Stem Cell Research:
Strengthening Governance to Further the Voters' Mandate

The Little Hoover Commission's Review of the California Instutite for Regenerative Medicine

June 2009

State of California

LITTLE HOOVER COMMISSION

June 25, 2009

The Honorable Arnold Schwarzenegger
Governor of California

The Honorable Darrell Steinberg
President pro Tempore of the Senate
and members of the Senate

The Honorable Dennis Hollingsworth
Senate Minority Leader

The Honorable Karen Bass
Speaker of the Assembly
and members of the Assembly

The Honorable Sam Blakeslee
Assembly Minority Leader

Dear Governor and Members of the Legislature:

In the California Institute for Regenerative Medicine, California has made an investment in innovation that is envy of the world. Known as CIRM, the institute is the product of Proposition 71, which promised voters they could turn California into the global epicenter of biotechnology. The institute since has directed more than $700 million toward scientific exploration, in the process, leveraging an additional $900 million in private and institutional money that has built new facilities, lured scientists to California and spurred growth in the state's life-sciences industry. This money marks the first phase of a planned $3 billion public investment, to be financed through the sale of bonds authorized by voters in 2004.

In 2008, Senators Sheila Kuehl and George Runner asked the Commission to study CIRM and recommend ways to strengthen its governance structure, improve accountability and reduce conflict of interest. As CIRM matures, these issues take on greater consequence.

The Commission found that CIRM's governance structure is not adequate to protect taxpayers' interests or serve its own ambitious goals. The Legislature must take this opportunity to reform CIRM's governance structure to ensure that it can deliver on its mission of developing cures for the benefit of all, as well as provide transparency and accountability for California's taxpayers who will be paying off the bonds.

Proposition 71 set up CIRM to prevent political meddling, a reaction to the emotionally charged debate surrounding the use of embryonic stem cells for research. It barred legislative changes for CIRM's first three years and limited the Legislature's subsequent ability to amend the ballot initiative. The 10,000-word proposition laid out highly specific qualifications and detailed operational duties for its chairperson. Its very specificity prevents CIRM from evolving, institutionalizes inefficiencies and hobbles its ability to transition to new leadership.

CIRM's 29-member oversight committee includes representatives from institutions that have benefitted from grants the committee approved. This structure, along with overly long terms and the inability to nominate its own leaders or hold them accountable, fuels concerns that the committee never can be entirely free of conflict of interest or self-dealing, notwithstanding a court ruling that established the legality of such a structure. Legal is not necessarily optimal, however, and litigation over this issue

delayed CIRM from beginning its work. As long as the board remains in its present form, its structure will draw scrutiny, diverting CIRM resources.

To enhance CIRM's ability to fulfill its mission, the Legislature should reform the governance structure by taking the following steps:

- Decrease the size of the board to 15 members, of whom four should be independent members with no ties to CIRM-funded entities.
- Reduce terms to four years for all new members, allowing current board members to serve out their existing full terms.
- Streamline the appointment process to improve accountability, allowing the governor to appoint 11 members, subject to Senate confirmation.
- Realign the roles of the chair and the president to eliminate overlapping authority, improve clarity and bolster accountability.
- Allow the CIRM board to nominate and elect its own chair and vice chair from within the body and to set terms and conditions for removal.
- Require the CIRM board to begin formal planning for leadership transition.

The Legislature also should remove constraints imposed by Proposition 71 by eliminating the 50-person cap on staffing and the 15-person limit on outside scientific peer reviewers. CIRM should be able to draw on outside experts to evaluate grant proposals, as the "triage" process of internal prior review only will undermine the high standards CIRM previously has set. CIRM is moving beyond providing money for facilities, education and basic research. It now will loan money to businesses to advance promising treatments, a high-risk venture. In the event a business succeeds with a marketable cure, however, CIRM would benefit through stock warrants. It is essential to CIRM's credibility to ensure the process is as open as possible.

As needed as these improvements are, the Commission believes that a transition to a stronger governance structure should be prospective and strategic, and minimize disruption that might slow CIRM's ambitious and creative agenda.

Some of the reforms that the Commission recommends CIRM can undertake on its own, others will require legislation. The Commission sought to avoid making recommendations that would require going back to voters. Though counsel for CIRM has made clear its belief that the recommendations cannot be enacted short of a ballot initiative, the Commission believes that its recommendations will further the voters' intent. Through each recommendation, the Commission seeks to strengthen CIRM for the long term and speed its success.

Sincerely,

Daniel W. Hancock
Chairman

The Commission approved this report with a vote of 8-1. A dissenting opinion accompanies the report.

STEM CELL RESEARCH:
STRENGTHENING GOVERNANCE TO FURTHER THE VOTERS' MANDATE

Table of Contents

Executive Summary i
Background 1
Structure Lacks Coherence, Accountability 13
Recommendations for Improving Governance 29
Conclusion 43
The Commission's Study Process 47
Appendices 49
- Appendix A: November 2008 Public Hearing Witnesses 51
- Appendix B: Letter from Senators Sheila Kuehl and George Runner 53
- Appendix C: Current CIRM Organizational Structure 55
- Appendix D: CIRM Timeline 57
- Appendix E: 2005 Policy Enhancements 59
- Appendix F: Letter from Senator Dean Florez 65

Notes 67

Table of Sidebars & Charts

Current and Proposed Board Compositions ix
Authority for Restructuring the State's Stem Cell Agency x
Stem Cell Arms Race 3
Amending the California Stem Cell Research and Cures Act 7
Current CIRM Organizational Structure 11
CIRM-funded Grants by Institution 15
Lessons for CIRM: Restructuring the Red Cross 20
Chairperson Criteria 21
New CIRM Labs 23
Internal Policing 24
Connecticut's Peer Review Compromise 25
Grant Monitoring 26

Application & Award Process for CIRM Funding..... 27
Current and Proposed Board Compositions..... 32
CIRM and Consultants..... 33
Authority for Restructuring the State's Stem Cell Agency..... 40
Composition of Stem Cell Agency's Governing Board..... 41

Executive Summary

Approved by voters in November 2004, Proposition 71 gave California the constitutional right to conduct a politically controversial type of stem cell research using human embryos. The measure was a reaction to President George W. Bush's restrictions on federal funding for certain human embryonic stem cell research and a bid to jumpstart a new industry in California. Although private funding was not restricted, California voters responded by authorizing $3 billion in research funds to support stem cell science and create a new state agency, the California Institute for Regenerative Medicine (CIRM), to oversee the distribution of the money to universities, research institutes and biotechnology companies. The ballot measure also created a 29-member governing board, the Independent Citizens Oversight Committee (ICOC), to craft policies for CIRM and give final funding approval for research requests.

Although Proposition 71 passed with almost 60 percent of the vote, skepticism continues to surface from detractors, the media, members of the Legislature – even early backers – about the agency's ability to direct funding to science that will best lead to new medical treatments and cures. Much of the criticism has been directed at the ICOC, which is composed of officials from top universities, research institutes and the biotechnology industry, as well as advocates from disease groups that will benefit from the funding. The legality of this governance structure has been upheld by the courts, though what is legally allowable may not necessarily be optimal. As long as CIRM's governance structure exists in this form, skepticism will remain, generating scrutiny that will take away from CIRM's main focus – driving transformational scientific research and finding cures.

In April 2008, Senators Sheila Kuehl and George Runner asked the Little Hoover Commission to make recommendations on ways that CIRM's governance structure might be improved to better ensure public accountability and reduce conflicts of interest. The Commission has identified several recommendations to more adequately guide the state's unique investment in stem cell science – more than $6 billion once bonds are repaid – and improve the agency's efficiency in meeting the voters' goals.

In terms of outcomes, the governance structure and issues of transparency and accountability will be more critical to CIRM going forward. Despite the weaknesses of its existing governance structure, CIRM has been successful in getting money out the door quickly and establishing California as a global leader in stem cell science. Its investment of more than $700 million since 2004 has provided demonstrable results, including new and expanded facilities under construction, an influx of out-of-state and foreign scientists, published articles on research progress and growth in California's life-sciences industry. Moreover, it has leveraged the state's investment by attracting $900 million in matching funds. The Commission found that the method CIRM has developed to distribute grants, based on practices of leading federal grant-making entities, has been defensible, though room exists for process improvement. The Commission can see no downside to more transparency: Connecticut, for example, has not suffered from a lack of interest from grant seekers by using its more open process for a state-run $100 million stem cell research program. CIRM, however, is moving in the other direction by introducing an additional, closed-door element of the review process that involves an internal staff screening of funding requests.

Criticism that CIRM's governing board remains an insiders' club undermines the legitimacy of the agency. Some 80 percent of the funds to date have been awarded to institutions with representatives on the ICOC. The fact that CIRM funding has gone largely to prestigious California universities and research institutes is hardly surprising and should be expected, given the goals of Proposition 71 and the considerable expertise resident in these research centers. Such institutions would be natural recipients of such research money under Proposition 71. Even though the names of the institutions applying for research funds are redacted during the review and approval process, criticism about the makeup of the agency's governing board was an issue the Commission heard repeatedly – and one that can be addressed by incorporating more transparency into CIRM's operations. For example, the frequent occurrence of members recusing themselves because of conflicts of interest shows a structural defect in the governing board.

Though CIRM's original grant distribution process follows a best-practices model, CIRM's organizational structure deviates from good-governance characteristics of corporate, nonprofit and public-sector boards. The rationale may have been reasonable in 2004, when human embryonic stem cell science was the subject of political controversy. The detailed provisions of the ballot initiative, which placed the governing board outside of the normal scope of accountability compared to other state agencies and boards, provided stability, diversity and the political protection to get the agency up and running. But today, only five years

later, Proposition 71 already looks like a relic of another era. President Barack Obama is removing restrictions on federal funding for human embryonic stem cell research, and CIRM struggles at times against the rigidity of its governing statutes to adjust to the changing political and scientific landscape and plan for the future.

Much of Proposition 71 now seems overly prescriptive in defining the governance and oversight structure of CIRM. Among the weaknesses the Commission found:

- The 29-member board is too big and has had trouble assembling quorums.
- The board lacks truly independent voices to balance out those of interested board members.
- The founding board members' terms are too long and are not conducive to adding fresh perspectives about the agency's future given the rapid advancement of stem cell science.
- The multiple appointing authorities for board members cloud accountability.
- The board chair position, as structured, conflates day-to-day management with the independent oversight that the board is supposed to provide, straddling the roles of accountability and operations.
- The 50-person cap on CIRM staffing is arbitrary and has led to a potential overreliance on more expensive, outside contractors.
- A second arbitrary cap limits to 15 the number of out-of-state scientists that CIRM can use to conduct a first-level review of grant applications. To operate within the cap, CIRM has created an internal pre-application triage process to ease the workload on the peer-review panel, but the process creates a layer of opacity when the agency should be striving for more public transparency.

Some of the Commission's recommendations for governance improvement can and should be adopted by the ICOC. The board has made internal changes on its own in the past. Other proposed reforms will require legislative action. There are limits, however, to how far the Legislature can amend CIRM's organizational structure without requiring another vote of the people – a tack the Commission has tried to avoid. A key provision in Proposition 71 stated that any legislative alteration must "enhance the ability of the institute to further the purposes of the grant and loan programs created by the measure."

The ability of the Legislature to amend statutes that have been enacted through voter initiatives, even when amendments are authorized, has

been subject of occasional litigation, but the standards and criteria under which the Legislature can make these changes are vague.

Counsel for CIRM and the Americans for Cures Foundation provided the Commission with legal opinions that question whether some of the Commission's potential recommendations could be enacted into law without voter approval. In their view, the Commission's recommendations do not fall within the category of "permissible *clarifications*, but instead constitute impermissible *policy alterations*."

According to the Attorney General's Office and the Legislative Counsel, in the general sense, the courts have not provided clear guidance as to what constitutes a "permissible clarification" that "furthers the purpose of the grant and loan programs." Efforts to amend laws created by ballot measures often are subject to dispute, which can end up in litigation and must be resolved on a case-by-case basis on whether the intended change furthers the purpose of the initiative.

While the Commission understands there is a potential controversy here, which could lead to litigation, this is a sufficiently open question that persuades the Commission to recommend the following governance changes in the interest of furthering the purpose of Proposition 71 and improving the prospects for long-term success of the agency's mission.

That is, in improving efficiency and transparency at CIRM, the Commission believes that the recommendations will further the voters' mandate.

To that end, CIRM's governing board should be reduced to 15 members, to be selected from similarly diverse backgrounds as the current board, but injected with four truly independent voices from the business and science community who have no affiliations with CIRM-funded entities.

Board terms should be reduced to four years, to encourage new voices and debate. Such changes should be introduced as board members' terms expire.

To enhance accountability and transparency, the governor also should appoint a majority of its members, with confirmation by the state Senate, as is standard with many state boards. The newly recast board should be known simply as the Board of Directors, to more accurately reflect its composition.

To strengthen lines of communication and provide clear direction for the agency, the co-CEO management approach at CIRM should end, with the agency president placed in charge of all operations and the chair fulfilling

only oversight duties, external affairs and board administration. The administrative limits set in Proposition 71 require a careful allocation of staffing and resources: the current overlapping roles of the president and the board chair complicate this effort, creating multiple reporting channels and functional redundancy.

The board should be given more flexibility to choose its own leadership. The statutory references to the nominating process, job duties and qualifications for board chair and vice chair should be modified, allowing the board to select a chair and vice chair from among its members. The board should determine an appropriate term for the chair and vice chair that allows for regular re-election or replacement based on performance.

While a leaner, more efficient board can bolster its oversight of CIRM, an existing outside entity should continue to monitor the agency's overall performance. The Citizens Financial Accountability Oversight Committee (CFAOC), led by the state controller and established by Proposition 71, already reviews financial audits of CIRM. The committee can enhance its mission by holding regular meetings to review CIRM's programmatic and strategic performance under authority already statutorily designated to it.

Expanding the role of the CFAOC would create an important, regular check on CIRM as it enters a critical stage of maturing from its start-up phase into an operational mode. Proposition 71 backers promoted CIRM as a fixed-duration experiment, with funding sunsetting after 10 years, but CIRM is launching a loan program to biotechnology companies, backed with stock warrants, that could provide a continuous revenue stream to the agency. A new strategic plan under consideration also lacks clarity on how funds will be spent in the future. What is clear is that CIRM leaders are positioning CIRM to exist beyond the 10 years promised to voters. The ICOC chair, for example, testified to the Commission about his desire to ask voters to extend CIRM's lifespan through another bond measure.

Establishing a coherent governance structure based on best practices will allow these conversations to take place in an environment that can enhance public trust and confidence that CIRM is furthering the goals of Californians who supported Proposition 71, not those of interested parties.

The Commission is cognizant of CIRM's institutional knowledge, the importance of continuity and CIRM's good standing in the scientific community.

The Commission also appreciates the complexities and disruption that can occur with an agency reorganization, and particularly at CIRM, with its roster of ongoing projects, many of which are international in scope. The Commission intends that its recommendations be implemented over a period of time, allowing for an appropriate transition in order to minimize disruption to CIRM's creative and ambitious agenda. Shortening the length of board terms, for example, should be introduced and phased in as current board members' terms expire.

The Commissioners' observations, taken together with research, witness testimony and extensive staff interviews of ICOC board members and others have formed the basis for the study's findings and recommendations. Members of the CIRM staff and members of the ICOC have been generous with their time and have made themselves readily available to the Commission's staff as well as to Commissioners in sharing information, ideas and reactions.

In developing its recommendations to strengthen CIRM's governance structure and improve transparency and accountability, the Commission sought to avoid the need to go back to the voters of California. These recommendations are designed to be implemented by CIRM's governing board, and where that is not possible, through legislation that can change existing statutes to, the words of Proposition 71, "enhance the ability of the institute to further the purposes of the grant and loan programs created by the measure."

Recommendation 1: The Legislature should restructure the CIRM governing board around principles of efficiency and transparency.

- ❑ The Legislature should amend the Health and Safety Code to reduce the board size, shorten terms and restructure membership.
  - ✓ Decrease board size to 15 from 29. Keep diversity of membership but add independent voices to the board: five patient advocates from unspecified disease groups, two independent business leaders and two independent scientists with no ties to CIRM-funded institutions; two University of California officials, one university official (non UC); two private sector biotechnology executives, and one leader of a California research institution.
  - ✓ Reduce terms to four years for all members.
- ❑ The Legislature should amend the Health and Safety Code to streamline the appointment process for CIRM board members. Allow the governor to appoint 11 of 15 board members, subject to Senate confirmation. Legislative leaders should

continue to appoint two members. The UC system president should appoint two UC representatives.

- ❑ The Legislature and CIRM should realign the roles of chair and president to eliminate overlapping authority and to enhance clarity and accountability.
  - ✓ The Legislature should modify all statutory references in the Health and Safety Code to the nominating process, job duties and qualifications for the chair and vice chair to invest this authority with the board.
  - ✓ The CIRM board should elect a chair and a vice chair from within the existing board, subject to set terms and conditions for re-election/removal.
  - ✓ The CIRM board should clarify that the president manages all day-to-day operations.
- ❑ The Legislature should amend the Health and Safety Code to rename the board to more accurately reflect its composition. The Independent Citizens Oversight Committee should be called the Board of Directors.

Recommendation 2: The Legislature and CIRM should improve efficiency and transparency for distributing grant and loan funds.

- ❑ The Legislature should amend the Health and Safety Code to remove the 50-employee cap on staffing.
- ❑ The Legislature should amend the Health and Safety Code to remove the 15-person limit on peer reviewers. CIRM should modify its triage plan to review grants internally.
- ❑ CIRM should explore options for greater disclosure of the peer review process.
  - ✓ CIRM should poll CIRM's peer reviewers anonymously about their willingness to participate in the review process if their financial disclosure statements are made available to the public. The results of this poll should be made public.
  - ✓ CIRM should conduct a trial grant application round that identifies all applicants.
  - ✓ CIRM should provide full grant evaluations to applicants.
- ❑ CIRM should amend all meeting minutes to specify individual board members' votes and recusals, and continue the practice moving forward.

Recommendation 3: The CFAOC and the CIRM governing board should use their authority to enhance oversight.

- The Citizen's Financial Accountability Oversight Committee (CFAOC), chaired by the State Controller, should exercise its existing authority, or be statutorily authorized if necessary, to conduct performance audits and hold regular meetings to review CIRM's programmatic and strategic performance, in addition to overseeing CIRM's annual financial audits.
- The governing board should hold its members accountable by adopting removal provisions in its bylaws.

Recommendation 4: The CIRM governing board should begin planning for CIRM's future through an open process.

- The CIRM governing board should create succession plans for board leadership.
- CIRM's strategic plan should provide clear transparent direction for spending funds, with measurable benchmarks.
- CIRM should develop a transition plan for the eventual expiration of bond funding.

Current and Proposed Board Compositions

"Independent Citizens Oversight Committee" Current 29-member board		*"Board of Directors" Proposed 15-member board*	
Appointing Body	***Position***	***Position***	***Appointing Body***
UC Chancellors	5 Executive officers from UCs with a medical school	2 Executive officers from a UC with a medical school	UC President
G, Lt.G, T, C	4 Executive officers from other California universities	1 Executive officer from a California university	G
G, Lt.G, T, C	4 Executive officers from California research institutes	1 Executive officer from a California research institute	G
G, Lt.G, T, C	4 Executive officers of commercial life science entities	2 Executive officers of a commercial life science entity	G
G	1 Patient Advocate - Alzheimer's Disease	2 Independent scientists	G
G	1 Patient Advocate - Spinal Cord Injury	2 Independent business leaders	G
Lt. G	1 Patient Advocate - MS/ALS	3 Patient Advocates - unspecified disease groups	G
Lt. G	1 Patient Advocate - Type II Diabetes	1 Patient Advocate - unspecified disease group	Senate
C	1 Patient Advocate - Cancer	1 Patient Advocate - unspecified disease group	Assembly
C	1 Patient Advocate - Parkinson's Disease	0 Chair of the board	**
T	1 Patient Advocate - Heart Disease	0 Vice chair of the board	**
T	1 Patient Advocate - Type I Diabetes		
Senate	1 Patient Advocate - HIV/AIDS		
Assembly	1 Patient Advocate - Mental Health		
*	1 Chair of the board		
*	1 Vice chair of the board		

Key

G = Governor
Lt. G = Lieutenant
T = Treasurer
C = Controller
Senate = Senate Rules Committee
Assembly = Speaker of the Assembly
***** = Nomination from G, Lt. G, T, C and elected by ICOC
****** = Selected from within board membership

Authority for Restructuring the State's Stem Cell Agency

LHC Recommendations	CIRM/ ICOC	Legislature
Recommendation 1		
Decrease board size to 15 from 29 and alter membership		X
Reduce length of terms to four years		X
Streamline appointment process		X
Modify statutory references to the nominating process, job duties and qualifications for the chair and vice chair		X
Give authority to board to elect a chair and vice chair from within the existing board, subject to set terms and re-election/removal		X
Clarify that CIRM president manages all day-to-day operations	X	X
Rename ICOC to Board of Directors		X
Recommendation 2		
Remove 50-employee cap on staffing		X
Remove 15-person limit on scientific peer reviewers		X
Modify triage process	X	
Poll peer reviewers about their willingness to participate in the grant review process if their financial disclosure statements are made public	X	
Pilot a grant application round that identifies all applicants	X	
Provide full grant evaluations to applicants	X	
Amend all meeting minutes to specify individual members' votes and recusals and continue the practice moving forward	X	
Recommendation 3		
Extend authority of CFAOC to conduct performance reviews of CIRM		X
Adopt removal provisions for nonparticipating board members	X	
Recommendation 4		
Create succession plans for founding leadership	X	
Establish clear transparent direction for spending research funds, with measurable benchmarks, in the strategic plan update	X	
Develop a transition plan for expiring bond funding	X	

Background

In 2008, Senators Sheila Kuehl and George Runner asked the Little Hoover Commission to examine the state's stem cell agency and make recommendations for improving its governance structure. They said a study by the Commission was warranted to ensure public trust and confidence and protect the integrity of the stem cell program from real or perceived conflicts of interest.[1]

The California Institute for Regenerative Medicine (CIRM) and its governing body, the Independent Citizens Oversight Committee (ICOC), were established in 2004 by Proposition 71 – an initiative which passed with 59 percent voter approval.[2] The initiative created a new state agency with a focus on human embryonic stem cell research and gave Californians a constitutional right to conduct stem cell research.[3] It mandated the institute to "support all stages of the process of developing cures, from laboratory research through successful clinical trials" and authorized $3 billion in state general obligation bond funding over 10 years to achieve its goals.[4] The total cost to taxpayers ultimately will be $6 billion including financing costs.[5]

Ethically controversial, the research involves using stem cells from early stage human embryos and fetal tissue. But to stem cell researchers, embryonic stem cells have been considered the gold standard because of their plasticity and potential for unlimited self-renewal, making them potential candidates for regenerative medicine and tissue replacement. The field is still relatively new, and after President George W. Bush restricted federal funding for certain human embryonic stem cell research, work in the field was limited in the United States, through private money still could be used.

California responded to the federal restrictions with Proposition 71, which employed a high-profile ballot campaign backed by scientists, business leaders, politicians and patient advocates such as Michael J. Fox and Christopher Reeve.[6] Nothing like it had been attempted before. In approving Proposition 71, voters essentially signed on to an industrial policy aimed at making California the epicenter of human embryonic stem cell research, with the promise of creating a new high-tech industry that would generate jobs and wealth, and the potential for medical breakthroughs in spinal cord injuries, Parkinson's Disease, heart disease, cancer and other illnesses.[7] The proposition's success

prompted other states to follow with their own stem cell research initiatives, though none on the scale of California's.

Based on the request by Senators Kuehl and Runner, the Commission focused its study to the effectiveness of CIRM's governance structure. The study sought to identify:

- The qualities of a good governance model.
- The perceptions and reality of how CIRM follows good governance principles.
- Steps CIRM and its governing board have taken to address past criticism about how the organization performs under its current governance structure.
- Recommendations for further improving the governance structure, based on principles of good governance.

In defining the scope of its study, the Commission deferred to the majority of voters who approved Proposition 71 and did not examine whether stem cell research is an appropriate use of state dollars. In focusing on governance, the Commission by design excluded other areas of interest, several of which already have been subject to review. These excluded areas include: the return on investment the state should expect from Proposition 71; CIRM's intellectual property policies; ethical issues of human embryonic stem cell research, and the use of the initiative process to shape statewide policy and funding decisions. Though these issues may merit additional study, the Commission centered its inquiry on whether CIRM is organized appropriately to fulfill its mission and to identify what changes are needed to improve its structure.

For its review, the Commission conducted a public hearing in November 2008 and solicited testimony from CIRM leaders, stakeholders, supporters and critics. Commissioners and Commission staff also attended several ICOC meetings and subcommittee meetings, and interviewed more than a dozen ICOC members and former members individually, in addition to speaking with other interested parties.

This report addresses the following concerns:

- ***Independence.*** Authors of the initiative, wary of government interference, made CIRM's funding virtually independent from state government. Proposition 71 was drafted as a reaction to the political climate that existed in 2004, specifically President George W. Bush's restrictions on certain federally funded human embryonic stem cell research.[8] California responded by creating a safe harbor, free of political influence, for scientists to conduct such research. The political climate has since reversed – in his

first months in office, President Barack Obama began lifting many of those restrictions, raising questions of whether the current level of insulation still is needed.[9]

- ***Transparency and conflicts of interest.*** The CIRM governing board is comprised of university officials, research institute leaders, biotech executives and disease advocates whose organizations or causes have and will continue to benefit from the grant funds. Aspects of the funding process remain closed to the public.
- ***The balance of power.*** CIRM has adopted a co-CEO leadership structure between the board chair and the agency president. The board chair oversees several daily administrative duties at CIRM, which gives the chair a dominant role over other members, creates potential conflict with the CIRM president and blurs the lines of accountability.
- ***A highly specific governance structure.*** The 10,000-word ballot language locked in a highly specified governance structure for CIRM, including the composition of the governing board, the procedures for electing its chair and vice chair, the specific qualifications and duties of the chair, vice chair and president, as well as limitations on the agency's staff and operational budget.[10]

Stem Cell Arms Race

Once California voters approved Proposition 71 in 2004, the heady promise of embryonic stem cell science and an accompanying biotech revolution launched a research arms race.

States including Connecticut, Illinois, Massachusetts and New York embarked on their own stem cell initiatives. Some countries have made a scientific breakthrough a top priority. But the downfall of a prominent South Korean scientist, under pressure to catapult his country into the global lead, has given pause in the rush toward this cutting-edge life science and underscores the need for transparency and accountability.

In late 2005, Hwang Woo Suk was exposed for faking his breakthrough research about cloning human stem cells in the journal *Science*, embarrassing his American collaborators and fueling ethical concerns not only about the nature of his work but of all stem cell research.

One analyst summed up the experience this way: "South Korean is belatedly learning that biotechnology is not the forum in which to play out its industrial policy ambitions. Unlike electronics or information technology, where the country excelled by building upon technology pioneered by others, biotechnology is a cutting-edge sector teeming with critics. And the field requires a highly sophisticated regulatory system."

Source: Choe Sang-Hun. January 11, 2006. "Lesson in South Korea: Stem Cells Aren't Cars or Chips." The New York Times.

Strengthening Transparency and Accountability

Proposition 71 created a unique organizational structure for CIRM that does not appear to have prevented research funds from being distributed and put to work – $700 million as of April 2009 – as stipulated by the proposition. That investment has secured intellectual capital and infrastructure and made California a global leader in stem cell science.[11]

A September 2008 study of CIRM's activities noted that it was too early to make a broad assessment of CIRM's economic benefits but initial findings included:

- At least 45 senior researchers from out of state were recruited to join California institutions.
- More than $900 million in matching funds have been raised to fund research, lab construction and facilities improvement related to stem cells.
- Stem-cell related companies have increased activities in California by expanding lab space and hiring new scientists.[12]

Much has changed since the ballot initiative became law, and more change is likely given President Obama's lifting of federal restrictions on funding for human embryonic stem cell research. Globally, stem cell science is advancing far more quickly than anticipated, particularly in the area of adult stem cell research development that is not given preference in Proposition 71. The rapidly changing political and scientific environment raises questions about whether the organization is flexible enough to adapt to the field it is supposed to lead.

Jesse Reynolds, project director for biotechnology in the public interest at the Center for Genetics and Society, told the Commission that the justification for California's stem cell program has largely dissolved and it is time to re-evaluate its mission.[13] John Simpson, project director for the stem cell oversight and accountability project at Consumer Watchdog, suggested that with anticipated National Institutes of Health funding for stem cell research, California should reconsider spending the entire $3 billion that voters authorized.[14]

CIRM's backers argue that long-term stability for funding is needed, and that California can better leverage its investment with an injection of federal funds. CIRM's ability to fund human embryonic stem cell science dwarfs that of the federal government. Even if federal stem cell research is doubled to $80 million annually, as promised by President Obama, the federal contribution will account for less than of a third of CIRM's annual outlay.

It is not clear, however, what direction the agency will head in the future – even conversations with past and present ICOC members revealed no consensus to these critical questions:

- How will CIRM know when its job is done?
- What happens when CIRM runs out of money?
- Is the mission of Proposition 71 best served by transforming CIRM into a self-sustaining operation?

Proposition 71 has been described as California's version of the Manhattan Project. Without question, it is an ambitious leap into

industrial policy. Politically charged and ethically controversial, the voter initiative provided the funding and infrastructure that moved California to the forefront of human embryonic stem cell research. It demonstrably has built an industry center that has lured scientists from around the world to California and created the infrastructure and environment to foster growth.

Components of CIRM's Governance Structure

The main components of the CIRM governance structure include:

- An agency based in San Francisco, limited to 50 employees, which coordinates the grant application and award process, including ongoing monitoring of grants. Key officials include a president and a chief scientific officer. Proposition 71 limits CIRM's operating budget to 6 percent of bonds sold. With this budget, CIRM currently employs a staff of about 42. CIRM's administrative costs typically range between 4-5 percent of its funding distribution, although CIRM's operating budget can be and has been supplemented by outside donations.[15]
- A 29-member governing board, the Independent Citizens Oversight Committee, that sets policy and makes final funding decisions for research and facilities applications. The board is comprised of:
    - Five executive officers from University of California campuses that have medical schools, to be appointed by the campus chancellor.
    - Four executive officers from other California universities, one each to be appointed by the governor, lieutenant governor, state treasurer and state controller.
    - Four executive officers from California research institutes, one each to be appointed by the governor, lieutenant governor, state treasurer and state controller.
    - Four executive officers from commercial life science entities, one each to be appointed by the governor, lieutenant governor, state treasurer and state controller.
    - Ten patient advocates from specific disease groups, two each to be appointed by the governor, lieutenant governor, state treasurer and state controller, and one each appointed by the Assembly Speaker and the Senate Rules Committee.
    - A chairperson and a vice chairperson, nominated by the governor, lieutenant governor, state treasurer and state

controller, then elected by the members of the governing board.

All board members serve six-year terms, except the patient advocates and UC executive officers, who serve for eight years. The chair and vice chair also serve for six years. All board members can be reappointed to one additional term.

Proposition 71 also established three working group committees, comprised of governing board members and outside experts, to make recommendations on research and facilities funding and to shape ethical guidelines for CIRM-funded research.[16] The governing board separately has established several subcommittees and task forces for finance, governance, intellectual property and other issues on an as-needed basis.

Adversarial Climate for Change

Discussion about CIRM's governance structure has never been easy at the state Capitol, and discussion about changes to it are even less so. A lawsuit from opponents delayed the sale of bonds for two years, forcing additional borrowing for CIRM and creating an atmosphere of defensiveness among its leaders and backers, who have strived to keep the agency and its operations independent.

As part of Proposition 71, the Legislature could make no changes to the CIRM structure for the first three years of the institute's existence; afterward, legislative changes required 70 percent approval in the Assembly and the Senate as well as the governor's signature.[17]

The stated intent was to protect California's stem cell program from political meddling during a time when stem cell research was a high-profile national political issue. But the proposition's authors did little to lower the political temperature in Sacramento.

Because lawmakers were locked out of reforming CIRM during its formative years, several misperceptions emerged about the agency, said Donna Gerardi Riordan, former director of programs at the California Council on Science and Technology. "By excluding legislators from participating in the creation and design of CIRM, the framers of Proposition 71 were short-sightedly taunting the state's most powerful and skillful political players," Ms. Riordan wrote in 2008.[18] She continued:

> "Some legislators … reacted by using their seniority and media savvy to mobilize often rancorous public attention

around specific hot-button financial and ethical issues that, in large measure, were already being addressed by CIRM and the ICOC. … It devolved at times into an unfortunate 'us-versus-them' conflict that made it impossible to produce any useful substantive guidance for CIRM and the ICOC. A painful irony is that many of the legislators leading efforts to scrutinize CIRM's activities were among the state's earliest and most ardent stem cell research advocates."[19]

Amending the California Stem Cell Research and Cures Act

Proposition 71 added a new section to the California Constitution, several statutory provisions to the Health and Safety Code and the authorization to raise money for stem cell research through general obligation bonds. The ability to alter the state's stem cell program is, by design, limited. Amending the Constitution requires the approval of voters, through a ballot measure triggered either by the Legislature or a signature-gathering effort of the people. The Legislature generally can amend statutes on its own, with approval by the governor. Proposition 71, however, required a unique waiting period that prohibited the Legislature from amending the statutory provisions for three years and, after that, requiring a 70 percent vote of both houses of the Legislature and approval by the governor. Only amendments that further the purpose of the act are allowed – a condition that is subject to dispute and might require judicial resolution. The bond provisions of Proposition 71 cannot be amended.

Constitutional provisions	*Statutory provisions*
▪ Established the right to conduct stem cell research. ▪ Created the California Institute for Regenerative Medicine (CIRM) to make grants and loans for stem cell research. ▪ Authorized CIRM to use state issued bonds to fund its operations and research. ▪ Banned CIRM from funding research involving human reproductive cloning. ▪ Insulates CIRM funding from legislative budget process. ▪ Exempted CIRM and employees from civil service requirements.	▪ Authorized $3 billion in general obligation bonds to fund CIRM activities. ▪ Created Independent Citizens Oversight Committee (ICOC) to govern CIRM. ▪ Specified ICOC membership, appointment process, terms of office and functions. ▪ Created working groups to assist ICOC with funding decisions and ethical guidelines. ▪ Required annual report, independent financial audit, and oversight committee chaired by the state controller. ▪ Exempted ICOC from some open meeting and records laws. ▪ Permitted ICOC members who represent organizations seeking CIRM funds to serve on the board. ▪ Delegated authority to ICOC to establish intellectual property agreements.

Sources: California Constitution, Article XXXV; Health and Safety Code, Section 125290.10 et seq. Also, Secretary of State. November 2004. "Official Voter Information Guide: Proposition 71: Text of Proposed Laws." Pages 147-155. Sacramento, CA. http://vote2004.sos.ca.gov/voterguide/. Accessed November 5, 2008. Also, Douglas J. Woods, Supervising Deputy Attorney General. Sacramento, CA. May 4, 2009. Personal communication.

Former CIRM president Zach Hall said the high hurdle for legislative amendments has protected the stem cell project from political interference, but it also has made it difficult to modify the many detailed terms in the proposition.[20] Indeed, at least six legislative efforts – all unsuccessful – have been attempted to amend the CIRM statutes since its inception. Some of them have been led by politicians, such as Senator Deborah Ortiz, who were among CIRM's early backers.

In the 2005-06 legislative session, SB 18 (Ortiz) called for an audit of CIRM but was vetoed. SB 340 (Battin) clarified that revenues from CIRM-funded research should be returned to the state General Fund; the bill died in committee. SB 401 (Ortiz) attempted to tighten conflict-of-interest procedures; the bill died in committee. In the 2007-08 legislative session, SB 771 (Kuehl) initially addressed licensing revenues from CIRM-funded research but the provisions were amended out of the bill. SB 1565 (Kuehl and Runner) addressed intellectual property and affordable-drug access from CIRM-funded research but was vetoed.[21]

Yet for all of CIRM's defensiveness and Capitol lobbying, the discussions that came out of the legislative process in some cases changed CIRM's behavior and procedures. CIRM, for example, has opened up more of its working group meetings to the public and enhanced its internal financial disclosure requirements.[22]

Opportunities for Reform

Though the Legislature cannot control CIRM's budget, the agency is not free from its scrutiny. For an organization of its size, with annual operating budget of $13 million, CIRM has received more attention – internal and external – than most agencies in state government. It has faced examination by the state appellate court and reviews by the Bureau of State Audits and the Fair Political Practices Commission. CIRM also is subjected to an annual outside financial audit by an oversight committee headed by the state controller. These audits, however, have focused on financial and legal performance and compliance, not on performance.

Additionally, Proposition 71 required CIRM to develop its internal regulations – for intellectual property, grant administration and medical standards – through the state's months-long administrative law process, which includes an extensive opportunity for additional public review and comment.[23]

Although the creation of CIRM was enshrined in the state Constitution, its governing procedures are found in the state Health and Safety Code,

which can be amended by the Legislature. The Legislature polices CIRM and has the authority to change CIRM's governing statutes and request additional audits and independent reviews. The Legislature also has input through the two members of the ICOC who are appointed by legislative leadership.

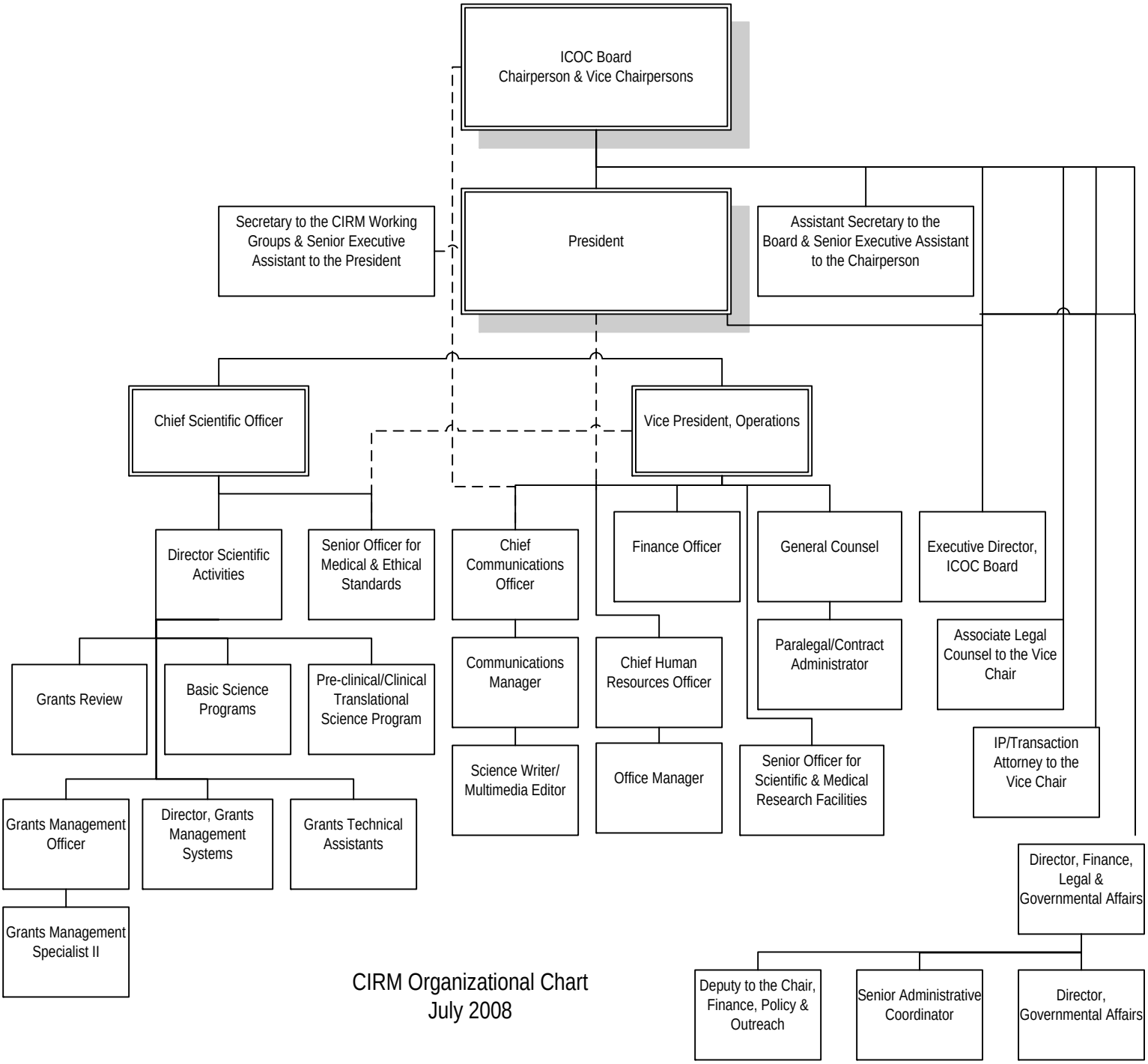
Proposition 71 also created a unique mechanism for review in the Citizens Financial Accountability Oversight Committee (CFAOC), chaired by the state controller, to serve as an ongoing check on CIRM's financial practices and performance.[24] The five-member committee, which holds annual public meetings, is comprised of representatives appointed by the state controller, the state treasurer, the Senate President pro Tempore, the Assembly Speaker and the board chair. The State Controller's Office provides staff support and the ICOC provides per diem expenses for the committee members. The committee, however, has not exercised its authority to look beyond CIRM's finances to review the agency's general performance.

Powerful Personalities at the Top

The actions and personal style of ICOC chair Robert Klein have been at the core of many of the criticisms of the stem-cell agency, and have made him a lightning rod for calls for more accountability. That he is a component of much of the discussion is unavoidable as he drafted, championed and donated money for Proposition 71 and now serves as the paid, part-time chairman of the governing board. His passion and leadership made Proposition 71 a reality, and his financial and political skills helped CIRM survive its early challenges. At the same time, the media have chronicled how Mr. Klein has alienated members of the Legislature and at least one newspaper has called on Mr. Klein to resign.[25]

Mr. Klein's high profile obscures the degree to which other members of the ICOC have taken on a more assertive role to clarify the chairman's responsibilities, question CIRM spending practices, monitor the agency's financial health and provide direction that at times conflicts with Mr. Klein's preferences. Mr. Klein is far from the only strong personality on the ICOC. In attending ICOC meetings and reviewing minutes from previous meetings, it is clear that the chair does not rule by fiat. Board members demonstrate deep familiarity with the issues as well as independent thinking and, as observed by the Commissioners and staff at ICOC meetings and subcommittee meetings in 2008 and 2009, a ready willingness to express views at odds with the chair's or those of the rest of the board.

CIRM and its advocates have reacted defensively to past legislative actions, but ongoing changes in leadership and tone signal the potential for a markedly different stance. In March 2009, the state's stem cell leaders elected Art Torres, a former state Democratic Party chairman and former state senator, to serve as vice chair of CIRM's governing board.[26] This step, cited by board members as an effort to forge relationships in the state Legislature and in Congress, moves CIRM out of its political isolation and presents opportunities to work with the Legislature on substantive structural reforms. Designed to be fenced off from politics, CIRM now is prepared to engage the process.



CIRM Organizational Chart
July 2008

Structure Lacks Coherence, Accountability

To an extent not entirely acknowledged by its detractors, CIRM has evolved, adopting several measures recommended by critics that have substantially improved transparency. The organization that exists today is not the same organization that received a "C-" from a watchdog group in 2006 for its commitment to accountability and transparency.[27]

Early on, the agency drew criticism for the way it structured its meeting rules – Proposition 71 entitled CIRM's working groups to meet behind closed doors to review ethical standards, facilities grants and scientific research grants. It has since adopted stronger financial disclosure requirements for CIRM working group participants, opened up the working group meetings to the public (except for the confidential peer review process to evaluate grant applications) and posted summaries of the meetings, including transcripts from subcommittee meetings, on CIRM's Web site.[28]

University of California, Berkeley, law professor Kenneth Taymor, a frequent CIRM observer, told the Commission that CIRM now makes substantial efforts to provide access to its work. It goes beyond the traditional practice of making meeting agendas and documents available by providing online transcripts of all meetings and subcommittees. "This is a very commendable exercise in good governance and all indications are the institute is committed to continuing and where possible improving this transparency," Mr. Taymor said.[29] Additionally, the governing board permits public comments during the discussion of each agenda item – not just at the end of a long session – which has turned one member of the public, John Simpson of Consumer Watchdog, into a frequent contributor during the meetings. Beginning in 2009, CIRM has increased access through a live audio feed of its board meetings.

Its improvements to date, however, have been in the area of procedural, not structural, changes. The agency's unique governance structure remains intact. CIRM's governing model differs from a typical board in many ways, including the nomination process of leadership, the accountability and reporting structure, length of terms for board members, a supermajority quorum rule and multiple appointing authorities.

To evaluate CIRM's governance structure, the Commission heard from governance experts who identified the following characteristics of a good governance model, based on best practices of nonprofit and corporate boards:

- A clear division of labor between operations and oversight functions, with well defined roles and lines of communication.
- An appropriately sized board that is engaged and free of bias.
- A well-organized and functioning staff with linear lines of communication and clear delineation of duties.[30]

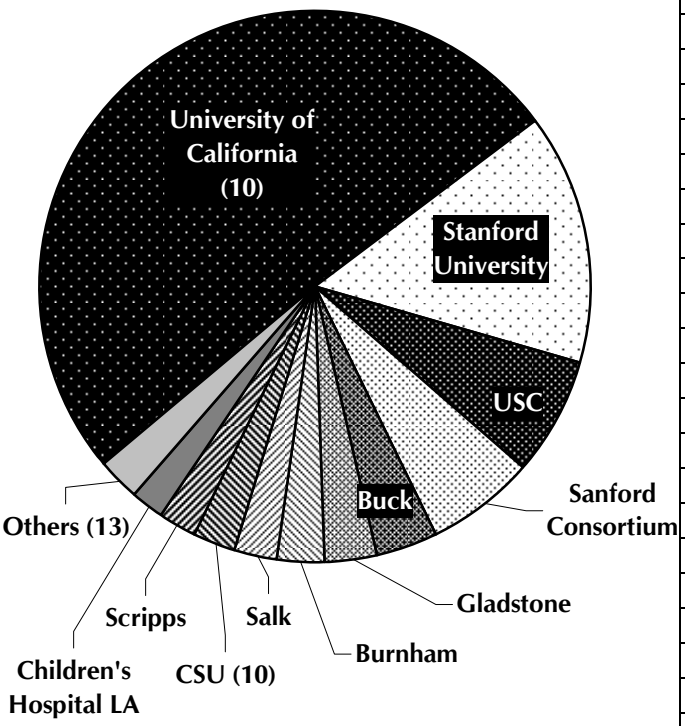
Board Not "Independent"

Stem cell research opponents as well as advocates have found ample cause to critique this structure. The Independent Citizens Oversight Committee, for example, is not independent: 18 of its 29 members represent institutions that are eligible for grants from CIRM. The word "citizens" understates the extent to which the committee is comprised of the heads of major research institutions, universities and biotechnology companies, and stakeholders from advocacy groups organized around specific diseases who have substantial professional connections to the field of stem cell research.[31]

The authors of the initiative foresaw and addressed the conflict-of-interest issue. Proposition 71 took the issue off the table, declaring that there was no conflict of interest as long as interested parties recused themselves from participating in funding decisions regarding their representative institutions.[32] The ballot initiative also stipulated that the patient-advocate representatives on the ICOC do not have a conflict of interest by supporting grants to institutions that conduct research on diseases from which the board member or a member of his or her family suffers.[33]

In 2006, the Alameda County Superior Court upheld these provisions, rejecting arguments that ICOC members are engaged in improper self-dealing.[34] In response to a lawsuit filed by opponents of Proposition 71, the state appellate court also noted that the ICOC follows the practice of more than 90 state regulatory boards and commissions, such as the California Milk Producers Advisory Board, in which industry members can serve on those boards as long as they do not participate in decisions affecting their own interests in a manner different from the interests of other members of the industry.[35]

CIRM-funded Grants by Institution
(as of April 2009)



Notes: The Sanford Consortium is made up of the Scripps, Salk and Burnham Institutes and UC San Diego. Also, institutions in bold have current or past representation on the ICOC.

Source: California Institute for Regenerative Medicine. "Approved CIRM Grants as of April 2009." http://www.cirm.ca.gov/info/grants.asp. Accessed April 22, 2009.

Institution	*Grant Award*
University of California (10)	
UC San Francisco	$83,808,866
UC Los Angeles	$57,074,184
UC Irvine	$56,157,567
UC Davis	$41,067,279
UC San Diego	$37,664,719
UC Berkeley	$34,626,605
UC Santa Cruz	$19,383,633
UC Merced	$8,494,301
UC Santa Barbara	$8,490,842
UC Riverside	$6,055,762
Stanford University	$101,245,022
University of Southern California	$49,418,708
Sanford Consortium for Regenerative Medicine	$43,000,000
Buck Institute for Age Research	$25,429,364
The J. David Gladstone Institutes	$21,305,030
Burnham Institute for Medical Research	$19,571,395
The Salk Institute for Biological Studies	$17,544,343
California State University (10)	
CSU San Diego	$3,441,860
CSU San Jose	$1,733,760
CSU Channel Islands	$1,733,406
CSU San Marcos	$1,732,164
CSU San Francisco	$1,713,558
CSU Humboldt	$1,616,363
CSU Pomona	$1,436,797
CSU San Luis Obispo	$1,396,509
CSU Long Beach	$1,337,700
CSU Sacramento	$1,321,440
Scripps Research Institute	$15,322,221
Children's Hospital Los Angeles	$14,219,310
Others (13)	
City of Hope National Medical Center	$4,131,703
Ludwig Institute for Cancer Research	$2,473,053
California Institute of Technology	$2,071,823
Pasadena City College	$1,727,991
VistaGen Therapeutics, Inc.	$971,558
Gamma Medica-Ideas, Inc.	$949,748
Vala Sciences, Inc.	$906,629
Novocell, Inc.	$876,022
Invitrogen Corporation	$869,262
Fluidigm Corporation	$749,520
Human BioMolecular Research Institute	$714,654
Children's Hospital Oakland	$55,000
Cedars-Sinai Medical Center	$46,886
Total	***$693,886,557***

The court noted: "Merely because a board member derives income from within a given industry, he or she does not lose the ability to be objective. Nor does that person lose the capacity to make decisions beneficial to the public's interest." [36]

California's 1st Circuit Court of Appeal also agreed that "specific and limited" conflicts of interests are necessary "in order to allow individuals with the necessary expertise from academic and commercial entities that do have financial interests in the subject of stem cell research to serve on the ICOC."[37]

Recusals Should Be Rare

Michael Klausner, a Stanford Law School professor and expert on corporate and nonprofit board governance, said it is common for members with conflicts of interest to serve on boards, as they can bring special expertise to the organization, and it is appropriate as long as strong recusal policies are consistently followed. Recusals, however, should be rare. If many members regularly recuse themselves, it shows institutional conflict and is structurally problematic.[38]

Even though a board with interested parties can operate within legal bounds, the Commission is concerned that the lack of disinterested members on the ICOC weakens the board's ability to make sound decisions and limits the likelihood that there will be substantial debate and dissent among board members about key funding and policy decisions. Such a dynamic also erodes confidence that the board is capable of making broader strategic decisions that go beyond awarding research dollars.

In the state's stem cell program, an ICOC member must recuse himself or herself from voting on or discussing funding for his or her employer. Members also must recuse themselves because of financial and personal ties to potential grantees. CIRM lawyers screen the board members' disclosure forms for potential conflicts during each grant round and announce the recusals at the open meetings. In one extreme case, the final decision awarding $271 million for facilities was decided by only seven of the 29 ICOC members. In the end, it was only patient advocates or members from the private sector who had no institutional conflicts of interest.[39] The authors of Proposition 71 foresaw this situation and carefully defined the governing board's vote threshold to mean a majority of those members eligible to vote, not of the entire 29-member body.[40]

At typical meetings, board members regularly and frequently recuse themselves for conflicts. During the December 9 and 10, 2008, ICOC meeting in Irvine, the Commission observed that all but six ICOC board

members were identified as having a conflict at some point during funding discussions and recused themselves from voting on those specific grant applications.[41] Though CIRM posts meeting transcripts online, it does not do not disclose the votes of individual ICOC members in the meeting minutes to allow the public to track voting and recusal patterns on funding decisions. Based on anecdotal evidence, the incidence of recusals is troubling and creates the potential for members "logrolling" votes. It may be legal, but it is not optimal.

After observing several ICOC meetings, "there was an element of the meetings being one of a club deciding how to allocate monies among themselves in a pre-ordained decision," Mr. Taymor told the Commission.[42]

Challenge Posed by Large Board

Experts told the Commission that adding independent members as a counterweight would help improve debate and assuage concerns that funding decisions are pre-determined.[43] Adjustments to the current ICOC composition likely would need to be made to accommodate extra members on an already large board.

Another option would be to use an intervening board comprised of independent voices, such as a panel of out-of-state scientists, to make all funding decisions, while retaining the ICOC to focus on long-term scientific and strategic planning and other policies.[44] This concept, however, would eliminate a primary duty of the governing board as laid out in Proposition 71.

The large size of the board (29 members) coupled to the requirement for a 65 percent quorum poses a challenge to ICOC operations. In testimony to the Commission, Mr. Klein said the large board was modeled after the 26-member University of California Board of Regents with the goal of tapping into a wide spectrum of knowledge and diversity to oversee the funding strategy – starting with basic research, moving to the development and translational phase and ending with commercialization.[45]

The ICOC breaks its large board into several subcommittees and task forces to focus attention on specific issues, such as finances, governance and intellectual property.[46] Indeed, board members make a considerable time commitment when serving on the ICOC.

In testimony, CIRM President Alan Trounson said the ICOC's large and diverse board ensures that CIRM does not become narrowly focused or vulnerable to capture by any one of the representative groups. He added

that Australia's national stem cell agency – where he served as founding CEO – used a small group of seven directors who, in pushing for faster commercialization of research, set a 10-year timeframe to turn the agency into a private biotechnology company. The organization imploded in 2008 after he left – the CEO was fired and the entire board resigned – and has since reassembled to focus more on funding research that could lead to commercial spin-offs.[47]

Experts testified to the Commission that large boards are ineffective because some members often assume that other, more conscientious board members will take on the genuine work involved in board duties, such as closely scrutinizing budget documents.[48] In practice, this does not appear to be a problem for the ICOC members, who display a high level of engagement at board meetings. Agenda items frequently take longer than anticipated to cover because of the lengthy – and assertive – membership debate. This depth of conversation is not without cost, especially given the ICOC's restrictive quorum rules. Board members inevitably leave lengthy meetings, precluding the board from meeting its supermajority quorum requirement included in Proposition 71.[49]

Commissioners and staff observed this dynamic while attending the December 9, 2008, meeting of the ICOC in Irvine, Calif. Shortly before 10 p.m., after meeting for more than five hours, several board members departed, leaving the board without a quorum. The board was forced to adjourn without taking action on a new round of research grants. The board reconvened the next morning for further discussion and ultimately approved the new round of funding.

The quorum rule was included in Proposition 71 as an additional check to prevent any one group from dominating funding and policy decisions. To that degree, it is sound. In combination with CIRM's large board, however, the quorum requirement has been problematic, but the size of the board is the central problem. The ICOC since has adopted a rule allowing up to five members to participate by telephone. Mr. Klein has said the telephonic rule was designed to accommodate the patient advocate representatives on the board who suffer from disabilities or who are responsible for the care of others, but other non-patient advocate board members have used the option more frequently.[50]

Terms Overly Long

The multiple appointing authorities for board members and the length of their terms – six to eight years – also weakens public accountability. Board members can be reappointed once, which could cover the life of the 10-year program, though they cannot be removed except for misconduct or other violations. Mr. Klein said the diffusion of

appointment authority, as well as fixed terms, protects the organization against the politicized nature of stem cell funding. "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," Mr. Klein said in written testimony.[51] This threat since has receded with the lifting of restrictions on federal funding of human embryonic stem cell research, underscored by CIRM's explicit engagement in the political realm with the election of a former state majority party official as ICOC vice chair.

Co-CEOs: Board Chair and President

In a rarely seen arrangement, the ICOC chair is assigned duties in the daily operations of CIRM, as is the president. The co-CEO structure, built into Proposition 71, has led to confusion over role definition and may have contributed to turnover in the president position.[52] In other cases where the board chairs are full-time employees – the state air and water boards, for example – the chairs are appointed by the governor and confirmed by the Senate.[53] What is unusual compared to other heads of state boards and commissions is the current ICOC chair's level of involvement in daily operations and management. For example, the board chairman is given direct-line authority over numerous positions at CIRM, including legal, finance and governmental affairs positions.[54] This arrangement complicates the ability of the board chair to serve as an objective evaluator of the agency's activities – a role the oversight board is required to fill.

The splitting of daily operational duties at CIRM raises additional concerns because of the initiative's 50-person cap on CIRM staff and its 6 percent ceiling on general administration and grant oversight expenses. The overlapping roles lead to need for additional communication and coordination that can be inefficient given the 50-person limit on allowed positions at CIRM. The restrictions are admirable from the perspective of economizing on administrative overhead and signaling to voters that the new agency would be small and efficient; however, they introduce undesirable governance distortions, UC Berkeley's Taymor told the Commission.[55]

The fixed number of employees divided between the CIRM president and ICOC chair can erode the strength and autonomy of the president, who is charged with carrying out the essential functions of the institute to grant funds for scientific research.[56] The work of developing grant programs, evaluating grant applications and monitoring grant awards is labor intensive for CIRM, but under the current structure, up to eight positions out of 42 are assigned to the chair and vice chair, a deployment which

Lessons for CIRM: Restructuring the Red Cross

In May 2007, following numerous investigations of the American Red Cross in the wake of its mismanagement of its responses to Hurricanes Katrina and Rita, President George W. Bush signed legislation overhauling the governance structure of the organization for the first time since 1947.

Investigations of the non-profit agency, which operates under a congressional charter, surfaced organizational and managerial problems and criticized the Red Cross for its weak and unwieldy board. An internal investigation also revealed deeper governance problems, primarily around the roles and responsibilities of the organization's board and staff. The review found that the organization's charter contained vague language regarding the role of the "principal officer" and did not clearly delineate the roles and authority of the organization's board chairman and chief executive officer. Some critics argued that this confusion led to the organization's high executive turnover.

Using the well-established principles of governance for non-profit and corporate organizations as a guide, the Red Cross internal review recommended among other changes:

- The role of the board should be oversight of the organization, while management should focus on the organization's operations.
- The role of the board chairman should be to lead the board, while the role of the chief executive officer should be in managing the operations of the organization.
- The size of the board should shrink to better facilitate discussion and prioritization and provide more effective and efficient oversight.

The reforms were intended to ease recurring clashes between board members and management and address complaints that the organization was too bureaucratic and unaccountable.

The Red Cross Modernization Act of 2007 enacted many of the recommendations of the internal review. It downsized the Red Cross board from 50 members to a maximum of 20 members by 2012 and clarified that the role of the board was to focus on governance and strategic oversight. The new charter also clarified the "principal officer" language and defined the roles and authority of both the board chairman and chief executive officer.

Sources: American Red Cross, Board of Governors. October 2006. "American Red Cross Governance for the 21st Century." Also, Ben Gose. July 26, 2007. "Ready or Not?" The Chronicle of Philanthropy. Also, Elizabeth Schwinn. 2006. "Red Cross Proposes Sweeping Governance Changes." The Chronicle of Philanthropy. Also, Jacqueline Salmon. June 27, 2006. "Chapter Overhaul Adds to Red Cross Turmoil." Washington Post. Also, The Associated Press. May 11, 2007. "President Bush signs bill overhauling how Red Cross Governs itself." International Herald Tribune. Also, Nicole Gaouette. December 14, 2005. "Red Cross Chief Quits; Internal Politics Blamed." Los Angeles Times.

places a drag on organizational efficiency. For example, a lawyer is assigned to the board while separate lawyers are assigned to the agency.

In early organization meetings, several ICOC members questioned giving so much authority to the chairman, but the arrangement since has become institutionalized. At a June 2006 meeting, Mr. Klein called the placing of CIRM staff under his authority a "watershed issue" of importance to him. ICOC member David Baltimore, a Nobel laureate, remarked that, "No one would ever set up an organization that has split authority like this except Bob [Klein], I'm afraid, because that's not an efficient or effective way to run an organization, to have two heads of two different elements that have to interact. The notion of having a CEO is that the CEO has complete control of the organization." [57]

As long as the chair and president are in agreement, the diffusion over executive authority and overlap may be inconsequential to governance even if not the most efficient or transparent arrangement, the Commission was told. Indeed, CIRM president Alan Trounson, with a background in science, told the Commission he was more than happy to cede issues of bond financing to Mr. Klein.[58] However, the structure provides a false sense of stability. When the two differ on a matter, the arrangement gives rise to inefficiency, complicates communication and encourages duplication.[59] The arrangement led, in part, to the early departure of the first CIRM president, who resigned in 2007.[60] There is little to guarantee that the next president and chair would see things in the same way.

Complicating the issue, the highly specific requirements set out in Proposition 71 for a person to qualify as ICOC chair limits the ability to replace the chair or to have the ICOC consider changing chair responsibilities to meet the evolving needs of the institute. By statute, as written by Mr. Klein, the ICOC chair is required to have a documented history in successful stem cell research advocacy, experience with state and federal legislative processes, experience establishing government standards and procedures, legal experience and direct knowledge and experience in bond financing.[61] When Proposition 71 passed, the only name forwarded for nomination was Mr. Klein's, drawing criticism that he had tailored the wording to fit his background.[62] Without doubt, Mr. Klein's experience and expertise have been immense assets to CIRM, particularly in its formative stage, but the specificity of the Proposition 71 language creates an impediment to finding a replacement should Mr. Klein depart or be unable to complete his term. In testimony, Mr. Klein told the Commission he planned to serve a single six-year term, which would end in December 2010. [63] The board recently began discussing the need for succession planning, a process that will be complicated by Proposition 71's strict prescription on the qualifications for the candidates.

Unlike in typical board models, CIRM's chair and vice chair are not elected from the pool of ICOC board members by a vote of their fellow board members. The governor, lieutenant governor, treasurer and controller nominate a chair and vice chair according to the narrow criteria laid out in the initiative, and the board elects a chair and vice chair from the nominees.[64] This arrangement also impedes smooth and effective succession by placing the chair and vice chair outside the board, rather than being fellow members who are elected to lead.

Chairperson Criteria

- Six-year term
- Nominated by governor, lieutenant governor, state controller and state treasurer; elected by ICOC members.
- Mandatory criteria:
  - ✓ Documented history in successful stem cell research advocacy.
  - ✓ Experience with state and federal legislative processes that must include some experience with medical legislative approvals of standards and/or funding.
  - ✓ A member of a disease advocacy group.
  - ✓ Cannot be concurrently employed by or on leave from any prospective grant or loan recipient institutions in California.
- Additional criteria for consideration:
  - ✓ Experience with governmental agencies or institutions (either executive or board position).
  - ✓ Experience with the process of establishing government standards and procedures.
  - ✓ Legal experience with the legal review of proper governmental authority for the exercise of government agency or government institutional powers.
  - ✓ Direct knowledge and experience in bond financing.

Source: Health and Safety Code, Section 125290.20(6).

The initiative authorized the ICOC to set salaries for the chair and vice chair. This arrangement leaves it unclear whether the chair reports to the ICOC or is an employee of the institute, the relationship further obscured by the lack of a process for removing the chair or vice chair. The normal linkage of election (and re-election) by peers or between pay and accountability do not exist together as they do on typical boards.[65] In cases in state government where the governor separately appoints board or commission chairs, those individuals are accountable to the governor or to the Legislative confirmation process. This linkage does not exist in the ICOC governance structure.

The ICOC Governance Subcommittee has taken steps to address this concern by drafting performance standards and evaluation protocols for the ICOC chair and vice chair, as well as the CIRM president, though that effort is undermined by the board's lack of statutory authority to replace the chair and vice chair should their performance or evaluations be subpar.[66] In typical boards, terms for the chair generally range from one to four years, not six years. The unusual length of the term erodes accountability and also weakens the agency's ability to adapt its leadership to rapid changes in the political or scientific environment.

Personality-Driven Structure

In addition to the tightly specific job qualifications for the chair, a vacancy for the vice chair position in 2009 further illustrates how the dynamic of personalities can influence the stem cell agency leadership. Under the multiple-appointing authority provisions of Proposition 71, the governor nominated one candidate for vice chair and the lieutenant governor, state controller and state treasurer nominated a different candidate for the post. The ICOC held closed-door meetings in March 2009, citing a personnel exemption, and created a second vice chair position, then laid out the duties for the vice chair jobs. Board members said they wanted to keep both candidates instead of picking just one.[67] The organizational merits of creating two vice chairs had never surfaced in any previous ICOC meeting and only were presented in the context of the specific individuals who were nominated for the post, diluting accountability and raising the question of what happens when three or more candidates are in contention.

In conversations with Commission staff, Mr. Klein and Dr. Trounson emphasized that CIRM has been served well by their respective skill sets and that changing the arrangement would hurt the organization's effectiveness.[68] The Commission is cognizant of the disruption that change can bring, but it is confident that a reasonable transition plan

can be implemented. Transition also is inevitable – Mr. Klein said he is planning to step down as chair at the end of his term in 2010.

An agency governance structure that features key positions built around specific individuals does not serve the best interests of the mission of the agency or the state of California, however well-qualified the individuals may be. Such a situation distorts accountability and succession planning and could, in the event of an abrupt departure of the individual, leave the agency leaderless for an extended period. A more efficient and balanced board is possible and more appropriate as CIRM matures. For CIRM to prosper and sustain itself, such changes are essential.

CIRM's personality-driven organizational structure does not follow best practices for good government. Despite some initial efforts to modify organizational procedures, it is unclear if the governing board is able or willing to move beyond its current structure.

Funding Process Served Early Goals

The state's stem cell agency has focused the last four years on funding basic science, new facilities and training for lab technicians. In general, the process has been fairly straightforward, and to the degree that it has already created human capital, new infrastructure and economic activity, the state has benefited and will continue to benefit.[69]

A 23-member Scientific and Medical Research Funding Working Group – including 15 nationally recognized, out-of-state stem-cell scientists – makes recommendations on funding proposals based on competitive peer review of the scientific merit of the applications, with the full governing board making the final funding determination. Ten ICOC patient advocate representatives also participate in and monitor the review, though they do not take part in the scoring process.[70]

Most of the $700 million distributed as of April 2009 has been awarded to institutions that are represented by the board members – more than 80 percent, based on a Commission analysis – although the distribution of funds going to top-flight institutions and research centers should not be surprising.[71] Even though the

New CIRM Labs

CIRM's ability to leverage $900 million in private capital to help build new labs for stem cell research deserves commendation.

Using private donations and institutional matching funds, CIRM spread its infrastructure dollars around to 12 institutions. However, the economic recession is jeopardizing the completion of the projects, and the need for separate facilities for human embryonic stem cell research has faded with changes in federal law.

The Sanford Consortium (the Scripps, Salk and Burnham institutes and UC San Diego) stands out for wisely pooling resources. But even it had trouble finding enough money to break ground on the project. It is understandable that CIRM would want as many labs as possible to flower, but its dispersion strategy may have been a political decision to improve stakeholder support instead of a strategic decision to allocate a more efficient distribution of funds to a smaller number of consortiums.

Sources: Robert Klein, Chair, Independent Citizens Oversight Committee. Sacramento, CA. November 20, 2008. Testimony to the Commission. Also, Terri Somers. April 17, 2009. "Stem cell consortium $43 million richer." San Diego Union-Tribune.

Internal Policing

Missteps by board members have made the California Institute for Regenerative Medicine vulnerable to criticism that its board members need to be more cognizant of conflict-of-interest rules, which have not always been followed. For example, 10 applications were disqualified in December 2007 when ICOC members from the institutions seeking grants wrote letters of recommendation for the applications. The members' letters violated ICOC conflict-of-interest rules. In addition, the Fair Political Practices Commission – the state ethics panel – investigated and later reprimanded one board member because he violated conflict-of-interest rules when he circulated a seven-page letter urging the full board to reject the peer-review group recommendation not to fund a project by his institute. The CIRM staff immediately flagged the letter as a potential violation, and the board member temporarily stepped aside until the FPPC completed its investigation.

A February 14, 2008, letter from interim CIRM president Richard Murphy stated that the conflict-of-interest violations were inadvertent and innocent and that CIRM itself dealt with the violations. For example, four board members thought recommendation letters were allowed and issued letters for projects from their institutions as part of their professional roles as medical school deans or institute presidents. The board concluded that the letters conflicted with state conflict-of-interest laws, though none of the 10 applicants received grants.

After controversy arose, the institute developed a formal appeals process.

Sources: Senate Health Committee. April 1, 2008. "SB 1565 – Bill Analysis." Sacramento, CA. Office of Legislative Counsel. http://leginfo.ca.gov/pub/07-08/bill/sen/sb_1551-1600/sb_1565_cfa_20080401_144106_sen_comm.html. Accessed November 5, 2008. Also, Terri Somers. September 25, 2008. "Appeal plan is proposed for stem cell panel grants." San Diego Union-Tribune. http://www.signonsandiego.com/news/business/biotech/20080925-9999-1n25stem.html. Accessed September 30, 2008.

names of the institutions applying for research funds are redacted during the review and approval process, the largest recipients have been the University of California system, Stanford University and the University of Southern California.[72] Another board comprised of experts who had no ties to these institutions very likely would have made grants to this group.

Conflict of Interest Rules

The grant review process follows the practice of leading government scientific grant-making agencies, such as the National Science Foundation (NSF) and the National Institutes of Health (NIH), of employing a confidential peer review process for evaluating proposals and announcing only the winners. CIRM's processes for granting funds and screening for conflicts of interest have been reviewed – and endorsed – by the National Academy of Sciences, which held a two-day "best practices" workshop in California within a month of the passage of Proposition 71 to offer guidance for the newly created agency.[73] This was not unexpected – Proposition 71 required the agency to adopt conflict-of-interest rules for its working group members based on NIH standards.[74]

In 2007, the state auditor noted that members of CIRM's peer-review group, though not subject to state conflict-of-interest laws, follow CIRM's specialized conflict-of-interest policies that at times exceed NIH standards. For example, the NIH considers a reviewer to have a conflict of interest if the reviewer received a financial benefit of $10,000 or more from an institution applying for funds; CIRM set the threshold at $5,000.[75]

Compared to state laws, CIRM's conflict-of-interest policies also require reviewers to disclose personal, past and current professional interests and long-standing scientific and personal differences that could bias their evaluations – a requirement that goes beyond that for public officials, who must disclose only financial conflicts. The CIRM disclosure forms are not made public but are available for auditors to review.[76]

The membership of the scientific review committee is made public, although the smaller subset of specific reviewers assigned to evaluate individual applications is not disclosed, which follows practices at other leading federally funded grant-making entities. Summaries and scores of all grant proposals are available to the public, with identifying information about the applicants redacted. The identities of winning applicants are later identified and publicized.

CIRM also goes beyond NIH practices in that the final grant approval process is conducted openly at board meetings, with discussion, debate and appeals from rejected applicants. CIRM's governing board generally follows the peer-review recommendations, which are scored on a scale of 1-100 and grouped into categories of strong, moderate and weak contenders. Of 295 grants approved as of April 2009, the board had adjusted the peer review recommendations 56 times, mostly to approve funding for additional applicants in the middle category, according to CIRM, although the public tracking of such information is difficult and the data is not readily available. In only three instances did the ICOC reject funding for applicants placed in the top tier by the peer review panel.[77]

Peer Review Process is Defensible

Mr. Simpson, of Consumer Watchdog, told the Commission that the confidential peer review flouts normal open, good-government procedures with a "trust us, we're scientists" attitude. "Secrecy shrouds the entire application process," Mr. Simpson said.[78]

While the Commission appreciates Mr. Simpson's concerns, it does not agree with his conclusion. A confidential peer review process is appropriate for a first-line evaluation of grant applications because it upholds the scientific integrity of the grant distribution process.

Connecticut's Peer Review Compromise

In 2005, the Connecticut legislature created a stem cell research fund to distribute $10 million in grants each year for 10 years. Unlike California, Connecticut runs its stem cell program through the state's public health agency and early on had to navigate the issue of openness with a scientific community that was used to a certain level of confidentiality. Like California, Connecticut also uses a 15-member peer review committee to initially screen applications, with an advisory committee giving final approval for awards.

Similar to California's practice, each grant application is forwarded to a smaller panel of reviewers, whose identities are not disclosed. Connecticut officials said keeping the reviewers' identities anonymous enables frank discussion and enhances the quality of the reviews. Recruitment also would be difficult if the reviewers were attached personally to specific, possibly negative evaluations, officials said.

The process differs from California because the full peer review committee in Connecticut then reconvenes in an open, public meeting to discuss the applications before forwarding recommendations to the advisory board. All written material used for the reviews, including the identities of all applicants – successful or unsuccessful – are available to applicants, as well as the public. Proprietary information is redacted.

"We had to go above and beyond to be as transparent as possible," said an official involved in drafting the rules.

As the procedures for the grant review process were being finalized, the scientific community predicted a sudden withdrawal of applications that had already been submitted. Letters were sent to all applying institutions advising them that their materials were subject to disclosure, but no institutions pulled their applications, said one official. "There was no impact on the application process," he said.

Another official added that the initial concerns from the scientific community have dissipated and the number of grant applications have remained steady: "It has played out less horrifically then people might think."

Sources: Warren Wollschlager, chief, and Marianne Horn, director of legal services, Office of Research and Development, Connecticut Department of Public Health. Hartford, CT. April 21, 2009. Personal communication. Also, Connecticut Department of Public Health. "Stem Cell Research Program – Grants. Frequently Asked Questions." http://www.ct.gov/dph/cwp/view.asp?a=3142&q=389700.

Grant Monitoring

CIRM has developed grant administrative procedures to continually monitor its grantees' work, including site visits to facilities being funded by CIRM. In 2009, researchers began submitting annual progress reports to the CIRM peer-review panel.

"It's not a perfunctory exercise," said CIRM vice president John Robson, at an oversight committee headed by the controller's office. "If it turns out there's no progress, we can cut the grants. I suspect people are going to lose the grants."

The task of monitoring $3 billion in research and facilities funds is daunting, making it all the more essential for CIRM not to be bound by Proposition 71 staffing limitations that could inhibit the ability to adequately monitor and intervene when research dollars are being misspent or misused.

CIRM staff will provide an analysis of the progress reports, and actions against grant recipients will be made public. The full progress reports, which might contain proprietary information, will be available only to the peer-review group in closed session – a provision of Proposition 71.

Sources: Citizens Financial Accountability Oversight Committee. Sacramento, CA. April 14, 2009. Don Gibbons, communications director, CIRM. San Francisco, CA. April 22, 2009. Personal communication.

The Commission found that CIRM's method for distributing grant funds is largely defensible. From the standpoint of the public, however, the lack of transparency combined with the absence of independent voices on the ICOC leaves the agency open to the perception that its process is vulnerable to bias or interference.[79] Skepticism that the process is not entirely free of bias was a recurring concern heard by the Commission during its study. While the appearance of a potential conflict is greater than the actual problem, the large taxpayer investment in stem cell research merits a high degree of accountability over the ICOC decision-making process.

Internal Review of Applications

These concerns take on greater significance as CIRM transitions away from the fairly straightforward task of awarding grants to academic researchers and building research facilities. As envisioned in Proposition 71 and CIRM's strategic plan, CIRM now is preparing to shift into a business-oriented mode, opening its funding process more widely to private sector participation. It is launching a lending program for companies that show the most promise to turn research into potential drugs that will attract the private money required for extensive clinical trials. CIRM will retain stock warrants in these companies that, along with loan repayments, ultimately could provide a revenue stream for CIRM's continued operations if and when state bond money runs out. An update to the strategic plan calls for the ICOC to double the funds it initially set aside for such research.[80] Going forward, funds will be steered toward research that will result in federal Food and Drug Administration trials within four years.

The strategic plan update entails a substantive shift, largely unnoticed, to CIRM's grant-review process. Because CIRM will be reaching out to the private sector more vigorously beginning in 2009, the institute is concerned about overwhelming the out-of-state scientists on its peer review committee with funding requests.[81] In accordance with Proposition 71, the institute is limited to using 15 peer reviewers to screen applications for funding at any given time. CIRM is worried that that number may be insufficient.

To work within the confines of the cap, CIRM staff proposed, and the ICOC endorsed, a pilot project to "triage" grant and loan applications received in 2009 by a smaller committee of CIRM staff and outside experts. The applications will be winnowed based on criteria approved by the ICOC; successful applications will be forwarded to the peer review committee for the traditional screening. "We felt that we needed to really more efficiently use the time and energies of our grants working group, which is really stressed to the limit, so that they can be reviewing the best possible science while they're here in California," CIRM chief scientific officer Maria Csete told the ICOC at a December 2008 meeting.[82]

Although CIRM leaders point to other nonprofit grant-making organizations that use this approach, this step of triaging applications internally deviates from the best practices on which CIRM is modeled – a process that CIRM leaders frequently credit the National Academies with endorsing.

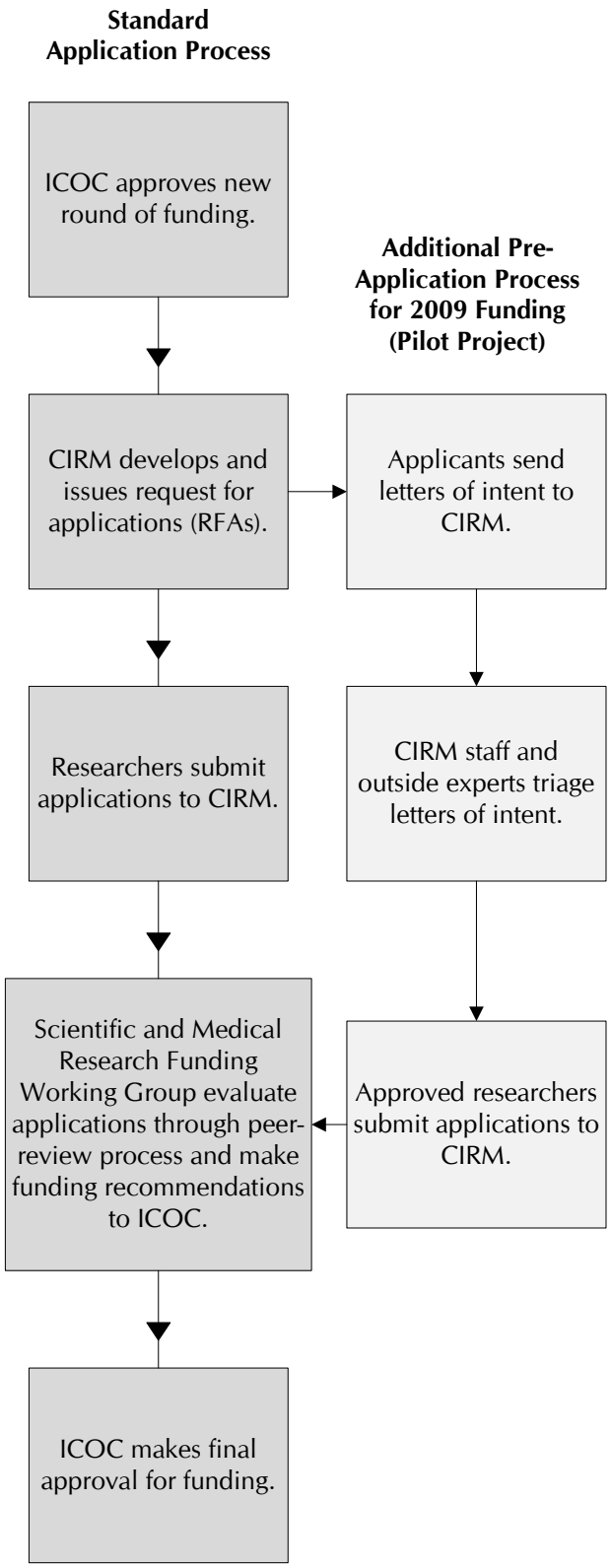
Several ICOC members have raised concerns that accusations of bias from an additional, internal screening process could undermine the mission of CIRM, though ICOC member Oswald Steward, a spinal cord researcher at UC Irvine, was the only member to vote against the triage plan. "I think that this is … the place where CIRM puts itself at serious risk," he said at an ICOC meeting.[83]

The Commission shares this concern. CIRM already has generated skepticism about the way it awards funds. Adding a new layer of opacity only will bolster such criticism.

Strategic Plan Update is Vague

In 2004, voters signed on to a 10-year project to fund stem cell research, but with a new strategic plan now under review, Mr. Klein is

Application & Award Process for CIRM Funding



pushing for a permanent program. He has raised the possibility of another bond issue when funding runs out, and he has said that his program to award loans instead of grants could provide continued funding for CIRM.[84]

CIRM's movement toward permanency, however appropriate, has progressed without extensive public discussion. In its 2006 Scientific Strategic Plan, CIRM laid out a thoughtful and sequential process for distributing the $3 billion over 10 years. Just a few years into the plan, the 2008 proposed update eliminates the detailed funding streams. In fact, it is not clear how the remaining funds will distributed, other than a stronger emphasis on providing more dollars to biotech companies.

Adjustments Warranted

Under the timeframe laid out in Proposition 71, CIRM might exist for only another few years. This raises the question of the value of investing time and effort in strengthening CIRM's governance structure only to have the institution itself sunset. Discussion governance, however, is not simply an intellectual exercise. CIRM is enshrined in the state Constitution and will exist, if in name only, after funding dries up. Proposition 71 does not have a sunset clause, and CIRM leaders have signaled their intent to extend the organization's lifespan after the $3 billion is spent, potentially through another ballot measure.[85]

Additionally, a model structure for CIRM could be used for other state agencies outside of the executive branch and as policy-makers look to emulate CIRM for other start-ups. The Public Utilities Commission and the University of California, for example, have been working with the Legislature to establish a quasi-independent Climate Change Institute, modeled after CIRM, that would be funded by a fee on utility bills.[86]

Should CIRM's funding continue beyond the initial investment voters approved in 2004, an adequate governance structure must be shaped to suit a more permanent mission. More immediately, reasonable reforms to CIRM's governance structure can increase public confidence as the agency prepares to spend its remaining authorization – more than $2 billion – on medical research.

CIRM and its governing board have been entrusted to spend taxpayer money on the best stem-cell-based science that can lead to cures for innumerable diseases. Buttressing that trust will enhance legitimacy for the program, and particularly during difficult economic times, provide reassurance that the state's large investment is used wisely.

Recommendations for Improving Governance

A state agency can perform appropriately despite an awkward or even inadequate governance structure, but this does not mean that its structure cannot be or should not be improved.

In its 2007 study of the State Allocation Board, for example, the Commission found that the board functioned well for many years with a flawed structure that defied description in a normal organizational chart. The board, which decides how to allocate billions of public dollars on school construction projects around the state, will always generate criticism and seconding-guessing of its motives because of the scope of its work. The Commission found that the best strategy to address that problem is to add more transparency and accountability into the governance structure.[87]

In the case of CIRM, the organization has performed its job reasonably well according to its mission laid out in Proposition 71 in terms of distributing $3 billion in research dollars for scientists, buildings and training. But there is a disconnect: as specific as the provisions of Proposition 71 were, they still could not guarantee, mandate or control confidence in the process. Over time, the very provisions designed to protect CIRM from political involvement only invited it. The provisions so carefully detailed are now outdated and, at the same time, constrain CIRM from moving forward to fulfill its mission. Changes should be made that would improve and instill public confidence in the agency's decisions and prepare it for its future challenges when its new, untested processes likely will come under even more scrutiny.

Currently, CIRM's governance structure leaves the agency vulnerable to criticism that only invites more scrutiny, diverting it from its mission. CIRM should take every opportunity to bolster its system and support legislative reforms that will strengthen it. The case already has been made that voters are willing to forgo $3 billion today in exchange for the promised future benefits of stem cell research. Such innovation is the hallmark of California's entrepreneurial spirit and drive.

To enhance public credibility and acceptance, it is critical for the public to better understand how CIRM and its governing board make decisions.

While the public may have access to ICOC budgets, meeting transcripts and information about grant recipients, CIRM and the public would benefit from even more transparency, and given the long terms for board members, greater accountability as well. Some details, particularly during the scientific peer review of grant applications, likely will and should remain confidential. A more efficient and independent governance structure, however, can improve clarity and transparency over the process.

The components of good governance include:

- An easily grasped chain of command, with clear delineation of duties and decision-making,
- Accountability,
- Transparency and openness,
- Flexibility and responsiveness to changing environments, and
- Stability that allows for long-term planning, turnover and inclusiveness.

Proposition 71 was written too tightly to accommodate needed changes; CIRM has responded by pursuing half-step internal remedies when statutory reforms are needed. The Commission has developed its recommendations to more adequately address issues that have surfaced because of the initiative's restrictiveness. For example:

- CIRM staff will triage funding requests through a new, closed process because Proposition 71 capped the number of out-of-state peer reviewers, now overwhelmed by the current number of applications.
- Board members now are allowed to participate in meetings telephonically so that the ICOC's 29-member board can meet its quorum requirement.
- The board plans to conduct evaluations of its leaders' performance, which illustrates a desire for greater accountability, yet without the ability to remove its chair or vice chair for poor performance, it may be merely an exercise without consequence, particularly given the ICOC's inability to nominate a replacement should one be necessary. Unlike typical boards, the ICOC chair is not selected from within the board and cannot be replaced. Under Proposition 71, the governor, lieutenant governor, state controller and state treasurer nominate candidates for chair and vice chair, who are then elected by the board.
- The board has created a second vice chair rather than choosing between two nominees, highlighting the conflict introduced by

having multiple appointing authorities as prescribed by Proposition 71.

CIRM and its governing board make changes to their operations as they see necessary, even if the changes appear at odds with the spirit of Proposition 71. These CIRM-initiated changes suggest that Proposition 71 is sufficiently malleable when considered necessary by CIRM, but raise concerns as to whether CIRM's governing board can provide effective and independent oversight to protect the public's interest.

Board Structure Should Be Streamlined

Creating a more efficient and accountable governing board for CIRM is the first step. The current board, though productive, is too large. The 29-member committee should be reduced to 15. The Commission found the rationale for a supermajority quorum was sound and problems with meeting this requirement should be eased by reducing the board's size. The diversity of the board membership can be preserved by proportionately reducing the seats allocated to each of the representative groups. Four independent voices – unaffiliated scientists and business people – should be included in the 15-member board as a counterweight to the interested parties whose institutions often receive grant funds.

To reduce the opportunities for conflict of interest to arise and to encourage fresh viewpoints to enable CIRM to adapt to changing conditions, the terms for board members should follow standard four-year terms to avoid the appearance or potential of special-interest capture. These provisions can be implemented incrementally as the terms of current board members expire. The fact that a court has said the structure was legal is insufficient. A structure can be legal and still not optimal, as is the case with CIRM.

A strong case has not been made for the ICOC members to continue serving long terms. Shorter terms, leading to more turnover of board members could help address criticism that the ICOC is an insider's club and could introduce fresh points of view to match the speed at which stem cell science develops. As several members approach the end of their six-year terms, the Legislature has an opportunity to shorten the terms of new ICOC members and phase in new members with minimal disruption.

Current and Proposed Board Compositions

"Independent Citizens Oversight Committee" Current 29-member board		"Board of Directors" Proposed 15-member board	
Appointing Body	**Position**	**Position**	**Appointing Body**
UC Chancellors	5 Executive officers from UCs with a medical school	2 Executive officers from a UC with a medical school	UC President
G, Lt.G, T, C	4 Executive officers from other California universities	1 Executive officer from a California university	G
G, Lt.G, T, C	4 Executive officers from California research institutes	1 Executive officer from a California research institute	G
G, Lt.G, T, C	4 Executive officers of commercial life science entities	2 Executive officers of a commercial life science entity	G
G	1 Patient Advocate - Alzheimer's Disease	2 Independent scientists	G
G	1 Patient Advocate - Spinal Cord Injury	2 Independent business leaders	G
Lt. G	1 Patient Advocate - MS/ALS	3 Patient Advocates - unspecified disease groups	G
Lt. G	1 Patient Advocate - Type II Diabetes	1 Patient Advocate - unspecified disease group	Senate
C	1 Patient Advocate - Cancer	1 Patient Advocate - unspecified disease group	Assembly
C	1 Patient Advocate - Parkinson's Disease	0 Chair of the board	**
T	1 Patient Advocate - Heart Disease	0 Vice chair of the board	**
T	1 Patient Advocate - Type I Diabetes		
Senate	1 Patient Advocate - HIV/AIDS		
Assembly	1 Patient Advocate - Mental Health		
*	1 Chair of the board		
*	1 Vice chair of the board		

Key

G = Governor
Lt. G = Lieutenant
T = Treasurer
C = Controller
Senate = Senate Rules Committee
Assembly = Speaker of the Assembly
* = Nomination from G, Lt. G, T, C and elected by ICOC
** = Selected from within board membership

In conversations with Commission staff, Mr. Klein and Dr. Trounson defended the diversity and size of the ICOC membership as critical to including perspectives from specific institutions because of their research specializations.[88] Proposition 71, however, cites the broad categories of representative groups that are to serve on the ICOC; it does not specify individual research centers by specialty. Reducing the size of the governing board can be done in a way that preserves the proportionality of its representative groups and, by introducing shorter terms and generating more turnover, provides for an even greater diversity of opinion.

To provide clear lines of communication and authority within the organization, and to facilitate succession planning, the duties of the chair, vice chair and president should be realigned. The board should have authority to establish clear and distinct duties for the chair, vice chair and president. The roles should not be defined in statute, and the

board leadership should be nominated and elected from candidates within the existing membership. To enhance accountability, the board should have the ability to remove members for repeated absences, conflict-of-interest incidents and other reasons it deems necessary in order to function properly.

Placing appointment authority for more board members under the governor, with Senate confirmation, also would make members more accountable to the state's top executive and legislators. The governor should be given the ability to appoint 11 of the 15 board members, subject to Senate confirmation. Legislative leaders should continue to appoint two board members as part of an effort to incorporate their support and input for the project. The University of California president should appoint campus leaders to fill the remaining two seats on the board. The name of the Independent Citizens Oversight Committee should be changed to the more accurate Board of Directors.

Triage Process Should Be Modified

CIRM staffing restrictions were created in Proposition 71 to assure voters that the agency would not become a bloated bureaucracy. CIRM, however, needs more flexibility than Proposition 71 allows to complete its mission with transparency. Such staffing flexibility would entail allowing CIRM to direct and dedicate resources where they are most needed, such as toward the growing task of monitoring grantees and reviewing their progress reports. Though CIRM currently employs about 40 people, it is planning to bring on additional staff and quickly could bump up against the 50-employee cap. Removing the cap on CIRM staff also would reduce the need to shift work that could be handled in-house to potentially more expensive contractors.

Another Proposition 71 cap limits to 15 the number of scientists who can participate in the peer review of grant and loan applications at any given time. Lifting the cap is essential to maintaining transparency. Because of this cap, CIRM is concerned that the peer review panel is too small to adequately review the expected number of applicants for funding. While this process was adequate to award initial funding for basic science research, it potentially will hobble CIRM's ability to support its next phase of loan-making and distributing grants to groups that include for-profit entities. Because of the restriction, CIRM is now piloting an internal process to triage applications before they are reviewed by a panel

CIRM and Consultants

While the Commission did not audit CIRM's finances, it offers the general observation that the administrative limitations written into Proposition 71 have permitted CIRM to rely heavily on outside consultants. A contract attorney, for example, has been used since CIRM's inception to, among other duties, perform tasks at ICOC meetings such as swearing in new board members and advise board members of potential conflicts of interest during funding discussions – routine functions that could be handled by CIRM's in-house attorneys. CIRM also has retained a former ICOC member and one-time CIRM president as a consultant for a strategic planning project that has been completed.

The ICOC maintains a fiduciary duty to monitor contracts closely and end unnecessary ones. Given its limit on expenses, the board should consider adopting a "revolving door" policy to standardize its practices of hiring former board members and CIRM staff as consultants.

Sources: Independent Citizens Oversight Committee. Sacramento, CA. March 12, 2009. Committee meeting. Also, Independent Citizens Oversight Committee. Sacramento, CA. March 5, 2009. Finance Subcommittee teleconference meeting.

of independent, out-of-state scientists. Lifting the 15-person cap would give CIRM the needed flexibility to use the needed number of independent reviewers, preserving the outside objectivity in the review process. Instead of adding additional walls that separate itself from the public, CIRM should develop methods that provide greater openness to its processes.

Although CIRM leaders point to nonprofit grant-making organizations that use this approach, this step of triaging applications deviates substantially from the best practices on which CIRM is modeled – a process that CIRM leaders frequently credit the National Academies with endorsing. The public has an expectation of openness and transparency for a government agency that differs from the expectations of a private foundation.

Expanding the peer review panels will increase costs (CIRM already budgets about $500,000 a year for travel and expenses related to its review sessions), but it is a justifiable cost to ensure a consistent and fair funding process.

CIRM leadership has argued that fewer institutions would apply for funding if their identities became known and they were not successful. CIRM, however, should continually strive to improve the openness of its process. Based on Connecticut's experience of disclosing all applicants without negative consequence, CIRM should conduct a pilot project to evaluate if a more open process would inhibit researchers from coming forward and applying for CIRM funds. In an upcoming grant round, all applicants should be identified retrospectively. Disclosing names of unsuccessful applicants as well as individual reviewers will allow the public to better track CIRM's funding processes for fairness and bias. Judging by the apparent willingness of rejected applicants to identify themselves and their organizations in public appeals to CIRM, it is questionable whether the current lockout of applicant identities poses a real concern. The burden is on CIRM to demonstrate otherwise.

CIRM officials also have said the agency would lose potential reviewers if their financial disclosures were made public. CIRM should poll its reviewers anonymously to see if they would withdraw from the review process if their financial disclosures were made public, and make the results of the poll available to the public. Because of the high profile of California's stem cell effort, CIRM has developed an expanding list of more than 60 reviewers, from which it uses a maximum of 15 during a review session under the Proposition 71 requirements.

Oversight Functions Should be Enhanced

The balance between oversight and interference by the Legislature needs careful calibration for an organization like CIRM, which is designed to function on the periphery of normal legislative controls.

In approving Proposition 71, voters made clear their priority to set aside $3 billion to fund stem cell research, but they also provided for several levels of oversight to monitor the state's investment. CIRM's governing board, though mostly comprised of interested individuals, provides a first-line review of CIRM's activities, administrative expenses and research priorities.

The next level of oversight provided by Proposition 71 – the Citizens Financial Accountability Oversight Committee (CFAOC) – provides the potential to conduct higher level evaluations of CIRM's financial and programmatic performance, to ensure the agency stays on track. In practice, the CFAOC has focused narrowly on reviewing CIRM's financial audits and spending practices. The committee has the capacity and could be more valuable by expanding its scope to review, track and report CIRM's programmatic performance and adherence to the goals set out by Proposition 71 with regular, quarterly meetings.

Clarifying the functions of the CFAOC in statute would enable the committee to fully exercise that role. Because the initiative already specified that CIRM pays for certain CFAOC costs, additional staffing could be provided through CIRM's administrative fund.

Succession Planning Should Be a Priority

Much of CIRM's governing statutes were written to generate stakeholder input, support and stability for a new agency in start-up mode at a time when its core mission was at the center of considerable controversy. Now that the agency is firmly established and entering a more operational mode, CIRM's governance structure is outdated and inappropriate for its new tasks. The individual leaders who can navigate CIRM's entangled organizational structure today may not be around tomorrow. CIRM's leaders have the duty to create a streamlined and coherent organizational structure that serves the agency's future and its next generation of leaders.

CIRM could not exist without the time, effort and personal resources that Mr. Klein has devoted to it. As the author of Proposition 71, Mr. Klein drew up detailed qualifications for the ICOC chair that essentially guaranteed his appointment. The personality-driven structure may have

provided the organization initially needed stability and focus, but it does not portend well for sustainability. To structure the chair qualifications so prescriptively as to fit just one person is short-sighted, and an obstacle both to succession planning and allowing the organization's leadership to evolve as its environment changes.

As CIRM exits its start-up phase, it is unclear whether the founding leaders on CIRM's governing board can objectively evaluate the best course for CIRM's future, including the crucial question of whether it should exist beyond its initially intended 10 years.

Given that the longer-than-normal terms on the governing board limit turnover, current board members may lack the independent perspective required to determine when CIRM's contributions to stem cell science have peaked.

The board, however, is pushing CIRM toward permanent status. The race toward cures, embraced by voters, demands that CIRM's governance structure be adequately equipped to oversee this evolution. The governing board should begin planning a course for CIRM's future – one that is laid out clearly and succinctly for the public to evaluate.

When testifying before the Commission, Mr. Klein declined to identify substantive modifications he would make, in retrospect, to CIRM's governance structure. In a follow-up letter to the Commission, he said the board was working well in its current form.[89]

Voters gave tremendous regulatory flexibility to CIRM, along with equally high expectations for performance and accountability. The flexibility has been granted, now the state should ensure that CIRM's performance measures up to the high standard that voters envisioned.

Proposition 71 added a new section to the California Constitution, several statutory provisions to the Health and Safety Code and the authorization to raise money for stem cell research through general obligation bonds. By design, the ability to amend the state's program is somewhat limited. Amending the Constitution requires a statewide vote, triggered either by the Legislature or a signature-gathering effort of the people. The Legislature generally can amend statutes on its own, with approval by the governor. Only amendments that further the purpose of the act are allowed – the definition of which is open to interpretation and dispute, likely requiring judicial resolution. The bond provisions of Proposition 71 cannot be amended.

Counsel for CIRM and the Americans for Cures Foundation provided the Commission with legal opinions that question whether some of the

Commission's potential recommendations could be enacted into law without voter approval. In their view, the Commission's recommendations do not fall within the category of "permissible *clarifications*, but instead constitute impermissible *policy alterations*."

According to the Attorney General's Office and the Legislative Counsel, in the general sense, the courts have not provided clear guidance as to what constitutes a "permissible clarification" that 'furthers the purpose of the grant and loan programs." Efforts to amend laws created by ballot measures often are subject to dispute, which can end up in litigation and must be resolved on a case-by-case basis on whether the intended change furthers the purpose of the initiative.

While the Commission understands there is a potential controversy here, which could lead to litigation, this is a sufficiently open question that persuades the Commission to recommend the following governance changes in the interest of furthering the purpose of Proposition 71 and improving the prospects for long-term success of the agency's mission.

The Commission is sensitive to the value of CIRM's institutional knowledge, the importance of continuity and CIRM's good standing in the scientific community.

The Commission also appreciates the complexities involved in reorganizing an agency and the disruption that can occur, and why this is of particular concern for CIRM, given its roster of ongoing projects, many of which are international in scope. The Commission intends that its recommendations be implemented over a period of time, allowing for an appropriate transition in order to minimize disruption to CIRM's creative and ambitious agenda. Shortening the length of board terms, for example, should be introduced and phased in as current board members' terms expire.

To fulfill its ambitious mission, CIRM needs every advantage to move forward with efficiency and integrity. The ICOC has functioned as well has it has because of the talent and extraordinary commitment of its members, whose efforts have mitigated the shortcomings in CIRM's governance structure. As fortunate as California is to have the benefit of such individuals, the stakes are too high to take such structural weaknesses for granted. In the interest of propelling CIRM's mission, the Commission makes the following recommendations:

Recommendation 1: The Legislature should restructure the CIRM governing board around principles of efficiency and transparency.

- ❑ The Legislature should amend the Health and Safety Code to reduce the board size, shorten terms and restructure membership.
  - ✓ Decrease board size to 15 from 29. Keep diversity of membership but add independent voices to the board: five patient advocates from unspecified disease groups, two independent business leaders and two independent scientists with no ties to CIRM-funded institutions; two University of California officials, one university official (non UC); two private sector biotechnology executives, and one leader of a California research institution.
  - ✓ Reduce terms to four years for all members.
- ❑ The Legislature should amend the Health and Safety Code to streamline the appointment process for CIRM board members. Allow the governor to appoint 11 of 15 board members, subject to Senate confirmation. Legislative leaders should continue to appoint two members. The UC system president should appoint two UC representatives.
- ❑ The Legislature and CIRM should realign the roles of chair and president to eliminate overlapping authority and to enhance clarity and accountability.
  - ✓ The Legislature should modify all statutory references in the Health and Safety Code to the nominating process, job duties and qualifications for the chair and vice chair to invest this authority with the board.
  - ✓ The CIRM board should elect a chair and a vice chair from within the existing board, subject to set terms and conditions for re-election/removal.
  - ✓ The CIRM board should clarify that the president manages all day-to-day operations.
- ❑ The Legislature should amend the Health and Safety Code to rename the board to more accurately reflect its composition. The Independent Citizens Oversight Committee should be called the Board of Directors.

Recommendation 2: The Legislature and CIRM should improve efficiency and transparency for distributing grant and loan funds.

- ❑ The Legislature should amend the Health and Safety Code to remove the 50-employee cap on staffing.

- ❑ The Legislature should amend the Health and Safety Code to remove the 15-person limit on peer reviewers. CIRM should modify its triage plan to review grants internally.
- ❑ CIRM should explore options for greater disclosure of the peer review process.
  - ✓ CIRM should poll CIRM's peer reviewers anonymously about their willingness to participate in the review process if their financial disclosure statements are made available to the public. The results of this poll should be made public.
  - ✓ CIRM should conduct a trial grant application round that identifies all applicants.
  - ✓ CIRM should provide full grant evaluations to applicants.
- ❑ CIRM should amend all meeting minutes to specify individual board members' votes and recusals, and continue the practice moving forward.

Recommendation 3: The CFAOC and the CIRM governing board should use their authority to enhance oversight.

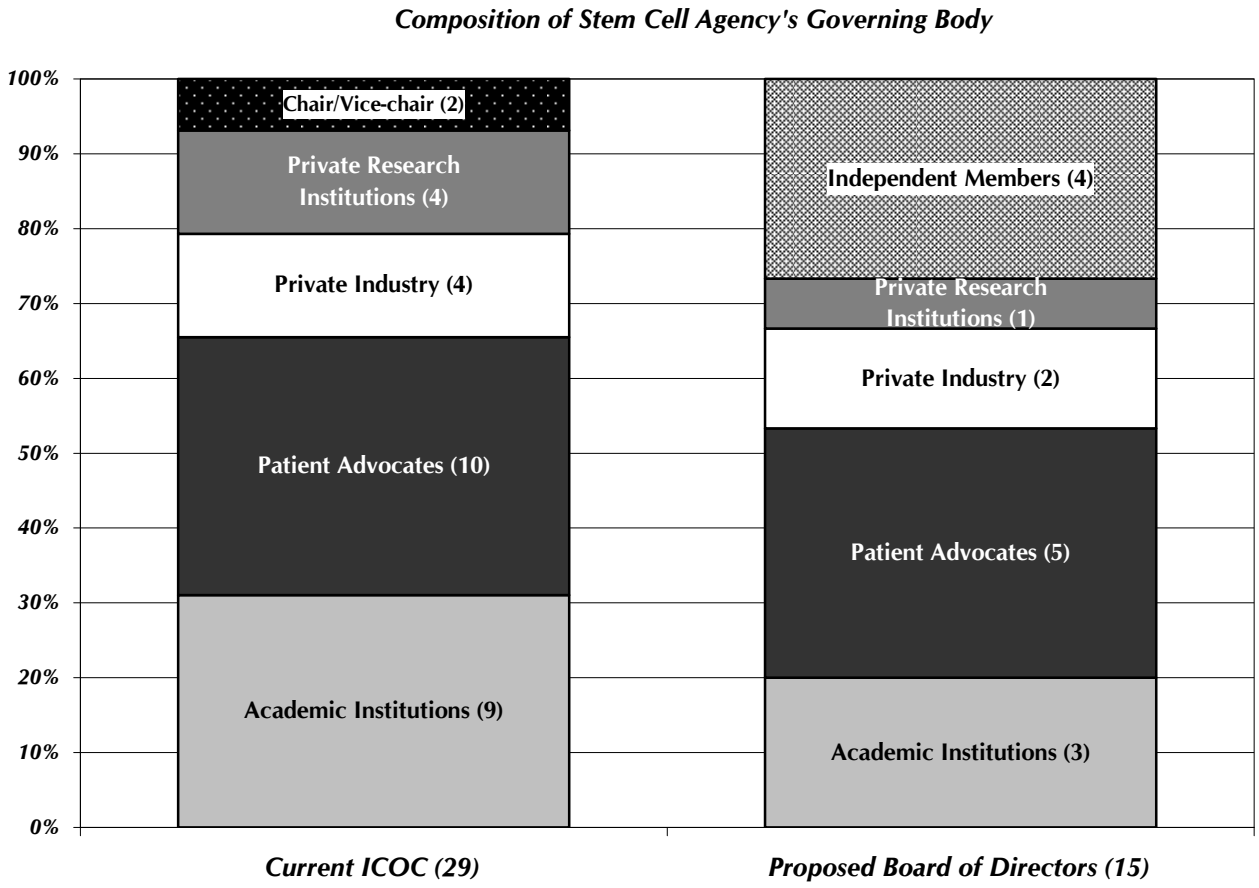
- ❑ The Citizens Financial Accountability Oversight Committee (CFAOC), chaired by the State Controller, should exercise its existing authority, or be statutorily authorized if necessary, to conduct performance audits and hold regular meetings to review CIRM's programmatic and strategic performance, in addition to overseeing CIRM's annual financial audits.
- ❑ The governing board should hold its members accountable by adopting removal provisions in its bylaws.

Recommendation 4: The CIRM governing board should begin planning for CIRM's future through an open process.

- ❑ The CIRM governing board should create succession plans for board leadership.
- ❑ CIRM's strategic plan should provide clear transparent direction for spending funds, with measurable benchmarks.
- ❑ CIRM should develop a transition plan for the eventual expiration of bond funding.

Authority for Restructuring the State's Stem Cell Agency

LHC Recommendations	CIRM/ ICOC	Legislature
Recommendation 1		
Decrease board size to 15 from 29 and alter membership		X
Reduce length of terms to four years		X
Streamline appointment process		X
Modify statutory references to the nominating process, job duties and qualifications for the chair and vice chair		X
Give authority to board to elect a chair and vice chair from within the existing board, subject to set terms and re-election/removal		X
Clarify that CIRM president manages all day-to-day operations	X	X
Rename ICOC to Board of Directors		X
Recommendation 2		
Remove 50-employee cap on staffing		X
Remove 15-person limit on scientific peer reviewers		X
Modify triage process	X	
Poll peer reviewers about their willingness to participate in the grant review process if their financial disclosure statements are made public	X	
Pilot a grant application round that identifies all applicants	X	
Provide full grant evaluations to applicants	X	
Amend all meeting minutes to specify individual members' votes and recusals and continue the practice moving forward	X	
Recommendation 3		
Extend authority of CFAOC to conduct performance reviews of CIRM		X
Adopt removal provisions for nonparticipating board members	X	
Recommendation 4		
Create succession plans for founding leadership	X	
Establish clear transparent direction for spending research funds, with measurable benchmarks, in the strategic plan update	X	
Develop a transition plan for expiring bond funding	X	


Composition of Stem Cell Agency's Governing Body
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Chair/Vice-chair (2)
Private Research Institutions (4)
Private Industry (4)
Patient Advocates (10)
Academic Institutions (9)
Independent Members (4)
Private Research Institutions (1)
Private Industry (2)
Patient Advocates (5)
Academic Institutions (3)
Current ICOC (29)
Proposed Board of Directors (15)

Conclusion

In 2004, Proposition 71 launched California to the global forefront of stem cell science. But in terms of governance, the state's stem cell program has lacked the flexibility to ensure that California Institute for Regenerative Medicine (CIRM) and its governing board, the Independent Citizens Oversight Committee (ICOC) can meet the high expectations for science – and government accountability – that voters envisioned.

The Commission has presented a set of recommendations designed to comply with the spirit and intent of Proposition 71 that will strengthen CIRM's governance structure. The current structure, carefully crafted into the ballot measure, gave CIRM leaders the independence and bureaucratic freedom to establish a new state agency within weeks of Proposition 71's passage in 2004. The unique aspects of CIRM's organization structure – from co-CEOs to a large governing board – all have reasonable justifications that aided CIRM in its start-up phase.

Going forward, with a new federal policy supporting human embryonic stem cell research, rapid changes in science and a sizeable investment already made by CIRM in terms of human capital and infrastructure, the governance structure prescribed by Proposition 71 becomes harder to justify. The Commission found it overly restrictive to CIRM's ability to achieve its mission.

CIRM has provided the Commission with a legal opinion developed by its counsel that takes the view that the Commission's recommendations cannot be implemented without going back to the voters. The Commission acknowledges that legislation implementing its recommendations could be subject to challenge, possibly litigation. It believes, however, that the legal questions are sufficiently open to warrant moving its recommendations to the legislative arena for further discussion. The Commission is confident that its recommendations serve the voters' intent.

Five years ago, Proposition 71 brought together 29 university officials, biotechnology executives, research scientists and patient advocates to form the ICOC and to develop a detailed, 10-year plan to distribute the $3 billion that California voters committed to stem cell science. Despite two years of court delays, more than $700 million already has been

awarded to research centers around the state, with another $900 million leveraged from matching funds. It is unclear, however, what is to become of CIRM when the $3 billion is spent. Conversations with many ICOC members revealed no clear consensus on the best approach for CIRM's future.

What is clear is that the conversation is not happening openly, even as CIRM's leaders are positioning the agency toward permanency – in a way that may not have been clear to voters. The governance structure has created an environment that initially embracing the diversity of viewpoints on its board, but now protects the founding leaders, dilutes accountability and limits turnover and, ironically, rejuvenation.

For example:

- Board members serve extraordinarily long terms – six to eight years – and can be reappointed once.
- A separately appointed chair shares overlapping administrative duties with the agency president, creating a conflict in his ability to perform an independent oversight role.
- Board members represent institutions and advocacy groups that stand to benefit from CIRM grants and loans.

The Commission's solution is to revamp and streamline the board – infusing it with truly independent voices to balance out the interested parties, who bring expertise and value to the mission. Terms must be shortened to spur the kind of turnover that is a critical element of healthy governing boards in the corporate, nonprofit and public sector. The roles of board chair and president also must be recast to clarify lines of responsibility and communication, with the president running the agency and the board chair filling oversight duties.

Implementation of these changes must take into account the need to preserve momentum and continuity and to protect the value of CIRM's institutional knowledge. To that end, the Commission's recommendations should be phased in to minimize disruption. Board members should be allowed to serve out existing terms, for example, and changes implemented as terms expire.

Much of the public focus on CIRM centers on the personal style of Robert Klein, the ICOC chair, and key backer and author of Proposition 71. Given that Proposition 71 detailed specific criteria for the board chair that uniquely fits Mr. Klein's extensive resume, discussion of his role is unavoidable. The ballot measure's very specificity will make finding Mr. Klein's replacement difficult. From the Commission's perspective, a governance structure that is built around specific individuals does not

serve the institution or the state well. Indeed, Mr. Klein told the Commission on repeated occasions that he is not seeking reappointment after his term ends in December 2010, yet the ICOC has not begun preparing a succession plan.

The rigidity of Proposition 71 was intended to provide stability for CIRM's entrepreneurial leaders. Now that CIRM is fully in an operational phase, the structure may not be sustainable in the long term.

The concerns that have been expressed about transparency and accountability at CIRM are hardly fading, and CIRM can lessen the disruption caused by audits and investigations by embracing meaningful change. To remain strong, CIRM should take every measure to improve its own governance structure. The Legislature should take it from there.

The Commission's Study Process

The Commission examined the governance structure of the state's stem cell agency, the California Institute for Regenerative Medicine (CIRM) and, and its governing body, the Independent Citizens Oversight Committee (ICOC), at the request of Senators Sheila Kuehl and George Runner.

Initiated in the spring of 2008, this study served as an opportunity for the Commission to review the state's stem cell agency and make recommendations to improve the agency's governance structure.

As part of the study, the Commission convened a public hearing in November 2008. At this hearing, the Commission heard from academic experts in corporate and nonprofit governance, citizens groups that have monitored the CIRM's operations, representatives from institutions that have received grant money from CIRM as well as the chair of the ICOC and the president of CIRM. Hearing witnesses are listed in Appendix A.

The Commission also convened two subcommittee meetings to discuss the scope and content of the Commission's study: one in November 2008 and another in May 2009.

In addition to the public hearing and subcommittee meetings, in December 2008 the Commission's California Institute for Regenerative Medicine Subcommittee observed the Independent Citizens' Oversight Committee meeting of the California Institute for Regenerative Medicine in Irvine, California. Commission staff also observed a number of the ICOC's governance subcommittee meetings during the course of this study.

Commission staff received valuable feedback from a number of experts representing various components of California's stem cell program as well as from experts in other states. The Commission greatly benefited from the contributions of all who shared their expertise, but the findings and recommendations in this report are the Commission's own.

All written testimony submitted electronically for the hearing, and this report is available online at the Commission Web site, www.lhc.ca.gov.

Appendices & Notes

- ✓ *November 2008 Public Hearing Witnesses*
- ✓ *Letter from Senators Sheila Kuehl and George Runner*
- ✓ *Current CIRM Organizational Structure*
- ✓ *CIRM Timeline*
- ✓ *2005 Policy Enhancements*
- ✓ *Letter from Senator Dean Florez*
- ✓ *Notes*

Appendix A

November 2008 Public Hearing Witnesses

Public Hearing on the California Institute for Regenerative Medicine
November 20, 2008

Michael Klausner, Professor of Law, Stanford Law School

Kenneth Taymor, Executive Director, Berkeley Center for Law, Business and the Economy

John Simpson, Director, Stem Cell Oversight and Accountability Project, Consumer Watchdog

Jesse Reynolds, Director, Project on Biotechnology in the Public Interest, Center for Genetics and Society

Susan V. Bryant, Vice Chancellor for Research, University of California, Irvine, and member, Independent Citizens Oversight Committee

Ralph O'Rear, Vice President, Facilities and Planning, Buck Institute for Age Research

Robert Klein, Chairperson, Independent Citizens Oversight Committee

Alan Trounson, President, California Institute for Regenerative Medicine

Appendix B

Letter from Senators Sheila Kuehl and George Runner

CALIFORNIA LEGISLATURE

Senate

STATE CAPITOL
SACRAMENTO, CALIFORNIA
95814

April 28, 2008

Mr. Daniel Hancock
Chairman
Little Hoover Commission
925 L Street, Suite 805
Sacramento, California 95814

Dear Mr. Hancock:

As the authors of SB 1565 of 2008, we are asking the Little Hoover Commission to conduct a study of the governance structure of the California Stem Cell Research and Cures Act, including the membership of the Independent Citizens Oversight Committee (ICOC) and the relative roles of the committee and the California Institute for Regenerative Medicine (CIRM).

As you know, Proposition 71, an initiative measure approved by the voters at the November 2, 2004, statewide general election, authorized the sale of $3 billion in general obligation bonds over 10 years for stem cell research and facilities in California, and established the CIRM to make grants and loans and the ICOC as the governing body for the CIRM.

Given the unique governing structure for this program and the level of investment of public funds in the program ($6 billion, including $3 billion in interest on the bonds), we believe an independent review of the program's governing structure by the Little Hoover Commission is warranted, in order to determine whether it is broadly protective of the public interest.

We are requesting the commission to complete its study and report by July 1, 2009, including recommendations on the ways the governance structure of the ICOC might better ensure public accountability and reduce conflicts of interest, consistent with the purposes of Proposition 71. Such a study, we hope, would help maximize the CIRM and the ICOC's ability to achieve the goals of Proposition 71 and protect the integrity of the institution from real or perceived conflicts of interest.

We appreciate your consideration of this request, as well as your ongoing work to improve state government efficiency, economy and service. Please feel free to contact us or Lark Park of the Senate Health Committee staff at (916) 651-4111 with any questions or concerns regarding this request.

Sincerely,

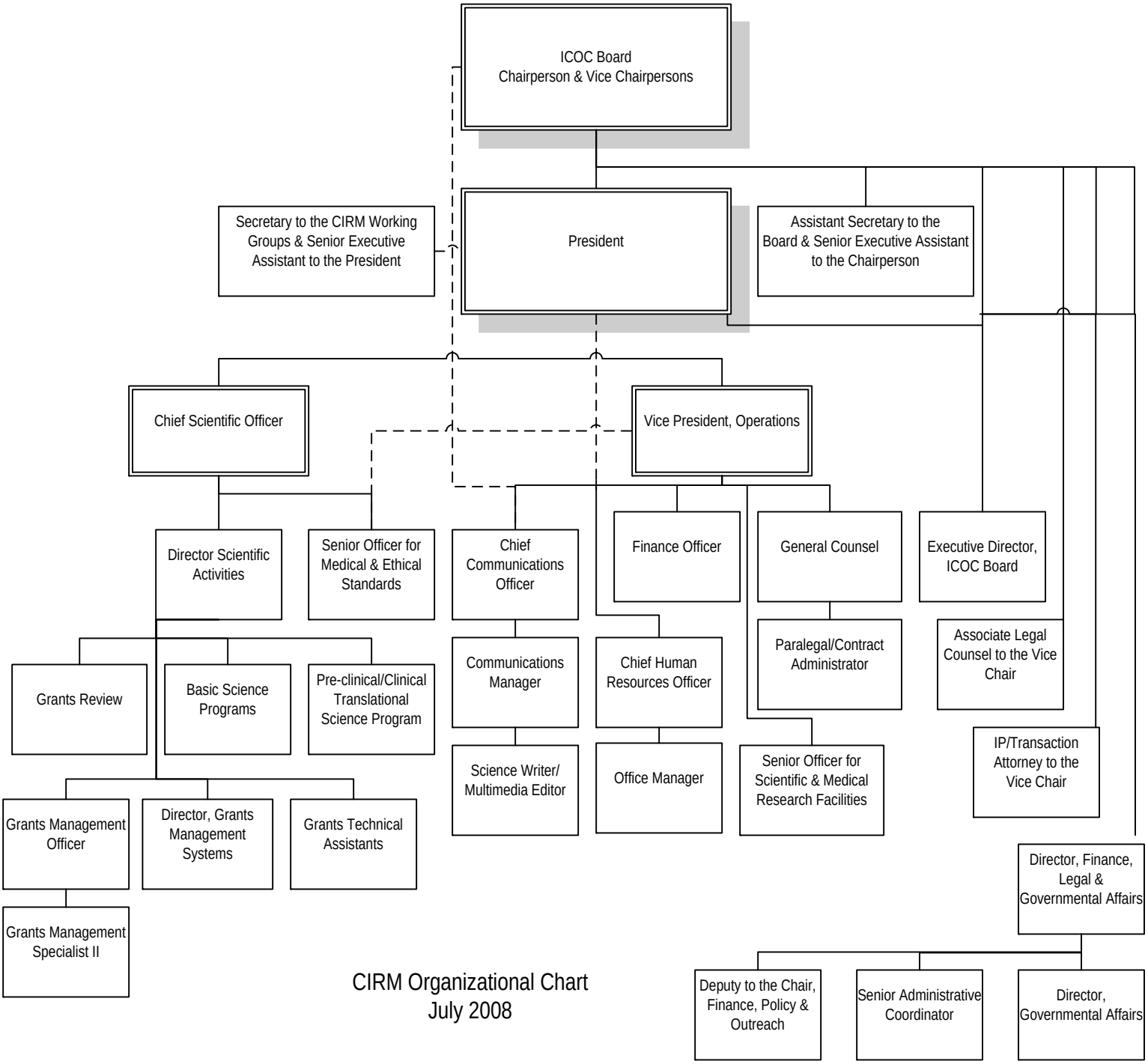
SHEILA J. KUEHL
23rd District

GEORGE RUNNER
17th District

cc: Stuart Drown, Executive Director
Little Hoover Commission
Senator Patricia Wiggins, co-author, SB 1565
Assemblymember Dave Jones, co-author, SB 1565
Robert Klein, Chairman, ICOC
Alan Trounson, President, CIRM

Appendix C

Current CIRM Organizational Structure



CIRM Organizational Chart
July 2008

Appendix D

CIRM Timeline

Building California's Stem Cell Agency: A Timeline

2001

August: President Bush restricts federal financing for human embroynic stem cell research.

2004

November: California voters approve Proposition 71, giving California the constitutional right to conduct stem cell research and authorizing $3 billion for research and new labs.

December: The Independent Citizens Oversight Committee elects Robert Klein as chairman.

2005

February: Taxpayer organizations and abortion opponents sue to block California from issuing bonds to fund CIRM. CIRM bond funding is frozen during litigation.

May: The California Institute for Regenerative Medicine (CIRM) chooses San Francisco as its headquarters.

June: CIRM accepts $5 million in private donation from Ray Dolby for start-up operations.

2006

May: Alameda County Superior Court rules in CIRM's favor; bond funding remains frozen during appeals.

July: Governor Schwarzenegger authorizes a $150 million state loan to fund CIRM activities and grants. CIRM receives $45 million in loans from foundations and private individuals.

2007

February: The Independent Citizens Oversight Committee awards first research grants.

California Court of Appeal rules in CIRM's favor.

May: State Supreme Court declines to intervene in court case, clearing the way for California to sell general obligation bonds for CIRM.

October: The State Treasurer raises $250 million for CIRM through a bond sale.

2008

May: CIRM awards $271 million to build new research labs.

2009

January: FDA approves first trial based on human embryonic stem cell research.

March: President Obama lifts some federal financing restrictions for human embryonic stem cell research.

April: The State Treasurer raises an additional $505 million for CIRM through a bond sale.

CIRM awards additional grants for a total of $700 million.

Appendix E

2005 Policy Enhancements

July 12, 2005 ICOC Meeting
Agenda Item # 10

ENHANCEMENT POLICIES RECOMMENDED BY THE LEGISLATIVE SUBCOMMITTEE OF THE ICOC

At its June 20, 2005 meeting, the Legislative Subcommittee of the ICOC recommended that the ICOC adopt the following policy enhancements to address concerns raised by the Legislature and to reassure the public regarding the CIRM's commitment to transparency and to the highest ethical standards. With respect to each of these policies, the Legislative Subcommittee recommended that the ICOC require notice to the Legislature and the public and a vote of 70 percent of a quorum of ICOC members to amend the final policies. Current CIRM policies and the recommended policy enhancements are set forth below. Please note that Legislative Subcommittee modified some of these items during its meeting. CIRM staff has attempted to include these changes below; however, this draft may be modified to reconcile it with the transcript of the Legislative Subcommittee meeting.

Conflict of Interest Policies for Working Group Members

Current Policy and Procedures: It is the responsibility of the CIRM to ensure that grants are awarded and policies established in a way that is fair and free from bias. To accomplish this, the ICOC has adopted Conflict of Interest (COI) Policies for each of its three working groups: Grants (adopted April 7, 2005); Standards (adopted April 7, 2005 and amended May 23, 2005); and Facilities (adopted May 23, 2005). These policies are based on those used by the National Institutes of Health, the National Academy of Sciences and the University of California Special Research Programs. Because each of the working groups has different functions, each of the three policies is different. At the time of appointment each working group member is given a copy of the appropriate policy and asked to sign a statement that he or she agrees to follow the CIRM COI policy.

The Grants and the Facilities Working Groups evaluate grant or facilities applications, respectively, and recommend them for funding to the ICOC. The CIRM staff is responsible for ensuring that working group members do not participate in discussions or evaluations of any application for which they have a conflict of interest. Prior to each working group meeting, every member of the working group is sent a list of the applications to be reviewed and asked to complete a pre-review certification form on which he or she identifies, under penalty of perjury, any grant applications for which he or she has a scientific, professional or personal conflict of interest. At the meeting, prior to consideration of each application, CIRM staff asks any working group member with a conflict in that application to leave the room during its discussion and

July 12, 2005 ICOC Meeting
Agenda Item # 10

evaluation. Staff maintains a record of which members voted on each application. After the meeting, all present sign a post-review certification form, again under penalty of perjury, confirming that they did not violate CIRM Conflict of Interest or Confidentiality Policies during the meeting. The pre- and post-review certification forms were approved at the ICOC meeting of April 7, 2005.

The Conflict of Interest Form for Standards Working Group members, whose task is to develop medical and ethical standards, describes several types of conflict of interest and asks members to identify and describe in detail the source of any conflict of interest that corresponds to the listed types. If a conflict of interest is identified, the CIRM President, or delegated staff member, is responsible for ensuring that the member does not participate in discussing or voting to recommend policies that would present a conflict of interest. A revision adopted May 23, 2005 restricts Standards Working Group members from deriving direct financial benefit from CIRM through grants, loans, or contracts.

Recommended Enhancement of Procedures:

1. <u>Financial Disclosure</u>

To aid in implementing CIRM Conflict of Interest Policies, each non- ICOC working group member will be asked to disclose to the CIRM, confidentially and under penalty of perjury, companies, institutions and real property in which he or she has an interest that could present a conflict. The categories are slightly different for each working group:

Grants Working Group:

a) All California-based academic or non-profit research institutions from which they receive current income or other benefit of $5,000 or more.

b) All biotechnology and pharmaceutical companies from which reviewers and their spouses receive current income or other benefit or investments of $5,000 or more.

c) Real property interests in California.

Standards Working Group:

a) All California-based academic or non-profit research institutions from which reviewers, close family members, or others with whom reviewers have a substantial common financial interest receive current income of $10,000 or more.

b) All biotechnology and pharmaceutical companies from which reviewers or their spouses receive current income or other benefit or investments of $10,000 or more.

c) All property interests in California of $10,000 or more (including real estate interests and interests in intellectual property such as patents and copyrights) held by reviewers, close family members or others with whom reviewers have substantial common financial interest.

Facilities Working Group:

a) All California-based academic or non-profit research institutions from which they receive current income or other benefit of $5,000 or more.

b) All construction, real estate or development firms from which they or their close family members receive current income or other benefit, or hold an investment, of more than $5,000.

c) All real property interests in California.

Each non-ICOC member of the Grants and Facilities Working Groups will be sent a copy of his or her disclosure form before each meeting and asked to update it. This will take place at the same time as the working group member receives the list of applications to be reviewed and completes the pre-review certification form for conflict of interest, described above.

2. Availability for Audit

The confidential disclosure forms for Grants and Facilities Working Group members will be kept on file at the CIRM offices where they will be available for review by a State or independent auditor. Also available will be the records of those present and voting during discussion and evaluation of each grant or facilities application. Comparison of the disclosure forms and meeting records will indicate whether any non-ICOC member of a Working Group has participated in a decision in which he or she has a financial interest, as defined above.

Conflict of interest and financial disclosure forms for the Standards Working Group and a record of who participated or voted on particular recommendations of the Working Group will also be on file at CIRM for audit by an independent or State investigator.

If CIRM or the auditor discovers a violation of conflict of interest, a report will be made to the Legislature along with a review of corrective actions taken by CIRM to prevent future occurrences.

Funding recommendations to the ICOC

Current Policy and Procedures: Consistent with Proposition 71, the applications recommended by the Grants and Facilities Working Groups for funding will be submitted to the ICOC by CIRM

July 12, 2005 ICOC Meeting
Agenda Item # 10

staff with the following information: (1) Title; (2) a Summary of the Proposal written by the applicant that includes a description of how the proposal could benefit the State of California; (3) a

brief summary of the scientific evaluation and the reasons for recommendation, along with any minority report, as applicable; (4) the scientific score of the application, based on criteria decided by the ICOC; and (5) the recommendation of the full Working Group.

Recommended Enhancement of Procedures: All of the information to be presented to the ICOC will be made available on the CIRM web site ten days before the ICOC meeting at which the grants will be considered.

Annual Report

Current Policy and Procedures: Proposition 71 requires the CIRM to submit an annual report to the public that sets forth its activities, grants awarded, grants in progress, research accomplishments and future program directions

Recommended Enhancement of Procedures: CIRM will submit an annual report to the Legislature that includes the following information:

1) The identity of recipients of research, training and facilities grants, loans and contracts awarded that year and the amount awarded in each case;

2) The disease and/or science category to which the grant, loan or contract relates;

3) The total number and total amount of grant applications awarded, with breakdown by disease and/or science category;

4) The total number and total amount of grant applications received with breakdown by disease and/or science category.

Meeting Procedures for Working Groups

Current Policies and Procedures: Under Proposition 71, the ICOC is required to consider and approve in public session all medical and ethical standards and all criteria and standards for considering funding applications, for awarding research and training grants, and for scientific and medical oversight of awards. In addition, the ICOC must make all decisions about funding grants, loans and contracts for research, training and facilities in public session. At its April meeting, the ICOC approved the practice of holding confidential Grants Working Group meetings for consideration of grant applications. At its May meeting, the ICOC approved open meetings procedures for the Standards Working Group, with provisions for public hearings to provide input and to make comments on draft findings and recommendations, and public votes on decisions and recommendation to the ICOC. The Standards Working Group will meet in confidential session

only when needed to protect patient privacy or to review a complaint regarding compliance, with final action to be taken in a public meeting. The ICOC also approved the concept of public meetings for the Facilities Working Group (May 23, 2005).

Recommended Enhancement of Procedures:

1. **Grants Working Group: Development of Criteria**

The Grants Working Group will meet in public session except for discussions related to evaluation of grant applications and recommendation of applications to the ICOC or discussions of other matters that may be considered in closed session under the Bagley-Keene Open Meeting Act or under Health & Safety Code section 125290.30. The Grants Working Group may request other mission-critical exceptions.

2. Facilities Working Group

The Facilities Working Group will meet in public, as approved by the ICOC in May, except where necessary to discuss scientific evaluation of proposals, to consider real estate negotiations or to consider other matters that may be discussed in closed session under the Bagley-Keene Open Meeting Act or under Health & Safety Code section 125290.30. The Facilities Working Group may request other mission-critical exceptions.

Records of the Working Groups

Current Policy and Procedures: Under Proposition 71, records of the working groups are exempt from the Public Records Act, with the exception of those records that are provided to the ICOC as part of the working groups' recommendations to the ICOC.

Recommended Enhancement of Policy: Provide public access to working group records, except for: (1) records that may be withheld under the Public Records Act and Health & Safety Code section 125290.30; (2) applications for research, training, and facilities grants, loans, and contracts and evaluations of such applications; and (3) economic disclosure forms filed by members of the Grants, Standards, and Facilities Working Group.

Conflicts of Interest Policy for Board Members and President

Current Policy: Proposition 71 requires board members and the CIRM staff to disclose economic interests consistent with the Political Reform Act. Thus, Board members and the CIRM staff are held to the same standards applicable to constitutional officers, members of the Legislature, and designated state employees. In addition, the ICOC has adopted a conflict of interest policy that requires board members to recuse themselves from participating in any decision regarding a grant, loan or contract with their employer, and any decision regarding a grant, loan or contract that financially benefits the member or his or her employer. The ICOC has also adopted a policy to

July 12, 2005 ICOC Meeting
Agenda Item # 10

preclude board members from applying for, or receiving salary support through, grants, loans or contracts from the ICOC.

Recommended Enhancement of Policy: Require board members and the CIRM president to divest themselves of, or to place in a blind trust, any investment or real property interest of $2,000 or more in any business organization that receives funding from, or research contracts with, the CIRM, and in any business organization that allocates more than five percent of the business organization's current annual budget to stem cell therapy.

Intellectual Property

Current Policy: Proposition 71 requires the ICOC to adopt standards that require that all grants and loans be subject to intellectual property agreements that that balance the opportunity of the State of California to benefit from the patents, royalties and licenses that result from the research with the need to assure that essential medical research is not unnecessarily hindered by intellectual property agreements.

Recommended Policy Enhancement: The Subcommittee did not have an opportunity to discuss a proposed enhancement to strengthen the CIRM's intellectual property agreements.

Appendix F

Letter from Senator Dean Florez

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California State Senate

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July 6, 2009

Daniel W. Hancock, Chairman
Little Hoover Commission
925 L Street, Suite 805
Sacramento, CA 95814

Dear Chairman Hancock:

As a member of the Little Hoover Commission, I would like to note, for the record, my concerns regarding the Commission's report on the California Institute for Regenerative Medicine (CIRM), which was released on June 26, 2009.

The report makes a series of recommendations to modify CIRM's governance structure and operations. In particular, the report recommends reducing the size of CIRM's governing board from 29 members to 15 members and concentrating the power of appointment in the Governor, who would be responsible for appointing 11 of 15 members. The report also recommends stripping the power of the Lieutenant Governor, the Controller, and the Treasurer to make appointments and to nominate candidates for chair and vice-chair. Finally, the report recommends eliminating the statutory duties of the chair and the vice-chair and the eligibility criteria for those positions.

I have several concerns regarding these recommendations. First, the recommendations, if adopted by the Legislature, would essentially rewrite Proposition 71. In adopting Proposition 71, the voters specified the governance structure they desired and limited the Legislature's ability to amend the law. Under Proposition 71, the Legislature may only amend the law to enhance CIRM's ability to further the purposes of its grant and loan program. The Commission's recommendations appear to be inconsistent with the voters' intent and therefore could only be accomplished by proposing another ballot measure. CIRM provided the Commission with legal memoranda from two prominent law firms concluding that these recommendations would require another vote of the people, yet the Commission barely paused to consider these legal issues. At a minimum, these memoranda raise a serious question about the scope of the Legislature's authority and create the risk of litigation.

Page 2

Although the report acknowledges this risk, it fails to note that litigation over the Legislature's authority to amend Proposition 71 would interfere with CIRM's ability to carry out its mission and dissuade the proponents of future ballot measure from authorizing legislative amendments. Furthermore, as demonstrated by the recent defeat of Propositions 1D and 1E, which would have amended Propositions 10 and 63, respectively, the voters are not generally supportive of legislative efforts to amend popularly enacted measures. These issues deserved greater attention than the Commission afforded them.

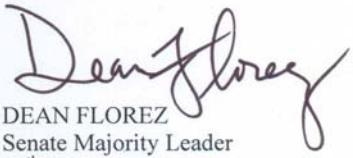
Second, as I stated at the Commission's meeting on July 25th, the Commission's recommendations appear to lack a firm foundation. For example, when I asked why a 15 member board was inherently better than a 29 member board, Commission members responded that an academic expert on non-profit governance had testified that the ideal board size was seven to nine members, but the expert himself stated that he did not have sufficient knowledge of CIRM's operations to opine about the ideal board size for CIRM. It is not clear to me that, given the scientific, financial, commercial, and governmental issues with which CIRM has to deal, a smaller board would be better suited to achieve CIRM's mission. In fact, as the report notes, CIRM has benefitted from a diverse and engaged board.

Third, I am also concerned about the Commission's attempt to shift power over the agency to the Governor. Like the Little Hoover Commission itself, CIRM was designed to be an independent agency. Proposition 71 therefore dispersed appointment authority to the Governor, the Lieutenant Governor, the Controller, the Treasurer, the Legislature, and UC Chancellors. By concentrating appointment authority in the Governor, the Commission would undermine the careful and deliberate balance struck by Proposition 71. In a controversial area like stem cell research, such a change would threaten the independence that CIRM needs to ensure the success of its mission.

Finally, I am concerned about the Commission's apparent rush to conclude its report. As one member said at the meeting, five minutes and a sandwich is not adequate time for Commission members to absorb the information that was presented. While I appreciate the substantial effort that Commission members and staff put into drafting the report, I am concerned that due to its rush to approve the report, the Commission gave disproportionate weight to CIRM's critics and did not consider a broader range of views on the complex issues that are the subject of the report.

Thank you for the opportunity to share my views with you. Please feel free to contact my office at (916) 651-4016 should you have any questions.

Sincerely-



DEAN FLOREZ
Senate Majority Leader
16th District

Notes

1. Senators Sheila Kuehl and George Runner. April 28, 2008. Sacramento, CA. Written communication. See Appendix B.
2. Secretary of State. December 10, 2004. "Statement of Vote: Vote For and Against Statewide Ballot Measures, November 2, 2004." Page xxi. Sacramento, CA. http://www.sos.ca.gov/elections/sov/2004_general/sov_preface_docs_11_2004.pdf. Accessed November 5, 2008.
3. Secretary of State. November 2004. "Official Voter Information Guide: Proposition 71." Pages 147-155. Sacramento, CA. http://vote2004.sos.ca.gov/voterguide/. Accessed November 5, 2008.
4. Secretary of State. See endnote 3. Pages 68-71.
5. Secretary of State. See endnote 3. Page 70.
6. Zach Hall. Winter 2009. "Stem Cell Research in California: The Intersection of Science, Politics, Culture and Law." Pages E1-E18. Minnesota Journal of Science and Technology. Minneapolis, MN. University of Minnesota. http://mjlst.umn.edu/pdfs/101_hall.pdf. Accessed November 4, 2008.
7. Secretary of State. See endnote 3. Pages 72-73.
8. Zach Hall. See endnote 6.
9. Office of the Press Secretary, White House. March 9, 2009. "Fact Sheet on Presidential Executive Order: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells." Washington, D.C. http://www.whitehouse.gov/the_press_office/Fact-Sheet-on-Presidential-Executive-Order/. Accessed June 1, 2009.
10. Secretary of State. See endnote 3. Pages 147-155.
11. California Institute for Regenerative Medicine. 2008. "Annual Report." San Francisco, CA.
12. Laurence Baker and Bruce Deal. September 10, 2008. "CIRM – Interim Economic Impact Review." Menlo Park, CA. Analysis Group.
13. Jesse Reynolds, Director, Project on Biotechnology in the Public Interest, Center for Genetics and Society. Oakland, CA. November 20, 2008. Written testimony to the Commission.
14. John Simpson, Director, Stem Cell Oversight and Accountability Project, Consumer Watchdog. Santa Monica, CA. November 20, 2008. Written testimony to the Commission.
15. Department of Finance. 2009. "Governor's Budget 2009-2010: Proposed Budget Detail. 6445 California Institute for Regenerative Medicine." http://www.ebudget.ca.gov/pdf/GovernorsBudget/6000/6445.pdf. Accessed June 11, 2009.

16. Health and Safety Code Sections 125290.10 et seq.

17. Secretary of State. See endnote 3. Pages 147-155.

18. Donna Gerardi Riordan. Summer 2008. "Research Funding via Direct Democracy: Is It Good for Science?" Pages 23-27. Issues in Science & Technology. University of Texas at Dallas.

19. Donna Gerardi Riordan. See endnote 18.

20. Zach Hall. See endnote 6.

21. SB 18 (Ortiz, 2005), SB 340 (Battin, 2005), SB 401 (Ortiz, 2005), SCA 13 (Ortiz, 2005), SB 771 (Kuehl, 2007), SB 1565 (Kuehl, 2007).

22. California Institute for Regenerative Medicine. August 5, 2005. "ICOC Meeting Agenda Item #10: Policy Enhancements Recommended by the ICOC Pending Refinements – Part I." San Francisco, CA.

23. California Institute for Regenerative Medicine. 2009. "Regulations Governing CIRM Grants." San Francisco, CA. http://www.cirm.ca.gov/reg/default.asp. Accessed June 1, 2009.

24. California Health and Safety Code 125290.30(c).

25. Terri Somers. March 10, 2005. "Stem cell institute leader in hot seat." San Diego Union-Tribune. http://www.signonsandiego.com/news/state/20050310-9999-1n10stems.html. Accessed September 27, 2008. Also, Sacramento Bee. November 25, 2007. "Editorial: Tangled loyalties at top of stem cell institute." http://www.sacbee.com/110/v-print/story/515572.html. Accessed August 20, 2008. Also, David Jensen. July 10, 2008. "Klein's Group Says Kuehl is Ignorant or Mindless or Craven and Dumb." California Stem Cell Report. http://californiastemcellreport.blogspot.com/2008/07/kleins-group-says-kuehl-is-ignorant-or.html. Accessed September 29, 2008. Also, Jesse Reynolds. July 15, 2008. "Stem cell lobbyists decide Sen. Sheila Kuehl isn't really craven, ignorant, mindless, and dumb." BioPolitical Times. http://www.biopoliticaltimes.org/article.php?id=4164. Accessed September 29, 2008.

26. Independent Citizens Oversight Committee. March 12, 2009. Sacramento, CA. Committee meeting.

27. Center for Genetics and Society. November 20, 2008. "The California Stem Cell Program at One Year: A Progress Report." Pages 12-16. Oakland, CA.

28. California Institute for Regenerative Medicine. See endnote 22.

29. Kenneth Taymor, Executive Director, Berkeley Center for Law, Business and the Economy. Berkeley, CA. November 20, 2008. Written testimony to the Commission.

30. Michael Klausner, Professor of Law, Stanford Law School. Sacramento, CA. November 20, 2008. Testimony to the Commission. Also, Kenneth Taymor, Executive Director, Berkeley Center for Law, Business and the Economy. Berkeley, CA. November 20, 2008. Testimony to the Commission.

31. California Health and Safety Code 125290.20(a).
32. California Health and Safety Code 125290.30(g).
33. California Health and Safety Code. See endnote 32.
34. People's Advocate, et. al. v. Independent Citizens Oversight Committee, et. al.; California Family Bioethics Council v. California Institute for Regenerative Medicine. May 12, 2006. "Final Statement of Decision." Oakland, CA. Alameda County Superior Court.
35. California Family Bioethics Council v. California Institute for Regenerative Medicine; People's Advocate, et. al. v. Independent Citizens Oversight Committee, et. al. February 26, 2007. California Court of Appeal, First District. (147 Cal.App.4th 1319).
36. California Family Bioethics Council. See endnote 35
37. California Family Bioethics Council. See endnote 35.
38. Michael Klausner. See endnote 30.
39. Zach Hall. See endnote 6.
40. California Health and Safety Code 125292.10(s).
41. Independent Citizens Oversight Committee. December 12, 2008. Irvine, CA. Committee meeting.
42. Kenneth Taymor. See endnote 29.
43. Michael Klausner. See endnote 30.
44. Kenneth Taymor. See endnote 29.
45. Robert Klein, Chair, Independent Citizens Oversight Committee. Sacramento, CA. November 20, 2008. Testimony to the Commission.
46. Robert Klein, Chair, Independent Citizens Oversight Committee. San Francisco, CA. December 22, 2008. Written communication.
47. Alan Trounson, President, California Institute for Regenerative Medicine. Sacramento, CA. November 20, 2008. Testimony to the Commission. Also, "2008 Review of the ASCC: Executive Summary." Tabled Document No. 2. Senate Standing Committee on Economics. February 26, 2009. Australia. Also, Elizabeth Finkel. October 24, 2008. "Last-Ditch Effort to Save Center at Vanguard of Stem Cell Research." Volume 322, pages 524-525. Science. Also, Elizabeth Finkel. March 20, 2009. "Stem Cell Center Looks to Recast Itself in Supporting Role." Volume 323, pages 1552-1553. Science.
48. Michael Klausner. See endnote 30.
49. John Simpson. See endnote 14.
50. Robert Klein. See endnote 45. Note: At least three ICOC members who are not patient-advocate representatives have participated in ICOC meetings by telephone, including City Hope CEO Michael Friedman and biotechnology executive Ed Penhoet at the March 12, 2009, meeting, and UC Davis Vice Chancellor Claire Pomeroy at the April 30, 2009, meeting.

51. Robert Klein. See endnote 46.

52. Terri Somers. April 18, 2007. "Stem cell leader to retire sooner." San Diego Union-Tribune. http://www.signonsandiego.com/news/business/biotech/20070418-9999-1b18stems.html. Accessed June 1, 2009.

53. Health and Safety Code, Sections 39510-39517. Also, Water Code, Sections 174-188.5.

54. California Institute for Regenerative Medicine. January 17, 2008. "Internal Governance Policy." San Francisco, CA.

55. Kenneth Taymor. See endnote 29.

56. Kenneth Taymor. See endnote 29.

57. Independent Citizens Oversight Committee. June 2, 2006. La Jolla, CA. Committee meeting. Note: The ICOC voted 13-5 to approve the internal governance policy.

58. Alan Trounson, President, California Institute for Regenerative Medicine. Sacramento, CA. November 20, 2008. Testimony to the Commission.

59. Kenneth Taymor. See endnote 29.

60. Constance Holden. April 27, 2007. "Stem Cell President Quits After Acrimonious Meeting." Volume 316, page 526. Science. Also, Terri Somers. See endnote 52. Also, Carl T. Hall. April 18, 2007. "State stem cell program head suddenly resigns." San Francisco Chronicle. http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/04/18/BAGO2PAK4O1.DTL&hw=hall+stem+cells&sn=001&sc=1000. Accessed June 1, 2009. Also, David Jensen. April 18, 2007. "Wright: 'Not the Best Day.'" California Stem Cell Report. http://californiastemcellreport.blogspot.com/2007/04/wright-not-best-day.html. Accessed June 1, 2009.

61. California Health and Safety Code 125290.20 (a)(6)

62. Terri Somers. December 14, 2004. "'Coronation' of committee head on stem cell funds disturbs some." San Diego Union-Tribune. http://signonsandiego.com/uniontrib/20041215/news_1n15klein.html. Accessed November 14, 2008.

63. Robert Klein. See endnote 45.

64. California Health and Safety Code 125290.20 (a)(6).

65. Kenneth Taymor. See endnote 29.

66. Independent Citizens Oversight Committee. March 5, 2009. San Francisco, CA. Governance Subcommittee meeting.

67. Independent Citizens Oversight Committee. March 5, 2009. San Francisco, CA. Governance Subcommittee meeting. Also, Independent Citizens Oversight Committee. See endnote 26.

68. Robert Klein, Chair, Independent Citizens Oversight Committee, and Alan Trounson, President, California Institute for Regenerative Medicine. San Francisco, CA. June 8, 2009. Personal communication.

69. Laurence Baker and Bruce Deal. See endnote 12.

70. California Health and Safety Code, Section 125290.60.

71. California Institute for Regenerative Medicine. 2009. "Funding Summary." San Francisco, CA. http://www.cirm.ca.gov/info/grants.asp. Accessed April 22, 2009. Note: When including the J. Gladstone Institute, which is independently funded but is affiliated with UCSF, the portion of grants awarded to institutions represented by board members increases to 90 percent.

72. California Institute for Regenerative Medicine. "Approved CIRM Grants as of April 2009." San Francisco, CA. http://www.cirm.ca.gov/info/grants.asp. Accessed April 22, 2009.

73. Robert Klein. See endnote 45. Also, Ralph J. Cicerone, President, National Academy of Sciences, and Harvey V. Fineberg, President, Institute of Medicine. Washington, D.C. January 2, 2008. Written communication to Robert Klein.

74. California Health and Safety Code, Section 125290.50(e)(1).

75. Elaine M. Howle. February 2007. "California Institute for Regenerative Medicine." Page 52. Sacramento, CA. Bureau of State Audits.

76. Elaine M. Howle. See endnote 75.

77. Don Gibbons, Chief Communications Officer, CIRM. San Francisco, CA. May 22, 2009. Written communication.

78. John Simpson. See endnote 14.

79. Kenneth Taymor. See endnote 29.

80. California Institute for Regenerative Medicine. January 28, 2009. "2008 Strategic Plan Update." San Francisco, CA.

81. California Institute for Regenerative Medicine. December 10, 2008. "Proposal for Pre-Application Review." San Francisco, CA.

82. Independent Citizens Oversight Committee. San Francisco, CA. December 23, 2008. Telephonic board meeting.

83. Independent Citizens Oversight Committee. See endnote 82.

84. Robert Klein, Chair, Independent Citizens Oversight Committee. Sacramento, CA. November 20, 2008. Written testimony to the Commission.

85. Robert Klein. See endnote 45.

86. Michael Gardner and Mike Lee. April 12, 2009. "Local coalition working to bring climate-change institute to area." San Diego Union-Tribune. http://www3.signonsandiego.com/stories/2009/apr/12/1n12climate232457-local-coalition-working-bring-cl/?uniontrib. Accessed April 30, 2009. Also, Duane Roth, President, CONNECT. San Diego, CA. March 12, 2009. Personal communication. Also, Office of Legislative Counsel. October 14, 2007. "SB 660 Senate Bill – Veto." Sacramento, CA. http://leginfo.ca.gov/pub/07-08/bill/sen/sb_0651-0700/sb_660_vt_20071014.html. Accessed April 30, 2009.

87. Little Hoover Commission. August 2007. "The State Allocation Board: Improving Transparency and Structure." Sacramento, CA.

88. Robert Klein and Alan Trounson. See endnote 68.

89. Robert Klein. See endnote 46.