerned by other proposals that may adversely affect CIRM's functions and mission, as well, but we felt that it was most important to share our overarching concerns with you first. We urge you to postpone your consideration of the draft recommendations to allow us time to engage in a meaningful dialogue regarding changes that CIRM could undertake to enhance public confidence in CIRM, as well as CIRM's effectiveness. This would give us an opportunity to prepare a thorough analysis of each of the recommendations, including, for example, an analysis of the value of the Board's diversity to the quality of the scientific judgments. Thank you for your consideration of our concerns.

Sincerely,



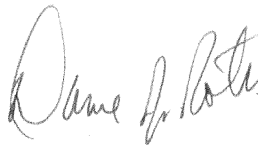
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