

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 sunset 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	