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Written Testimony for The Little Hoover Commission Nov. 20, 2008 Hearing John M. Simpson Director, Stem Cell Oversight and Accountability Project

Consumer Watchdog's Stem Cell Project is grounded on a simple premise: The people paying for the state's \$6 billion program – the taxpayers of California – should receive direct benefit from the research they are funding. Moreover, Californians should have affordable access to any of the fruits of the research for which they have paid.

We believe that because the California Institute for Regenerative Medicine (CIRM) is a public agency, its business must be conducted with the utmost transparency. If anything, because of the controversial nature of stem cell research, it is to CIRM's advantage to go beyond the minimum requirements applicable to California public agencies.

Consumer Watchdog launched our Stem Cell Oversight and Accountability Project in December 2005 with funding from the Nathan Cummings Foundation. More information about our organization is available at our website, www.consumerwatchdog.org. We had no position on Proposition 71 during the campaign, but once passed, we believed it essential that the public interest was protected. The Stem Cell Project has continued into its third year with support from the Cummings Foundation. During that period I have attended all meetings of the stem cell agency's board, the Independent Citizens Oversight Committee (ICOC) as well as almost all of the meetings of its subcommittees and various taskforces. As detailed in the attached biography, my background is in journalism. The observations and recommendations I am making about CIRM and the ICOC are based on the meetings I have attended, conversations with ICOC members, CIRM staff, former staff, grant recipients, applicants, scientists -- both academic and commercial -- and biotech executives.

Zach Hall, the first president of CIRM, referred to me as a "constructive critic." It is in that spirit that I offer this testimony. My suggestions are intended to improve the institute to enable it to better fulfill the goals envisioned when Proposition 71 was approved by 59 percent of the vote in 2004. After almost four years of operation there are clearly lessons to be learned and ways the agency can be improved. I will address the four topics raised by the Little Hoover Commission staff and then turn briefly to a fifth: intellectual property rights and provisions providing direct benefit for Californians.

I. Governance Structure

The fundamental flaw of Proposition 71 is that it created the ICOC and CIRM outside of the normal accountability structures of a public agency in California. While it's true the ICOC members are appointed by various elected officials, there is no provision to remove them from office. CIRM and the ICOC are not accountable in the usual way to anyone in state government. Compare CIRM's status with that of stem cell research programs in other states. In all of them the program was

incorporated into an existing state agency, rather than being set up as a new stand-alone unit of government.

The authors of Proposition 71 apparently envisioned a large oversight board as a way to draw on the expertise of many people. The 29 members must come from academia, the patient advocate community and the life sciences industry in a formula that is spelled out by the initiative. (I will address the composition of the board below.) Apparently fearing the possibility that stem cell research opponents could hijack the board, the authors of Proposition 71 required a supermajority quorum of 65 percent to conduct business.

In practice the size of the board, comprised as it is of many individuals with substantial time consuming commitments to their primary responsibilities, and the supermajority requirement have hamstrung its effectiveness. The ICOC regularly struggles to muster a quorum. On occasions when a quorum is present, discussion can be cumbersome simply because of the number of people involved. As a result issues frequently take longer than anticipated to consider. Then as the day progresses some members inevitably leave before the session is concluded. All too often remaining issues are hastily considered and brought to a vote before the board loses a quorum.

Currently all regular meetings of the ICOC require members to be present. There are no sanctions for repeated absenteeism. On Nov. 3 a special meeting of the ICOC was scheduled to adopt a plan that would allow up to five members per meeting to take part in regular ICOC meetings by telephone conference call. That meeting was canceled, but another special session is expected to adopt the plan.

Under ICOC by-laws subcommittee meetings may be conducted by conference call so long as notice is given of the locations and the remote sites are open to the public. Even so, many such meetings have been unable to take formal action because there was no quorum. The usual recourse in such cases is to take a straw vote and present that as the “sense of the committee members present.”

Recommendation: *CIRM should be incorporated into an existing state agency and be subject to normal accountability procedures of any state agency. Procedures to remove an ICOC member from a seat should be adopted. The board should be reduced in size to 15 members. Quorum requirements should be reduced to a simple majority. Sanctions should be adopted that could be imposed if board members are chronically absent, including removal from the ICOC.*

Another structural issue centers around the dueling roles of the chairman of the ICOC and the president of the stem cell agency. Although the president is described as the chief executive of the agency, the chairman is directly involved in CIRM’s management and has a substantial staff that reports directly to him. The structure is confusing and in the past led to unproductive tension between the chairman and the president.

The current Chairman Robert Klein has been serving in the position without pay. Many believe the job description in Proposition 71 was written to match his qualifications. It is unrealistic and unfair to expect a chairman to continue to function without pay.

Recommendation: *The ICOC needs to begin planning for a successor to the current chairman. The role of the chairman in CIRM’s day-to-day operations should be curtailed and the president should truly function as CIRM’s chief executive.*

II. Conflict-of-Interest and Open-Government Procedures

Proposition 71 created by design an oversight board that has built-in conflicts of interest. The largest group on the ICOC, the 13 members representing various research universities and institutes, work for the same institutions that will receive much of the research funding. The 10 patient advocates represent the views of various persons concerned with diseases that are expected to benefit from stem cell research. The four representatives from the life science industry cannot come from firms involved in stem cell research; they do offer an industry perspective.

One board member inappropriately attempted to influence a CIRM staff decision affecting a grant application from a researcher at his institution. The incident is under investigation by the Fair Political Practices Commission at my request. The ICOC member has recused himself from all ICOC meetings during the probe.

Although the representatives of the research institutions recuse themselves from consideration of specific grants to researchers at their institutions, they can shape broader policies to favor their institutions. It's highly unlikely that the 13 institutional representatives will act in any way that is independent of the interests of their employers. And, as has been repeatedly demonstrated, what is best for the state's universities and research institutions is by no means necessarily what's best for all Californians. Those representing the institutions that want the money ought not set the rules for how they get it. Unfortunately, that's not what Proposition 71 provides.

Similarly, patient advocate members speak for those afflicted with a particular disease. All members of the ICOC are there because of their specific ties to one group or another. There are no members representing the broad public interest.

Recommendation: *While the size of the ICOC should be reduced, criteria for membership on the smaller board should be expanded to include some representatives of the general public. Representatives of universities and research institutions could serve ex officio, but without a vote.*

CIRM's peer review process flouts normal open, good-government procedures. The so-called Grants Working Group reviews grant applications behind closed doors. The panel is composed of out-of-state scientists and patient advocates. CIRM insists the working group only makes recommendations. Actual awarding of grants is done by the ICOC. Therefore, CIRM says, there is no reason for the scientists on the working group to disclose their financial interests. Potential conflicts are recorded by CIRM staff, but are not available to the public. Applicants don't know which scientists are assigned as primary reviewers to their application. Secrecy shrouds the entire application process. Applicants are only identified if they receive a grant.

Recommendation: *The entire grant-making process should be transparent. CIRM is handing out roughly \$3 billion in public funds and the program will cost \$6 billion when bond financing is included. The public has a right to see how it is done. All applicants should be identified. In tracking the fairness of awards over time, knowing who sought, but did not receive funds can be as important as knowing who did get a grant. The default position for the entire review process – with a provision for executive sessions to consider proprietary information—should be open to the public. Failing that, at a minimum, the names of which reviewers handled which applications must be public record. Applicants may believe that there is a professional conflict with a particular reviewer – not uncommon in science – and can only raise their concern if they know who are their primary reviewers. Finally, because most grants are awarded as the working group “recommends” the*

members are de facto decision-makers. Working group members should be required to file the usual public financial disclosure forms.

III. CIRM's Performance In Distributing Grants

The initial rounds of grants were distributed to nonprofit research institutions and universities. Part of the reason for this was the nature of the grants. With the completion of an intellectual property policy for awards to commercial entities, applications for grants for disease team planning and developing new stem cell lines were opened to the commercial sector this spring. Twelve of fifty applications for new cell line grants came from companies. Nine of 59 disease team applications came from the for-profit sector.

In June the ICOC awarded \$23 million to 16 applicants in the new cell line awards. None went to companies. At the same meeting \$1.1 million was awarded for 22 disease team planning grants. One of the \$50,000 awards went to a commercial entity, Novocell.

Not surprisingly there is widespread unhappiness among many of the stem cell firms. A number of executives have said their applications were not treated fairly and that there is a bias toward academic research among the Grants Working Group scientists and on the ICOC. Many have expressed that view privately for fear of jeopardizing future applications. Similarly, academic scientists whose applications were turned down have been reluctant to publicly criticize the review and awards process. Who wants to bite the hand that you hope will feed you?

Basic research, often at universities is essential to furthering knowledge. Translating that knowledge to cures inevitably requires involvement of the private sector.

Recommendation: *CIRM must increase the number of scientists with corporate experience who serve on the Grants Working Group. As recommended above, the review process should be open to the public if there is to be faith in the process. It's possible that 20 applications from the private sector did not deserve an award based on a lack of scientific merit, but that is impossible to know when the decisions were made behind closed doors. "Trust us, we're scientists" simply is not the foundation for good public policy.*

IV. CIRM's Ability To Adjust To Changing Political And Scientific Environments

Both the political and scientific environments have changed substantially since 2004 when Proposition 71 was passed. At that time President Bush had banned federal funding of most embryonic stem cell research and researchers saw great potential in SCNT (somatic cell nuclear transfer) or so-called therapeutic cloning. Stem cell lines have been derived in other species using the method, including primates, but so far SCNT has not been successful in humans. Instead scientists have developed iPS cells (induced pluripotent stem cells), which appear to have the characteristics of embryonic stem cells. Essentially an adult cell is induced to behave like an embryonic stem cell. Although we have not reached the stage yet, human embryonic stem cells ultimately may prove to have been a step along the way that some day will not be necessary for cures.

Another realization is that successful cellular therapy could be further down the road than hoped, while the most immediate benefit of stem cell research will be using cells to test drugs and understand diseases.

On the political front Barack Obama is poised to lift the ban on federal funding of human embryonic stem cell research. Put simply both the political and scientific environments that prompted Californians to overwhelmingly pass Proposition 71 have dramatically changed.

I have found too often among stem cell research advocates a tendency towards a circle-the-wagons-you're-with-us-or-you're-against-us attitude. It should be possible to question how public money is being spent, without being tarred as anti-stem cell research. It made sense in 2004 to authorize \$3 billion in bonds for stem cell research. Given the current environment, such commitment may not be necessary.

CIRM is in the process of revising its Scientific Strategic Plan.

Recommendation: *CIRM and the ICOC must recognize that the political, scientific and economic environment have dramatically altered since the passage of Proposition 71. The Strategic Plan should reflect the new realities. It is also appropriate to consider seriously whether issuing all \$3 billion in authorized bonds is the correct policy in light of the new environment and economic realities facing the state. I have not reached a conclusion, but a thorough examination of the question is warranted.*

V. Intellectual Property Policy and Benefit To Californians

Everyone knows that all loans and grants come with reasonable requirements and conditions. When I sign a mortgage and take the bank's money, I agree to the bank's terms. Venture capitalists behave the same way. They provide money to companies and require clearly spelled out conditions and expectations. There is no reason it should be any different when the taxpayers of California put \$6 billion on the line. We are entitled to insist upon maximum public benefit for our investment. The rules governing ownership of the results of CIRM-funded research — intellectual-property rules — must be based on affordability, accessibility and accountability.

CIRM's intellectual property policy contains provisions that provide for a payback to the state if research funded by CIRM produces revenue. This makes California's policy better than the federal Bayh-Dole Act, which contains no such provision for federally funded research. CIRM's policy also has provisions that would require a company offering a drug, treatment or cure resulting from CIRM-funded research to offer an access plan for people without health insurance. It also requires drugs, treatments or cures, being purchased with public funds to be sold at a price determined by the CalRx program.

However, there is no adequate provision in the regulations to ensure that average Californians would have affordable access to the drugs and cures that result from the research they are paying for.

Recommendation: *The Attorney General should be able to intervene in cases of unreasonable pricing of drugs, treatments and cures that were developed as the result of CIRM funding.*

