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Society for Cardiac Angiography Interventions*

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*Chairman & CEO, Alliance Pharmaceutical Corp.*

**Joan Samuelson, Esq.**  
*Founder, Parkinson's Action Network*

**David Serrano Sewell, Esq.**

**Jeff Sheehy**  
*Communications Director  
UCSF AIDS Research Institute*

**Jonathan Shestack**  
*Founder & Vice President, Cure Autism Now*

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*Chair & Director-  
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December 22, 2008

Stuart Drown, Executive Director  
Eric Stern, Project Manager  
Little Hoover Commission  
925 L Street, Suite 805  
Sacramento, California 95814

Dear Messrs. Drown and Stern:

Thank you for the opportunity to provide an additional written submission in response to questions posed by members of the Little Hoover Commission during my testimony before the Commission on November 20, 2008. As I explained at the hearing, I am only a single member of the Governing Board of the California Institute for Regenerative Medicine and I cannot purport to speak for the Board as a whole. Furthermore, given the importance of this subject, I cannot respond to your request without seeking input from the Board. Unfortunately, because of time constraints, the Board has not had an opportunity to consider the questions you have posed.

However, on December 19, 2008, I consulted with the Legislative Subcommittee regarding your questions. One member expressed his belief that the Board was functioning well and that it was premature to discuss potential modifications. Another member expressed interest in the possibility of permitting patient advocates to appoint alternates. Although we did not reach consensus regarding potential modifications, we discussed seeking input from the Board regarding potential changes to Proposition 71. Therefore, I am not prepared to suggest any potential modifications at this time, but I intend to request input from the Board. Given the financial and programmatic challenges facing CIRM, the Board must focus in the short term on these immediate needs. Given the extraordinary number of meetings we have had and the current financial situation, it would be difficult to thoughtfully focus on potential long-term changes at this time, particularly because a number of the members of the Board believe that Proposition 71 is working well. At a later time, however, we would be open to a discussion of potential long-term changes.

Although I cannot prejudge the outcome of this process, I can affirm that the Board is working well. As I have noted in the past, the Governing Board of CIRM is the only state commission of which I am aware that has benefitted from the service of two Nobel Prize winners – David Baltimore, the former President of Cal Tech, and Paul Berg, an Emeritus Professor at Stanford and an alternate to Dr. Phil Pizzo. The State of California is fortunate that Dr. Baltimore, Dr. Berg, and other extraordinarily accomplished individuals have agreed to serve on the Board. (Attachment A, Biosketches of Members of the Governing Board of CIRM.) As even a casual observer of meetings of the Governing Board would recognize, the members of the ICOC are independent-minded and have strong and diverse views. Through debate on policies and on grant awards, the Board manages to forge consensus and benefits from the serious debate among its members.

Additionally, the Board is unique in that it benefitted at the outset from the work of the National Academies of Sciences, which convened a special meeting to discuss best practices in the implementation of Proposition 71. In the medical and ethical area, the State of Illinois last year adopted CIRM's medical and ethical standards, which were developed with the leadership of the National Academies of Sciences, as their own medical and ethical standards.

### **The Structure and Composition of the Board**

Although the Board is large, the size of the Board is beneficial because of the diversity of viewpoints and experience it affords CIRM. From patient advocates like Joan Samuelson and Jeff Sheehy, who have been on the frontlines advocating for people who suffer from Parkinson's Disease and HIV/AIDS, respectively, to scientists and clinicians who have spent their careers trying to find cures for diseases like cancer and hepatitis, the members of the Board offer invaluable expertise and experience to the Board's deliberations. Furthermore, through subcommittees and task forces, the Board has created a mechanism that permits members to focus acute attention on specific issues of concern. Examples of these subcommittees and task forces include, but are not limited to:

Finance Subcommittee

Legislative Subcommittee

Governance Subcommittee

Presidential Search Subcommittee

Interstate and International Subcommittee (under consideration)

Intellectual Property Task Force

Loan Task Force

California Supplier Task Force

RFA Guidelines Task Force

Pre-Application Review Task Force

California Council on Science and Technology Task Force

These subcommittees and task forces afford CIRM the opportunity to utilize the talents of the members of the Board in an efficient manner. The Board's recent adoption of a policy to

permit members to participate in regular meetings by teleconference has also enhanced the ability of members to contribute to CIRM. For those members who suffer from chronic diseases, like Joan Samuelson, or who care for a child with autism, like Jonathan Shestack, this policy will make it easier for them to lend their talents to the Board.

### **The Appointment Process and Removal**

Like many independent commissions and boards (*e.g.*, the Fair Political Practices Commission, the Little Hoover Commission, the Integrated Waste Management Board, the First Five Commission, etc.), Proposition 71 spreads the appointment authority over several appointing powers and/or mechanisms:

Governor

Lieutenant Governor

Controller

Treasurer

Speaker of the Assembly

President Pro Tem of the Senate

Chancellors of UC Campuses with medical schools

Four constitutional officers who nominate candidates for Chair and Vice-Chair with election by the Board

Given the politicized nature of funding for stem cell in this country and the importance of providing not only a stable funding source, but also a stable political environment, the diffusion of appointment authority in Proposition 71 serves important goals.

Proposition 71 also specifies that members shall serve fixed terms. Again, this is a feature shared by other boards and commissions in California and it serves important goals. As the Court of Appeals noted, many members of board and commissions serve fixed terms, meaning that they cannot be removed by their appointing authority. (*California Family Bioethics Council v. California Institute for Regenerative Medicine* (2007) 147 Cal.App.4<sup>th</sup> 1319, 1354-1355.) This feature permits members of the Board to focus on CIRM's mission rather than on the shifting political winds. It also provides the agency with stability. Of course, the fact that members serve fixed terms does not mean that they are beyond the law. Under Code of Civil Procedure section 803 and Government Code section 1770, the Attorney General can initiate an action to remove members for a variety of causes, including misconduct.

### **Conflicts**

California's conflict of interest laws are broad and complex and they serve an important purpose. I drafted Proposition 71 to protect against conflicts of interest while at the same time accommodating a board comprised of individuals with expertise. The Court of Appeals recognized that the voters had made a reasonable policy judgment that the benefit of obtaining the members' expertise outweighed the risks of conflicts, as long as members were precluded from participating in decisions to award grants to their own employers. (*California Family*

*Bioethics Council v. California Institute for Regenerative Medicine* (2007) 147 Cal.App.4<sup>th</sup> 1319, 1368.) We recognize that we have a special obligation, as the stewards of public funds, to avoid even the appearance of a conflict. We have therefore developed extensive conflict of interest policies and procedures to guard against conflicts from the Grants Working Group to CIRM staff to the Board. At the Board level, for example, in order to focus on the best scientific proposals, rather than on the identity of the applicant institutions and investigators, the summaries of the applications' benefits and strengths and weaknesses are anonymized and members typically do not know the identity of the applicant when they vote on the application.<sup>1</sup> In order to set an example, I have personally committed in writing not to hold financial interests of any kind in the biotech or pharma sectors based on my belief that the Chair must remain independent of any financial interest in the health care sector. In addition, staff diligently monitors members who may have a conflict to ensure that they do not participate in the discussion. Our conflict procedures have served the agency and the public well in the review of 809 applications and 253 awards.

### **2005 Legislative Enhancements**

We can continue to strengthen the transparency of CIRM and to improve our outreach to the California public. At the last Board meeting for example, the Board asked that the staff present a plan to incorporate members of the public, the research community, and the biotechnology sector in the process of updating CIRM's strategic plan. We are also in the midst of redesigning our website to enrich the opportunity for researchers, advocates, and members of the public to learn about CIRM's activities and to participate in our processes. Finally, we are working on a proposal for audio-webcasting board meetings. It is our hope that these steps will broaden our public reach and transparency. Hopefully, the public and the press will understand, as your staff and Commission members have observed, the importance of the robust discussion that precedes the approval of every grant, loan, and standard. We believe that these steps will further the progress we made through our work with the Legislature in 2005.

### **Ratio of Authority Between Chair and Board**

As the Chair of the ICOC, I have the statutory responsibility to manage the Board's agenda and work flow. My vote on any item on the agenda, however, carries the same weight as any other member's vote. I am just one voice, and as you no doubt observed when you attended the last Board meeting, I do not limit the debate. Members of the Board hold strong views and express them freely. Furthermore, I approach my statutory duties regarding the Board's agenda and work flow in a collaborative fashion with a leadership model rather than an authority model. To fulfill my statutory duties, I rely on the input of CIRM staff and the Board's subcommittees and task forces. Therefore, I firmly believe that the ratio of authority between the Chair and the Board as a whole is appropriate.

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<sup>1</sup> Through CIRM's extraordinary petition procedure, applicants may voluntarily identify themselves prior to the Board's consideration of their application. In addition, Board members may review a full application in closed session for the purpose of analyzing proprietary information, but this does not typically include the name of the institution or investigator.

## **Conclusion**

In response to your request, I will seek input from the Board as discussed above. I will also look forward to consulting with you on next steps so that we can assist you with your process. If you would be willing, I would personally like to meet with you and your subcommittee members, along with the Chair of our Finance Subcommittee, to obtain your input relating to our most immediate challenge – a financial crisis that could endure for the next two years or more. In preparation for such a meeting, I would be happy to share with you draft position papers on possible federal policy initiatives that could enhance CIRM's ability to achieve its mission.<sup>2</sup> I look forward to talking with you.

Sincerely,



Robert N. Klein  
Chairman, Independent Citizens' Oversight Committee  
CA Institute for Regenerative Medicine

Attachment (Board Member Biosketches)

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<sup>2</sup> Because the Board has not yet had a chance to approve these policy papers, they are drafts only.