The California Stem Cell Program at One Year:

A Progress Report

Center for Genetics and Society

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For more information or additional copies of this report:

The Center for Genetics and Society
436 14th Street, Suite 700
Oakland, CA 94612
1-510-625-0819 tel
1-510-625-0874 fax
www.genetics-and-society.org
info@genetics-and-society.org

About the Center for Genetics and Society

The **Center for Genetics and Society** is a nonprofit public affairs organization working to encourage responsible uses and effective societal governance of the new human genetic and reproductive technologies.

CGS works in a context of support for the equitable provision of health technologies domestically and internationally; for women's health and reproductive rights; for the protection of our children; for the rights of the disabled; and for precaution in the use of technologies that could alter the fundamental processes of the natural world.

CGS supports benign and beneficent medical applications of the new human genetic and reproductive technologies, and opposes those applications that objectify and commodify human life and threaten to divide human society.

CGS supports embryonic stem cell research, and public funding for it. We believe that this research should and can be conducted in a responsible manner, with effective oversight, and in the public interest.

CGS is a project of the Tides Center.

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Prologue

The debate over embryonic stem cells and cloning is a heated and contentious one. Until recently, it has been shaped largely by its proximity to the debate over the moral status of human embryos, with liberal and conservative forces quickly aligning in predictable ways. As a consequence, other social, political and ethical concerns raised by stem cell and cloning research, including many grounded in core liberal and progressive values, have not received the attention they urgently need.

This situation is now beginning to change. The cloning scandals centered in South Korea have cast a spotlight on a host of issues that have previously received only passing attention. These include the well-being of women who provide eggs for cloning research; the prospect of a market in eggs that could exploit economically vulnerable women; the lack of effective oversight and regulation of stem cell and cloning research; the dangers that desires for commercial gain and personal renown pose to the integrity of science; and the risks posed by exaggerated promises of biomedical breakthroughs.

In California, these and related questions have begun to figure in the public debate. In November 2004, voters passed a ballot initiative authorizing $3 billion in public funds for a new stem cell research program and a new state agency to administer it. The California program is the largest and politically most significant of several state-level stem cell efforts that have been undertaken to circumvent the Bush administration's restrictive policies on federal funding of embryonic stem cell research.

CIRM Progress Report: Overall grade for the first year: C–

Keeping Campaign Promises	**C–**
Ensuring returns on public investments	C
Maximizing health equity	D
Establishing Accountable and Responsible Governance	**C–**
Building organizational infrastructure	C
Minimizing conflicts of interest	D
Cooperating with the state legislature	D
Fostering transparency with open meetings	B
Providing responsible leadership	D
Establishing Ethical Safeguards and Research Standards	**C+**
Protecting women who provide eggs for research and other research subjects	C+
Preventing reproductive cloning and other unacceptable applications of stem cell technologies	C

The California stem cell initiative has pushed the debate about stem cell and cloning research into new and unexplored terrain. In the year since the passage of the stem cell initiative, elected officials, journalists, public interest groups, and the public at large have been forced to grapple with questions they have never before had to address.

What types of stem cell research should receive priority funding? How can the health of women who provide eggs for cloning research be protected? How should intellectual property rights be distributed among researchers, corporations, universities, and the state? What sort of public hearings and review are necessary before state funds are appropriated for controversial research? How do we ensure that any medical treatments resulting from state-sponsored stem cell research are affordable by the majority of California residents? How do we prevent stem cell and cloning technologies from being used for socially unacceptable purposes?

Stem cell technologies may someday point the way toward new and powerful approaches to treating disease. But if misused, these same technologies could also harm individuals, exacerbate health inequities, and open the door to unacceptable applications such as inheritable human genetic modification and reproductive cloning. If we are to realize the benefits of stem cell research and avoid the risks it poses, effective structures of regulatory oversight and control must be top priorities.

This report on the first year of California's experience in establishing and governing a major state-funded stem cell research program is meant to inform the continued debate in California, in other states, at the national level, and internationally. We believe that the lessons learned from this experience need to be taken to heart if research on stem cells and other emerging biotechnologies is to be pursued in a responsible and effective manner.

Introduction

Overall grade for the CIRM's first year:

C-

In November 2004 California voters passed Proposition 71, a landmark initiative authorizing $3 billion in taxpayer-supported bonds to support stem cell research in California. The proposition established the California Institute for Regenerative Medicine (CIRM) to distribute the funds and oversee the program.

Proposition 71 launched two experiments. The first is an experiment in a new field of biomedical investigation; the second an experiment in politics and policy. Never before has a state so generously funded an emerging scientific field. And never before has a state been faced with the task of establishing a system of regulation and oversight for a field of biomedical research that combines the promise of medical advance with such significant social risks.

CIRM-funded research is yet to begin, and the field of stem cell research is itself still in its very early stages. But the CIRM has been in operation for a year, and many critical decisions affecting the future of the program have been made during this period.

The Center for Genetics and Society, along with other public interest groups and experts in health law, women's health, public policy, and open government, has closely followed Proposition 71's implementation. We believe that this is an appropriate time to offer an initial evaluation of its performance on matters of governance, politics, and policy.

On these measures, the CIRM's first year has been a great disappointment. In terms of governance, the CIRM has often failed to operate as an accountable, responsible, and transparent state agency. In the area of politics, it has failed to establish a cooperative relationship with state legislators. And in the policy arena, the CIRM has fallen far short of the expectations raised during the initiative campaign that led to its creation: It has so far failed to adopt policies to ensure that any successful stem cell therapies will be affordable to most Californians, or to reassure Californians that they will see any share of financial returns that the research they are funding may generate.

As explained below, this report evaluates the performance of the California stem cell research program in several critical areas, and assigns a letter grade to each. For its overall performance during its first year, we believe that the CIRM merits a grade of C–.

Some defenders of the CIRM blame its shortcomings on the lawsuits that challenge Proposition 71's constitutionality. Until these suits are resolved by the courts, the state cannot sell the CIRM bonds that are authorized by the initiative. Although the suits have interfered with the CIRM's ability to provide funds for research awards, they have no bearing on the issues on which this evaluation is based. CIRM leadership could have used the delay imposed by the lawsuits to establish accountable and responsible governance structures. Unfortunately, this has not happened.[1]

The CIRM's first year has been a great disappointment. It has often failed to operate as an accountable, responsible, and transparent state agency. It has failed to establish a cooperative relationship with state legislators.

Public oversight and responsible governance of state-funded activities are cornerstones of democratic society. They will not hinder stem cell science; on the contrary, they are essential if success is to be realized. As Kathay Feng of Common Cause of California and Steven Blackledge of California Public Interest Research Group wrote in June 2005, "All it would take is one major scan-

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>
> *Kathay Feng, Common Cause of California and Steven Blackledge, California Public Interest Research Group*

dal, some sign of mismanagement or ethical lapse, and Californians' trust—and $6 billion investment—in stem-cell research could be permanently damaged. That is why it is critical we ensure that safeguards are in place."[2]

We recognize that many critical decisions about who will benefit and how the stem cell research program will proceed are still to be made. We know too that some members of the CIRM's governing board and staff are committed to improving the agency's performance. The CIRM still has the opportunity to develop and implement responsible policies. We hope that it will do so.

Report format

This Progress Report evaluates the performance of the CIRM and its governing board, the Independent Citizens Oversight Committee (ICOC), in three major areas:

1. Its record in honoring the promises made to California voters during the Proposition 71 campaign;
2. Its record in establishing itself as an accountable and responsible governing body;
3. Its record in establishing ethical safeguards and research standards.

In each of these areas, we have assigned a grade that reflects our considered assessment of the conduct and accomplishments of the California stem cell research program over the past year. We provide a narrative evaluation that explains each grade, and a set of recommendations for improvement.

The concluding section of this report identifies key challenges that the program faces in the coming year and beyond.

The California Institute for Regenerative Medicine

The California Institute for Regenerative Medicine (CIRM) is a new state agency that was created by the passage of Proposition 71 in November 2004.[1] The CIRM will distribute $3 billion of public money to fund stem cell research and build research facilities over the next ten years. The CIRM is mandated to prioritize funding for embryonic stem cell research and research cloning. The funds it allocates will be generated by the sale of state bonds at a total cost, including interest, of $6 billion to $7 billion.

The CIRM is governed by a twenty-nine member governing board, the Independent Citizens Oversight Committee (ICOC). It is composed of officers from public and private universities and nonprofit research centers, representatives of biotechnology corporations, and disease-specific patient advocates. Twenty-seven members are appointed by California elected officials and chancellors of the University of California system, who select them on the basis of the institutional or patient advocacy affiliations specified by Proposition 71. The chair and vice-chair are then elected by these members from candidates nominated by the elected officials.

Proposition 71 establishes three ICOC advisory committees, called Working Groups, one each for research grants, facilities grants, and research standards. The members of the Working Groups include the ICOC chair and some of the representatives of disease-specific advocacy organizations on the ICOC, as well as outside experts.

Proposition 71 amends the state constitution to establish a constitutional right to conduct stem cell research. It prohibits legislative modification for the first three years, and afterwards requires a 70% super-majority in both houses—a nearly impossible threshold—and the governor's signature.

The impetus for Proposition 71 was the restrictive policy on federal funding of embryonic stem cell research imposed by President Bush in August 2001. It was initiated by wealthy California families with children affected by conditions that may someday be treated with cell-based therapies, and supported by many researchers and disease-specific patient advocacy groups.

The campaign for Proposition 71 was based on claims of near-term cures, and promised economic benefits to the state. It drew support from many who opposed the Bush restrictions on stem cell funding, or who saw it as an opportunity to express their general opposition to the Bush administration. The "Yes on 71" campaign spent $35 million, almost half from venture capitalists, and the proposition passed by 59 to 41 percent.[2]

Notes:

1 The text of Proposition 71 is at http://www.yeson71.com/initiative.php.

2 Campaign expenses and returns are both published by the California Secretary of State, online at http://cal-access.ss.ca.gov/Campaign/Committees/Detail.aspx?id=1260661&session=2003 and http://www.ss.ca.gov/elections/sov/2004_general/contents.htm respectively.

Keeping Campaign Promises

Keeping promises:

C-

In evaluating the past year's performance, we have taken into account the text of Proposition 71 and statements made by the current CIRM leadership during the initiative campaign. Robert Klein was Proposition 71's chief author, campaign chair, and largest donor; he now chairs the Independent Citizens Oversight Committee (ICOC), the appointive body established by Proposition 71 to oversee the CIRM. Other prominent Proposition 71 supporters and campaign staff are now among the board and staff of the CIRM.[3] Thus, it is appropriate to hold the current CIRM leadership accountable to the language used in the campaign as well as in the initiative itself.

The Proposition 71 campaign repeatedly pledged that stem cell research would result in "cures for Californians," and that the $3 billion public cost of the stem cell research program, along with an estimated additional $3 billion in interest payments, would be recouped.[4] Television ads featured scientists in white coats describing stem cell–based cures as if they were certain and imminent.[5] Initiative promoters insisted that the program would at least pay for itself.[6]

These inflated promises helped persuade Californians to approve an unprecedented spending authorization on a fledgling field of research, at a time when our state was deeply in debt and cutting public services.

The low grades assigned here are in part motivated by two developments of great concern: first, recent disclosures that the leaders of the Proposition 71 campaign knowingly misled voters about the prospect of financial returns; and second, growing indications that the CIRM may be turning its back both on explicit pledges of financial returns to California and on implicit promises that any successfully developed stem cell treatments would be available to all Californians.

Ensuring returns on public investments

C

Both the affordability and accessibility of any successfully developed treatments, and the prospect of the state receiving a share of any profits, depend on the intellectual property (IP) agreements that the CIRM makes with the researchers and institutions that will receive its grants. The language of Proposition 71 requires that the CIRM pursue financial returns to the state. Though the proposition is unspecific about how and to what extent this should be done, supporters and CIRM leaders made it very clear during the campaign that the voters could expect such returns.[7]

However, some ICOC members have argued against policies that would provide a share of revenues to the state. Their statements have raised serious concerns about whether the CIRM will honor the promises made to California voters and the requirements of Proposition 71.

The editorial board of the *San Francisco Chronicle*, which strongly supported Proposition 71, voiced similar concerns soon after the election. On December 9, 2004, it wrote, "We recognize that with the stem-cell initiative still sitting on the landing pad, that talk of huge profits 10 to 20 years down the road may seem premature. But this is precisely the time to make sure the taxpayers' interests are safeguarded. It will be far more difficult to do so when and if profits start to materialize."[8]

In its deliberations to date on the kind of IP agreements it will adopt, the leadership of the CIRM has consulted with only a narrow range of stakeholders. Almost without exception, they have been industry and academic figures whose policy recommendations would perpetuate a system in which revenues are not shared with the state, and which provides no assurances of accessible pricing. Experts in public health, consumer and public interest groups, and critics of current policies have not been invited into the discussion in any meaningful way.[9]

ICOC deliberations about intellectual property have drawn heavily on a report prepared by a committee established by the California Council on Science and

Did CIRM leadership mislead voters about the prospect for financial returns?

According to a front-page article in the October 25, 2005 *San Francisco Chronicle*, ICOC Chair Robert Klein knew during the 2004 campaign that the public cost of the stem cell research program was likely to entail hundreds of millions of dollars more in interest payments than the estimates he and others were citing to voters. The article asserts that Klein, however, chose to conceal this information. If true, this constitutes a "bait and switch" approach that is a clear betrayal of the public's trust.[1]

The *Chronicle* reported that state legal experts told Robert Klein during the campaign that tax-exempt bonds probably could not be used to finance the stem cell institute if the state were to receive a share of revenue from successful inventions, as promised. If the CIRM relies on taxable bonds, the public cost of the program will wind up being between $423 million and almost $1 billion more than estimated in the campaign's economic analysis. If, on the other hand, tax-exempt bonds are sold, CIRM may be prohibited by law from sharing revenues with the state, which the campaign's economic analysis valued at up to $1.1 billion.[2]

Despite apparently knowing this to be the case, Robert Klein allowed the campaign to continue claiming repeatedly that the initiative would pay for itself, or even generate a surplus for the state. A week before the election, Klein himself asserted on national television that "the state of California will gain jobs, new tax revenues and intellectual property revenues to pay back the taxpayers."[3]

When asked why he did not inform the authors of the economic study funded by the "Yes on 71" campaign, which he chaired, Klein said, "I'd want to go back and review this area."[4] He has not publicly responded to this since.

A question that must now be asked is whether Robert Klein, and possibly other campaign supporters who were aware of the situation, were ever committed to having the state receive royalties.

Notes:

1 Bernadette Tansey, "Tax law casts doubt on stem cell royalties: State may not reap billions promised to voters last fall," *San Francisco Chronicle* (October 25, 2005) at http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2005/10/25/MNGTFFDK8J1.DTL.

2 See Tansey, supra note 1 and Laurence Baker and Bruce Deal, "Economic Impact Analysis: Proposition 71, California Stem Cell Research and Cures Initiative" (September 14, 2004) at http://www.yeson71.com/documents/Prop71_Economic_Report.pdf. The low end of the additional cost imposed by taxable bonds is from a letter by California Treasurer Phil Angelides to CIRM President Zach Hall (October 26, 2005), online at http://www.etopiamedia.net/empnn/pdfs/angelides-hall1.pdf. The high end is offered by Sen. Ortiz in Tansey, supra note 1.

3 *Newshour with Jim Lehrer* (October 27, 2004); transcript at http://www.pbs.org/newshour/bb/politics/july-dec04/stemcell_10-27.html.

4 Stuart Leavenworth, "Stem cell royalty promise just election ruse?" *Sacramento Bee* (November 7, 2005) at http://www.sacbee.com/content/opinion/story/13826776p-14667506c.html.

Technology. The committee is dominated by private industry and university technology transfer offices, which would see their own shares of profits diminish if the state were to receive a portion. The report was funded by the California Healthcare Institute, an industry advocacy organization.[10] In August 2005, the committee recommended that the CIRM dispense with any intention of providing a share of profits to California.

There are alternatives. Some analysts, including Merrill Goozner of the Center for Science in the Pubic Interest and Jennifer Washburn of the New America Foundation, assert that the CIRM has an opportunity to implement innovative policies that would address deep flaws in the status quo.[11]

Senator Deborah Ortiz (D-Sacramento) has played a key role in widening the discussion on the CIRM's intellectual property policies. In October, she convened a full-day legislative hearing to explore policy options.[12] Her proposed reforms included requirements for both financial returns to the state and affordable pricing.[13]

Maximizing health equity

In order to honor the promises of the Proposition 71 campaign and uphold fundamental principles of health equity, the CIRM must adopt policies that maximize the affordability and accessibility of any medical treatments that might result from the research it funds.

Concerns about the CIRM's commitment to health equity policies were expressed forcefully at a March 2005 Senate Health Committee hearing by John Yuasa, Health Policy Director at the Greenlining Institute. "It would appear from all the indications thus far that the stem cell program is being formed largely to benefit the rich at the expense of the poor and ethnic minority populations," Yuasa said. "In fact, it can be seen from recent revelations that this program has all the appearances of a subsidy program for the wealthy and is a snub at the ethnic minorities of California."[14]

To date, CIRM leadership has resisted the inclusion of affordability and accessibility of stem cell treatments as a key criterion in its policy considerations. Its resistance has been based on two lines of logic. Most often, CIRM representatives assert that their job is limited to advancing the science, not to ameliorating the defects of the nation's health care system. More recently, some members of the ICOC have argued that any plans to ensure affordability and accessibility—however modest—would exacerbate already excessive expectations, and could do more harm than good.[15]

"It would appear that the stem cell program is being formed largely to benefit the rich at the expense of the poor and ethnic minority populations. This program has all the appearances of a subsidy program for the wealthy and is a snub at the ethnic minorities of California."

John Yuasa, Greenlining Institute

These arguments are unconvincing. Of course, the cost of medical treatment is a complex topic, and depends to an important degree on the particulars of still-to-be-achieved research results. But two kinds of policies for which the CIRM is responsible will greatly affect whether stem cell–based treatments, if they are successfully developed, will be widely affordable and accessible.

The first concerns the pricing of any successfully developed stem cell treatments. The intellectual property arrangements discussed in the previous section will have a major impact on the price structure of any therapies brought to market. For example, the CIRM could require that any successful therapies developed with its money be made available to the state's medical insurance programs at reduced or no cost. Or it could require grant recipients to set aside a portion of any IP revenue in an accessibility fund.

The second kind of policy that will affect health equity has so far received little attention. It concerns the research directions that are prioritized by stem cell researchers, whether funded by the CIRM or from other sources. Part of the enthusiasm about stem cell research has been based on scenarios of "individually tailored" treatments—the "personal repair kit" to which Ron Reagan, Jr. referred at the 2004 Democratic Party convention.[16] This prospect assumes that treatments would

be developed using the technique known as research cloning or somatic cell nuclear transfer (SCNT).

But treatments based on stem cell lines derived from cloned embryos would be very expensive. Estimates by scientists and biotechnology leaders put the cost at $100,000 or more per patient.[17] Even biotechnology industry leaders recognize that this would be impractical. "We don't think it makes sense as a business model, producing cell therapies for a patient population of one," said Alan Robins, chief scientific officer of BresaGen. And according to Geron chief executive Thomas Okarma, "The process is a nonstarter, commercially."[18]

In contrast to stem cell lines created by research cloning, those derived from embryos that were created but not used for fertility purposes would likely cost significantly less. But while research cloning will at best lead to treatments that would be available only to a tiny number of wealthy individuals, it may turn out to be useful in basic research. This prospect may make it challenging to evaluate the likely eventual benefits of certain particular funding proposals.

Nevertheless, decision-makers at the CIRM can and should make affordability, accessibility, and health equity key criteria as they chart the basic research directions to be supported with public funds. Californians deserve no less.

Recommendations

- In developing policies regarding intellectual property rights, the CIRM should involve a diverse range of public-interest stakeholders, including advocates for low-income Californians, supporters of intellectual property rights reform, and representatives of state government.
- The CIRM should develop and adopt intellectual property policies that ensure financial returns to the state.
- The CIRM should develop and adopt intellectual property policies that ensure the affordability and accessibility of any successfully developed stem cell–based treatments.
- The CIRM should prioritize research directed at treatments likely to be affordable to the great majority of Californians.

Establishing Accountable and Responsible Governance

Accountable and Responsible Governance:

C-

Although the CIRM is a state agency, it has often operated with indifference to widely accepted norms of good governance. It has been slow in taking many steps necessary to build a responsible and accountable organization, and its stewardship of public funds has at times been loose and sloppy. It has resisted calls to open key meetings to the public, relenting only under pressure. The role of Robert Klein, the central figure in the California stem cell research program and the chair of the ICOC, has been called into question by his financial entanglements with stem cell research advocacy, his consistently uncooperative attitude towards the state legislature, and revelations that he withheld key information from voters during the Proposition 71 campaign.

Building organizational infrastructure

A new state agency must establish an operational foundation before proceeding with its program. The CIRM leadership has repeatedly stumbled on the critical tasks necessary for building a basic organizational infrastructure.

Fundamental decisions about an operating budget and a structure of staff accountability were not considered until May 2005, a full six months after the first meeting of the ICOC. The versions finally approved in September were incomplete: the budget document was vague and limited to general funding categories, and the organization plan failed to ensure that the CIRM staff was accountable to the President.[19] Indeed, a December *New York Times* article noted that the ICOC had just then, after almost a year, asked the President "to draw up a plan for how to draw up a strategic plan."[20]

At several junctures, the CIRM leadership appeared to be sacrificing financial responsibility to public relations. Two agreements totaling almost $500,000 worth of public relations services were among contracts signed without prior approval by the ICOC.[21] In September, the CIRM publicized an announcement of grants totaling $40 million to sixteen institutions, despite the fact that the agency had not yet secured the money with which to fund these awards.[22]

The CIRM's hiring practices and salaries have also raised concerns. The majority of the initial CIRM staff was hired in a manner that circumvented the open and competitive application procedures to which all public and most private institutions subscribe. Many were directly recruited from the Proposition 71 campaign, and given salaries approximately double those in similar positions at typical state agencies.[23]

Organizations representing California communities of color have asked CIRM leadership to put in place policies that set specific goals for diversity in hiring at all levels and in contracting.[24] These policies have not been forthcoming.

In February 2005, former United States Assistant Secretary for Health Philip R. Lee and public interest attorney Charles Halpern filed a petition addressing many of these failings. CIRM leadership issued a response that failed to address in a substantive manner the concerns they raised.[25]

Minimizing conflicts of interest

Proposition 71 established an agency with built-in conflicts of interest. It specifies that all members of the CIRM's governing board, the ICOC, represent institutions or constituencies that are likely to seek a share of the $3 billion of public funds authorized by the measure. The ICOC includes no voices or perspectives independent of these institutions and constituencies. In marked contrast to this arrangement, government boards that over-

see stem cell research in other countries are required to include a broad range of stakeholders.[26]

In December 2004, Deborah Burger, President of the California Nurses Association, called the composition of the ICOC "inadequately independent or representative of the broader public," and said that the "oversight committee should consist of people who can truly be deemed independent citizens, rather than special interests and corporate representatives."[27]

The relationship between the ICOC and the institutions it funds can be seen in the first round of training grants, announced on September 9, 2005. Of the 16 institutions that were awarded almost $40 million, 14 are represented on the ICOC. Viewed another way, all but two of the 17 ICOC members affiliated with an institution eligible for this round of funding saw their institutions receive grants.[28]

In addition to the institutional conflicts of interest written into Proposition 71, individual members of the ICOC have personal conflicts of interest based on business and financial relationships. In April 2005, the Center for Genetics and Society released a report revealing that seven of the 29 ICOC members have significant business interests in companies involved in stem cell research. These relationships, detailed in Appendix 3, include substantial equity investments and board memberships.[29]

> "Voters were told they would benefit from stem cell research, but if the drug companies own the treatments, it will be the top executives and shareholders that will profit."
>
> *Jerry Flanagan, Foundation for Taxpayer and Consumer Rights*

A notable example is that of ICOC member David Baltimore, who sits on the board of Cellerant, a California-based company dedicated to the commercialization of human stem cell products.[30] In July, Baltimore watered down a proposed strengthening of the ICOC's conflict of interest policies that was requested by the

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>
> *Deborah Burger, President, California Nurses Association*

Senate in a way that allows him to maintain an equity stake in the company.[31]

The situation is further clouded by the close relationship among the ICOC members, the research institutions that will receive CIRM grants, and pharmaceutical companies. The Foundation for Taxpayer and Consumer Rights, a liberal advocacy group, found that of the 16 institutions awarded CIRM training grants in September, 13 have significant links to the pharmaceutical industry. These links include major funding agreements, and board members in the employ of pharmaceutical corporations. FTCR's Jerry Flanagan said, "Voters were told they would benefit from stem cell research, but if the drug companies own the treatments, it will be the top executives and shareholders that will profit."[32]

Conflicts of interest are also a concern as they pertain to the ICOC Working Groups that review grants and make recommendations for funding. Reporters and public interest researchers discovered conflicts on the ICOC because its members are required to publicly disclose their personal financial interests. However, under Proposition 71, members of the powerful Working Groups are exempt from this requirement, and the ICOC has refused to adopt policies that would remove this exemption.

Cooperating with the state legislature

Proposition 71 specifically exempts the research it authorizes from "other current *or future* state laws or regulation" (italics added). It also effectively prohibits the state legislature from amending the measure in any manner.

The CIRM's leadership has fostered an adversarial relationship with California legislators. As early as December 2004, even before he was appointed chair of the ICOC, Robert Klein made it clear he wanted to take full advantage of the exemptions to public oversight that he had written into Proposition 71.[33]

When Senators Deborah Ortiz (D-Sacramento), a prominent supporter of Proposition 71, and George Runner (R-Antelope Valley) called a hearing in March 2005 to explore their growing concerns about the law, Klein refused to attend.[34] When they introduced a reform package later that month, CIRM leaders, instead of opening a dialogue that might have led to mutually acceptable compromise, were adversarial to the point of hostility.[35] They spent $50,000 on a private lobbyist to help scuttle the reform proposals—an unprecedented step for a state agency.[36]

This posture only serves to strengthen the claim made in lawsuits that the CIRM is operating outside the exclusive control of state governance.[37]

Later, when these lawsuits prevented the issuance of bonds, Klein turned to private organizations for high-risk, below-market-rate loans as a stopgap measure.[38] This approach, more appropriate for a private biotech start-up than for a state agency, raised further questions about potential conflicts of interest.

Fostering transparency with open meetings

Proposition 71 exempts the CIRM's three powerful Working Groups from key public interest laws, including California's open meetings act. CIRM leadership initially resisted calls from public interest groups to adopt a policy of open meetings (with a few exceptions universally recognized as necessary). CIRM President Zach Hall claimed that all Working Group activity consisted of "scientific peer review" and should therefore be conducted behind closed doors.[39] However, Proposition 71 spells out the activities and functions of the Working Groups, and the majority of them are not concerned with peer review.

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>
> *Charles Halpern, public interest attorney and member, Institute of Medicine*

This attitude was perhaps best exemplified by the first meeting of the ICOC, the agenda of which had been prepared in clear violation of the state's open meeting law. After public interest attorney Charles Halpern brought this to the attention of the ICOC and the Attorney General, the meeting was declared an "emergency session" and most of the agenda was tabled.[40] In his letter to the ICOC before this meeting, Halpern warned the board to avoid repeating the "promotional phase of Proposition 71, which was characterized by hyperbole and wishful thinking, reducing complicated science to disingenuous 30-second television spots."[41]

In February 2005, Terry Francke, general counsel of Californians Aware, noted that "the function of the Working Groups is overwhelmingly a public one, and their role is traditionally a public one. Moreover, public access to the Working Groups acts as vital insurance against conflicts of interest and in any event is protected by the California Constitution."[42]

After substantial pressure from public interest organizations, the ICOC eventually agreed to open Working Group meetings in most cases. However, some of the rules fail to explicitly state the specific reasons for which a meeting may be closed. And there is still no procedure that would allow members of the public to

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challenge an improperly closed meeting, a key provision of California's open meeting laws.[43]

Providing responsible leadership

Establishing accountability and responsible governance at the CIRM is largely dependent on the integrity of its leadership. A number of respected people have been hired in key positions at the CIRM, and it is to be hoped that they will be willing and able to lead the agency towards the sorts of governance structures that the stem cell research program so urgently needs.

But to date ICOC Chair Robert Klein has misused his authority in ways that have significantly undermined trust and confidence. His missteps and arrogance have been widely noted. The editorial page of the *Sacramento Bee*, for example, has dubbed Klein the "self-appointed czar" of the stem cell research program and a "rogue operator."[44]

A multi-millionaire real estate investor, Klein was the primary author of Proposition 71 and chair of the initiative campaign. He was the campaign's largest contributor, donating more than $3 million, loaning another million, and providing his corporate offices as campaign headquarters.[45]

Stem cell politics in the states and in Congress

As of January 2006, three states besides California have allocated public funds to human embryonic stem cell research. New Jersey was the first in the nation to do so, with $5 million in the grant pipeline and $380 million more pledged. Connecticut has passed legislation allocating $100 million over ten years, and the governor of Illinois included a $10 million line item in the state's most recent budget.[1]

A number of other states have considered similar programs. Supporters of state-funded stem cell research in Florida are working to place an initiative on the ballot which would set aside $200 million. In 2005, the New York and Illinois legislatures considered bills that would fund the research at $1 billion levels. Several other legislatures have voted on measures with smaller price tags.[2]

At the federal level, bipartisan support for overturning President Bush's restrictions on the federal funding of human embryonic stem cell research has grown. In May 2005, the House passed the Castle-DeGette bill, which would allow federal funding for research using surplus embryos from assisted reproduction procedures. Many prominent Republicans broke with the President and voted for it. The Senate version of the bill awaits action, and is expected to pass, but the President has promised a veto.[3]

Notes:

1 Kaitlin Gurney, "In a first, New Jersey awards stem-cell grants," *Philadelphia Inquirer* (December 17, 2005) at http://www.philly.com/mld/inquirer/news/local/states/new_jersey/13428845.htm; "Governor Rell Signs Law Establishing Stem Cell Research Fund, Ban on Human Cloning," press release (June 15, 2005) at http://www.ct.gov/governorrell/cwp/view.asp?Q=294840&A=1761; Gretchen Ruethling, "Illinois to Pay for Cell Research," *New York Times* (July 13, 2005) at http://www.nytimes.com/2005/07/13/health/13illinois.html.

2 Stacey Singer, "Group Urges $200 million for stem-cell research," *Palm Beach Post* (September 22, 2005); Mike McIntire, "With Eye on Rivals, Senator Proposes New York Institute," *New York Times* (January 17, 2005) at http://www.nytimes.com/2005/01/17/nyregion/17stem.html; Paul Gores, "Illinois looks at $1 billion plan for stem cell research," *Milwaukee Journal-Sentinel* (November 24, 2004) at http://www.jsonline.com/bym/news/nov04/278364.asp.

3 Ceci Connolly, "Frist Breaks With Bush On Stem Cell Research," *Washington Post* (July 30, 2005) at http://www.washingtonpost.com/wp-dyn/content/article/2005/07/29/AR2005072900158.html.

The qualifications for the position of ICOC Chair, which are detailed in the initiative itself, are widely acknowledged to be closely tailored to Robert Klein's resumé. Though he denied during the campaign that he planned to take a long-term position at the CIRM, the post-election search for other candidates was perfunctory.[46]

In December 2004, Robert Klein was nominated for ICOC Chair by the four elected officials given that responsibility by the initiative: the Governor, the Lieutenant Governor, the Secretary of State, and the Treasurer. In the 2002 election cycle, Klein had donated a total of more than $175,000 in cash and other non-monetary assets to the latter three of these. Once Chair, one of Klein's first acts was to introduce a resolution granting himself the powers of interim president. Provisions in the initiative gave the president extraordinary power to hire the initial staff of the CIRM, circumventing state civil service and other requirements.[47]

The majority of the staff hired by the CIRM in its first four months were people who had previously worked for the "Yes on 71" campaign and/or the stem cell research advocacy organization established by Klein immediately after the election.[48] That organization, the California Research and Cures Coalition, was in essence a re-creation of the "Yes on 71" campaign effort. It was initially chaired by Robert Klein and operated from his corporate offices. The coalition, which later changed its name to the Alliance for Stem Cell Research, works to generate support among the public, the press and key decision makers for stem cell research and the CIRM.[49]

In February 2005, it was revealed that the campaign retained considerable debt, $1 million of which was owed to Robert Klein. This raised the troubling prospect of Klein raising private money, to repay himself, while simultaneously serving as chair of a state agency slated to issue $3 billion in grants.[50]

Robert Klein has pledged to hold neither stocks in biomedical companies nor interests in real estate that may benefit from CIRM activities while he serves as Chair of the ICOC.[51] While commendable, this move does nothing to disentangle the dense web of financial, political and decision-making relationships that have characterized the California stem cell research program and its leadership from the beginning.

Taken as a whole, the record shows that Robert Klein has failed to provide the kind of leadership that would enable the CIRM to operate as an effective and accountable public agency. For this reason, we believe that he should step down as Chair of the ICOC. His departure would not in itself resolve the many problems that plague the agency, and would do nothing to address the conflicts of interest of other ICOC members. But it could open the door for the responsible leadership that is a prerequisite for other needed changes.

Recommendations

- Robert Klein should step down as Chair of the ICOC.
- CIRM leadership should adopt and publicly affirm a policy of cooperation, rather than confrontation, with California's elected officials and legislators.
- ICOC and Working Group members, and their immediate families, should be prohibited from having any financial interest in companies likely to benefit from CIRM activities, including pharmaceutical companies likely to market any successfully developed treatments.
- Hiring and personnel policies should be in line with those of other California state agencies. Diversity should be promoted as a core value of the CIRM, and data regarding diversity in hiring and contracting should be made public.
- Working Group members should be required to publicly disclose their personal financial interests, to the same extent currently required of ICOC members.
- Reasons for holding closed meetings should be explicitly stated with adequate public notice. Procedures to allow the public to challenge improperly closed meetings should be adopted.

Establishing Ethical Safeguards and Research Standards

Ethical safeguards:

C+

Human embryonic stem cell research raises a number of novel social and ethical challenges. Deriving stem cell lines from cloned embryos (rather than from embryos created but not used for fertility purposes) is particularly problematic because it requires large numbers of women's eggs and raises the prospect that cloned embryos could be misused.

Most countries with stem cell research programs have established comprehensive regulatory structures to set and enforce research standards, or are moving rapidly to do so.[52] The U.S. has no such regulatory structure, and the polarized politics of embryonic stem cell research make it unlikely that this will change in the near term. This situation makes it imperative that effective research standards and ethical safeguards be established in California. The CIRM must put in place the highest standards, and require its grantees to abide by them as a condition of funding.

The CIRM has adopted a set of recommended guidelines developed by the National Academies as its interim standards.[53] While these guidelines are helpful in some key areas, they remain inadequate.

The National Academies guidelines acknowledge the need for additional regulation of embryonic stem cell research. They recommend that institutions conducting such research establish their own oversight committees.[54] But institution-specific committees cannot be expected to provide the consistency and comprehensiveness that is needed in a state-wide program.

The National Academies guidelines also recognize the need for a national oversight body. But they provide no specific recommendations about such a body, except to assert that it should not be given authority to review specific research protocols or to enforce any of its decisions. What is needed in California, and in the nation as a whole, are public-sector bodies with the power to establish and enforce comprehensive regulations that apply to both publicly and privately funded research.

Protecting women who provide eggs for research and other research subjects

C+

The risks associated with egg extraction are more serious than most people realize. Data on the frequency of serious adverse reactions to hormones used in egg extraction procedures are inadequate, but life-threatening reactions and deaths have occurred. Media reports of two deaths in the United Kingdom surfaced in 2005; both women died as a result of egg extraction procedures for fertility treatment.[55]

Susan Fogel of the Pro-Choice Alliance for Responsive Research has noted that, "Unlike other types of medical research, where testing on human subjects occurs only much later in the process and after laboratory experiments have indicated that certain safety levels have been achieved, SCNT research requires that women be the first guinea pigs."[56]

"Unlike other types of medical research, where testing on human subjects occurs only much later in the process and after laboratory experiments have indicated that certain safety levels have been achieved, SCNT research requires that women be the first guinea pigs."

Susan Fogel, Pro-Choice Alliance for Responsive Research

Many women's health advocates, ethicists, and health law experts have long opposed suggestions that women be paid for providing their eggs for research. This practice would almost certainly induce low-income women to put themselves at unnecessary risk.

The CIRM and California stem cell researchers should take this issue seriously. The stem cell scandal that generated world-wide headlines at the end of 2005, centering on the research led by Hwang Woo-Suk and involving lies, cover-ups, and scientific fraud, first came to light with revelations that the researchers had used unethical and illegal methods to obtain women's eggs for their work.[57]

Some research advocates argue that paying women who provide eggs may be necessary to secure the large numbers of eggs that research cloning would require.[58] To their credit, CIRM leadership appears to have accepted an interpretation of Proposition 71's language that limits any payments for women who provide eggs to reimbursement for direct expenses, such as transportation and child care.

However, several members of the CIRM's research standards Working Group have advocated an interpretation that would allow CIRM-funded researchers to give egg providers additional compensation, as long as the funds for these payments came from a non-CIRM source. The CIRM should reject such a loophole, and officially affirm clear rules that limit reimbursement to out-of-pocket expenses.

In addition, safeguards need to be put in place to ensure that eggs donated for fertility purposes are not used for research without the express permission of the women who provided them. The CIRM should adopt requirements about medical care and informed consent that protect the health of women who provide eggs, and ensure that all CIRM-funded researchers adhere to these rules as a condition of their grants.

The protection of research subjects in clinical trials of stem cell–based treatments is another issue of great concern. Some prominent stem cell researchers are calling for an accelerated timeline for clinical trials on humans, bypassing normal animal studies. Yet stem cell studies are likely to pose greater risks for research subjects than are many other sorts of clinical trials, because of the novelty of the science involved and the charged political and economic atmosphere surrounding the field.

The extraordinarily high public profile of stem cell and cloning research has already created pressures for early positive results and for accelerating the move to the clinical trial stage. These pressures for haste constitute an additional risk factor for research subjects.

Preventing reproductive cloning and other unacceptable applications of stem cell technologies

California is one of 12 states in which reproductive human cloning is prohibited by law, and Proposition 71 states that the CIRM will not fund that application of cloning technology. But 38 states have no such law, and there is no national law against reproductive cloning.[59]

The creation of clonal embryos is the first key step in the process of reproductive cloning; the anticipated production of cloned human embryos for research raises the prospect of their misuse in efforts to create cloned human beings. Mechanisms to track clonal embryos and provide secure arrangements for their creation, storage, and transport would not be difficult to establish and are necessary to prevent this unethical practice.

In addition, it's important to note that stem cell techniques being developed for widely supported medical and basic research could also be used for socially unacceptable applications. These include efforts to create certain kinds of human-animal chimeras, or children who have been genetically "enhanced" with specified physical, behavioral or cognitive characteristics. The development and use of such techniques could open the door to long-repudiated eugenic practices.

The United Kingdom, Canada and other countries have established comprehensive structures of regulatory oversight to ensure that the techniques and skills utilized in human stem cell research are not used to create cloned or genetically modified children, or unacceptable human-animal chimeras. Unfortunately, the CIRM and its research standards Working Group have so far been unwilling to acknowledge the risks related to the misuse of cloned embryos and stem cell techniques, or to address ways to minimize them.

Recommendations

- The CIRM should adopt the highest ethical and safety standards for protecting women who provide eggs for research, and should prevent the emergence of a market in eggs that exploits low-income women. Specifically, before research cloning is funded, the CIRM should adopt:
  - requirements that egg extraction procedures be carried out by medical personnel who are not financially involved with stem cell research, since that conflict of interest could create pressures that would lead to unsafe practices,
  - protocols requiring that women receive follow-up medical care that would allow timely treatment of any developing adverse reactions,
  - provisions for covering the costs of treating any adverse reactions caused by egg extraction, since some women who provide eggs may not be insured, or may have insurance policies that do not cover experimental procedures,
  - safeguards to ensure that eggs donated for fertility purposes are not used for research without the express permission of the women who provided them,
  - an official position affirming that women who provide eggs are to be reimbursed only for direct out-of-pocket expenses, and
  - requirements that all CIRM-funded researchers agree to these regulations and protocols as a condition of their grant awards.
- The CIRM should adopt the highest ethical and safety standards for protecting research subjects in clinical trials, and exercise great caution in the face of any pressures for early clinical trials.
- The CIRM should adopt policies preventing the misuse of clonal embryos in efforts to produce cloned or genetically modified human beings. It should establish a system of tracking clonal embryos, and should require researchers it funds to sign agreements stating that they will not use the techniques they develop with public funding to assist efforts to produce cloned or genetically modified humans, or unacceptable human-animal chimeras, in California or elsewhere.

Conclusion: Key Issues in the Coming Year

The CIRM's first year of operation as a state agency has been a great disappointment. While some of its difficulties may be "start-up" problems that might be expected in any effort this large, the greater bulk are the result of numerous missteps and misjudgments, resistance to legislative and public oversight, and a tendency towards arrogance in the face of criticism.

We believe it is incumbent upon the CIRM's staff and board to enter the institute's second year with a new spirit, one that acknowledges—in deeds as well as words—the need for transparency, accountability and public oversight.

If all goes according to the CIRM's plans, it will soon begin issuing many millions of dollars in grants for embryonic stem cell research. Some of these grants will likely fund the cloning of human embryos and the genetic modification of stem cells in order to derive stem cell lines with specific genetic characteristics. The intent, of course, is that new lines of embryonic stem cells will advance research on degenerative diseases and chronic disorders, and that the knowledge derived from these investigations will provide the basis for new treatments and perhaps even cures.

But the creation of clonal and genetically modified human embryos raises unique ethical and regulatory issues. The CIRM's grants are likely to mark the first time in our nation's history that cloned human embryos will be publicly underwritten and managed, and the CIRM will face regulatory challenges never previously confronted by any other public body in the United States.

During the coming year, the CIRM will need to provide answers to a range of novel questions about the responsible regulation of the stem cell and cloning research it funds. These questions include:

- What mechanisms, controls, and agreements with grantees will ensure that neither cloned embryos nor techniques developed with CIRM funding are misused in efforts to produce a cloned or genetically modified child?
- What rules, protocols, and agreements with grantees will protect the health of women who provide eggs for research, and prevent the emergence of a market in eggs that exploits economically vulnerable women? What are the CIRM's and the state's responsibilities for any ill-health effects on women who provide eggs for research, or any adverse effects on subjects in clinical trials?
- What are the appropriate limits to the genetic modification and use of human stem cells?
- What are the appropriate guidelines and limits for the creation of chimeric animal-human embryos?

Other questions raised by California's stem cell research program appear to be more conventional. But they take on a unique sharpness because the CIRM's funds were allocated by a popular vote that was based on claims of major health and fiscal benefits made by research advocates. Such questions include:

- What intellectual property agreements or other arrangements will accelerate the research and development of treatments, while providing the promised public benefit of revenue returns to the state?
- What intellectual property arrangements will ensure that any successfully developed treatments are affordable, and thus accessible, to the public?
- What funding and research guidelines will permit the open-ended investigations required for new discoveries, while maximizing efforts likely to provide the most accessible benefits in treatments and therapies?
- What steps will the CIRM take to cooperate with elected legislators, minimize the conflict-of-interest dynamics built into Proposition 71, provide responsible leadership, and operate as a well-managed state agency?

Many of the most critical issues need to be discussed and resolved in the coming few months before the CIRM allocates its first research grants. Others will need to be addressed as the funding and science get underway.

Dishearteningly, the CIRM's performance over the past year in similar policy deliberations has been decidedly disappointing. But California's publicly funded stem cell research program still has an opportunity to transform itself into a model for the rest of the country and the world. The CIRM can set as a top priority the establishment of responsible regulation and effective oversight of the powerful new technologies whose development it hopes to fund.

Only if the CIRM puts effective regulations and oversight in place will it be able to ensure that responsible stem cell research and the public interest can move forward together.

Appendix 1: Timeline

Immediately after the passage of Proposition 71, questions and concerns about the initiative and its implementation began to appear in news articles, columns and editorials in California's major newspapers, including those that had endorsed it before the election. By spring 2005, most major newspapers in the state had published editorials raising concerns about the California stem cell research program, and news headlines critical of it had become routine. This timeline shows key events since November 2004, and related headlines and quotes from published news articles and editorials.

Key Events		Key Quotes/Headlines
	2004	
• Proposition 71 passes. • Controversies concerning accountability and profits follow immediately.	**NOV.**[60]	• "Stem Cell Firms Bet on Big Payoff," *Los Angeles Times* • "Divvying Up The Stem Cell Bonanza," *Business Week* • "California's New Stem-Cell Initiative Is Already Raising Concerns," *New York Times*
• All four elected officials charged with nominating a chair for the ICOC choose Robert Klein. • Public interest attorney Charles Halpern notifies Attorney General that agenda of first ICOC meeting violates California's open meeting law; most of the agenda is tabled.	**DEC.**[61]	• "The Legislature is not needed." — Robert Klein, responding to Sen. Ortiz's talk of reform • "Controversy embroils stem cell panel," *Sacramento Bee* • "Prop. 71's fine print contains surprises," *San Francisco Chronicle* • "'Coronation' of committee head on stem cell funds disturbs some," *San Diego Union Tribune* • "Editorial: Proposition 71 needs reform," *San Francisco Examiner*
	2005	
• At second ICOC meeting, Klein is unanimously approved as interim president of the CIRM.	**JAN.**[62]	• "Editorial: Stem cell panel must show accountability to the public," *San Jose Mercury News* • "Bumpy start for stem cell program," *San Francisco Chronicle* • "Stem cell panelists show holdings: Economic reports leave some observers uneasy," *San Jose Mercury News*
• Proposition 71 campaign reports debt of over $6 million, including $1 million to Klein himself. • Former US Asst. Sec. for Health Philip R. Lee and public interest attorney Halpern file petition with the ICOC calling for reforms.	**FEB.**[63]	• "5 with Prop 71 campaign land jobs at new institute," *San Diego Union Tribune* • "New criticism for stem cell program: Public health expert calls for more public oversight, lower salaries," *San Francisco Chronicle*
• Senators Deborah Ortiz (D) and George Runner (R) hold hearing to explore concerns about the law; Klein refuses to attend. • Senators Ortiz and Runner introduce reform package.	**MARCH**[64]	• "Robert Klein II, the self-appointed czar of California's quasi-public, $3 billion stem cell research program, is facing serious challenges these days." —*Sacramento Bee* editorial • "Management issues plague distribution of $3 billion in state stem cell research fund," *Los Angeles City Beat* • "Stem cell institute leader in the hot seat," *San Diego Union Tribune*
• Research by the Center for Genetics and Society reveals seven ICOC members have significant business relationships with companies involved in stem cell research.	**APR.**[65]	• "Stem cell panel facing allegations of conflict," *San Diego Union Tribune* • "Celling out: The directors of stem cell institute have direct ties to biotech firms that stand to gain," *San Francisco Bay Guardian* • "Stem-cell research clashes: Senate panel raises bar on conflict-of-interest rules," *San Jose Mercury News*

MAY[66]

- CIRM chooses to site its headquarters in San Francisco, which offered an estimated $17 million of subsidies, including free rent.
- ICOC votes to oppose most of the Ortiz-Runner reform package. CIRM hires a private lobbyist for $50,000 to help scuttle the proposed reforms.
- CIRM legal analysis suggests that tax-exempt bonds may not be able to be used for research that will generate a return to the state.

- CIRM "should get behind legislation by state Sen. Deborah Ortiz, D-Sacramento, to enact stricter conflict-of-interest rules on the research funded by Proposition 71." —*San Jose Mercury News* editorial
- "This isn't Klein's or his board's $3 billion—it's the public's. And public oversight is one of the best ways to guard against public money going astray." —*Los Angeles Times* editorial
- Robert Klein is "Rogue operator." —*Sacramento Bee* editorial

JUNE[67]

- Amid reports of internal dissension, CIRM secures a $5 million private grant to maintain operations.

- "We are getting killed by the press. We are getting killed by the Legislature. We are getting killed by people who support us." —ICOC member Jeff Sheehy, in a *Sacramento Bee* column
- "State's stem cell board opposes proposal for increased oversight," *San Francisco Chronicle*

JULY[68]

- ICOC discovers that CIRM has improperly awarded contracts worth hundreds of thousands of dollars without its approval, including two agreements for public relations totaling almost $500,000.

- "California Stem-Cell Agency Gets Off to Inauspicious Start," *Wall Street Journal*
- "Taxpayers unlikely to get quick stem cell windfall," *San Diego Union Tribune*
- Editorial: "Stem cell follies: Crank up the spin machine," *Sacramento Bee*

AUG.[69]

- A special committee of the California Council for Science and Technology recommends that CIRM leave all profits with researchers and businesses (none for the taxpayers), and notes that benefits are at least 20 years away.

- "Report finds stem cell windfall assumptions unrealistic," *San Diego Union Tribune*
- Editorial: "Stem cell funding is venture capital," *San Francisco Examiner*

SEPT.[70]

- ICOC approves $40 million in "training grants," despite having no funds. Of the 16 recipient institutions, 14 are represented on the ICOC.

- "Their own rules mean multimillion-dollar decisions are based on two-page memos." —*Sacramento Bee* editorial
- "Who will benefit more, consumers or drug firms?," *San Jose Mercury News*
- "Stem cell's shell game?," *Capitol Weekly*

OCT.[71]

- The *San Francisco Chronicle* reveals that Klein knew during the campaign of the conflict between tax exempt bonds and returns to the state.

- "Stem cell institute considers where to start," *San Francisco Chronicle*
- "Tax law casts doubt on stem cell royalties: State may not reap billions promised to voters last fall," *San Francisco Chronicle*

NOV.[72]

- Klein admits knowing of the tax complications during the campaign.

- "I'd want to go back and review this area." —Robert Klein, when asked why he didn't tell economic analysts about the tax complications during the campaign, in a *Sacramento Bee* column.

DEC.[73]

- ICOC adopts interim intellectual property policy with only a weak preference for affordable therapies.

- "I liken it to the Iraq thinking—we won the war and didn't know what to do afterward." —Paul Berg, ICOC substitute member

Appendix 2: The Independent Citizens Oversight Committee

The CIRM is governed by a twenty-nine member governing board, the Independent Citizens' Oversight Committee (ICOC). It is composed of officers from public and private universities and nonprofit research centers, representatives of biotechnology corporations, and disease-specific patient advocates. Twenty-seven members are appointed by California elected officials and chancellors of the University of California system, who select them on the basis of the institutional or patient advocacy affiliations specified by Proposition 71. The chair and vice-chair are then elected by these members from candidates nominated by the elected officials.

The initial members of the ICOC were selected in December 2004. The biographical information below was compiled from the CIRM website, press releases announcing the appointments, the Fair Political Practices Commission Form 700s filed by the members, and news reports.

Robert Klein, Chair: President of Klein Financial Corporation, a real estate investment banking consulting company; President of Klein Financial Resources, a real estate development company, and Chairman of the "Yes on 71" campaign. Klein was the chief force behind Proposition 71 and one of its chief authors. He donated more than $3 million to the campaign and his company donated another $700,000.

Edward Penhoet, Vice-Chair: Chiron co-founder and board member; Alta Partners principal; Renovis co-founder and board chair; Zymogenetics board member; Gordon and Betty Moore Foundation president.

David Baltimore: California Institute of Technology president; Cellerant co-founder and board member; Amgen co-founder and board member; BB Biotech board member; FasterCures/The Center for Accelerating Medical Solutions board member.

Robert Birgeneau: UC Berkeley Chancellor.

Keith Black: Cedars-Sinai Medical Center, Director of Dunitz Neurosurgical Institute.

Susan Bryant: UC Irvine, Dean of School of Biological Sciences.

Marcy Feit: ValleyCare Health System president and CEO.

Michael Friedman: City of Hope president; MannKind board member.

Michael Goldberg: Genomic Health board member; Zyomyx board member; iKnowMed Systems board member; Cemaphore board member; eHealthInsurance board member.

Brian Henderson: University of Southern California, Keck School of Medicine Dean.

Edward Holmes: UC San Diego, School of Medicine Dean.

David Kessler: UC San Francisco, School of Medicine Dean.

Sherry Lansing: University of California Regent; Stop Cancer founder and board chair.

Gerald Levey: UC Los Angeles, David Geffen School of Medicine, Dean.

Ted Love: Nuvelo president and CEO.

Richard Murphy: Salk Institute president.

Tina Nova: Genoptix president and CEO; Arena Pharmaceuticals board member.

Philip Pizzo: Stanford University, School of Medicine Dean.

Claire Pomeroy: UC Davis, School of Medicine Associate Dean.

Francisco Prieto: American Diabetes Association, Sacramento-Sierra chapter president.

John Reed: Burnham Institute president; Stratagene Holding Corporation board member; Isis Pharmaceuticals board member; Idun Pharmaceuticals board member.

Joan Samuelson: Parkinson's Action Network president.

David Serrano-Sewell: National Multiple Sclerosis Society volunteer; City of San Francisco deputy city attorney.

Jeff Sheehy: UC San Francisco, AIDS Research Institute Director of Communications.

Jonathan Shestack: Cure Autism Now founder, vice president, secretary and treasurer.

Oswald Steward: UC Irvine, Reeve-Irvine Research Center for Spinal Cord Injury Chair and Director.

Leon Thal: UC San Diego, Alzheimer's Disease Research Center Director; Department of Neurosciences Chair.

Gayle Wilson: Gilead Sciences board member. (Wilson's resignation from the ICOC was announced on January 3, 2006.)

Janet Wright: American College of Cardiology.

Appendix 3: Personal Conflicts of Interest on the ICOC

The California stem cell research program is compromised by two sorts of conflicts of interest. Proposition 71, which established the California Institute for Regenerative Medicine (CIRM), built conflicts of interest into the structure of the new agency. The proposition mandates that at least half of the CIRM's governing board, the Independent Citizens' Oversight Committee (ICOC), must represent institutions that are likely to conduct stem cell research.

In addition to these built-in institutional conflicts, some members of the ICOC have personal conflicts of interest. Initial research by the Center for Genetics and Society has revealed that seven of the twenty-nine ICOC members have significant business relationships with companies involved in stem cell research. These relationships include substantial equity investments and board memberships.

CGS has compiled summaries of the backgrounds and financial interests of seven ICOC members who have investments or leadership positions in companies that are currently, or have in the past been, involved with stem cell research. Worth of stock ownership is reported on Form 700s that were submitted upon appointment to the ICOC.[74]

ICOC Vice-Chair Edward Penhoet reported owning more than $1 million dollars in stock in three of the biotechnology companies on whose boards he sits:

- One, Zymogenetics, described the work of its "stem cell biologists" and its "Director of Stem Cell Biology" in a press release.[75]
- Penhoet is founder and board chair of Renovis, whose exclusive licensee AstraZeneca uses stem cells in their research programs.[76] Also on the eight-member Renovis board of directors is John Walker, who sits on the board of Geron, the largest and most prominent stem cell corporation.[77]
- Penhoet is founder and board member of Chiron. Several years ago, Chiron participated in stem cell studies.[78]

In January 2005, Penhoet told the *San Jose Mercury News*, "I'm not aware that any investment I have or any board that I serve on is involved in stem cell research." The news report continued, "Should that change, he said, he would resign from the company board and sell any holdings."[79]

David Baltimore sits on the board of Cellerant, a privately held California-based company dedicated to the commercialization of human stem cell therapies. Baltimore did not report how much equity he holds in the company.

Baltimore also serves on the board of Amgen, the world's largest biotechnology corporation, and has between $100,000 and $1 million dollars invested in it.

Amgen has a strategic relationship with ViaCell, a stem cell company. As recently as January 2005, a headline at *Forbes.com* read, "Amgen Profits From Stem Cell IPO." In exchange for a $20 million dollar stake in ViaCell, Amgen granted ViaCell a worldwide license to stem cell growth factors developed by Amgen. Furthermore, Amgen retains an option to collaborate with ViaCell on "product or products that incorporate an Amgen growth factor or technology."[80]

In addition to Baltimore, Edward Frizky is on the board of Amgen. Frtizky also has a seat on the board of Geron, the largest and most prominent stem cell corporation.

Tina Nova is the founder and CEO of Genoptix, Inc., which develops lasers applicable in stem cell isolation.[81]

Gayle Wilson owns between $100,000 and $1 million of stock in the biotech company Boston Scientific Corp., which researches and is commercializing stem cell therapies.[82]

This report was originally published in April 2005. It was amended in September 2005 to include the information on Cellerant.

Keith Black owns between $10,000 and $100,000 of stock in Genentech, which conducts stem cell research.[83]

John Reed serves on the board of Stratagene Holding Corporation, which utilizes stem cell research in the development of its products.[84]

Brian Henderson owns between $2000 and $10,000 of stock each in Genentech and Medtronic. Both companies engage in stem cell research.[85]

Other biomedical industry involvements

Other ICOC members have significant investments or leadership positions in the broader biomedical industry. These also raise concerns about conflicts of interest for several reasons:

- Proposition 71 funds are not restricted to stem cell research. In fact, the ICOC can decide to allocate funds to any other kind of biomedical research.
- Any discoveries made using CIRM funds will be licensed to companies for commercialization. These are likely to be pharmaceutical and biomedical corporations.
- A growing number of traditional pharmaceutical and biomedical corporations are now engaging in

Endnotes

1. The plaintiffs in the lawsuits are religious conservatives who are opposed to embryonic stem cell research in principle, and anti-tax conservatives who object to the use of state funds for a program such as the CIRM. But the arguments they raise in the lawsuits concern the governance of state agencies and legislative control of public funds. In November 2005, a group of pro-choice scholars and others filed an amicus brief in support of the suits. The amicus brief cites "1) lack of exclusive state control; 2) impermissible conflicts of interest; 3) misrepresentations of research to be funded; and 4) misrepresentations on financial returns to California." The amicus brief is online at http://www.genetics-and-society.org/policies/california/amicus20051117.html. Also see Marisa Lagos, "Future of state's stem cell agency in court's hands," *San Francisco Examiner* (November 20, 2005) at http://www.sfexaminer.com/articles/2005/11/20/news/20051119_ne02_stem.txt.
2. Kathay Feng, Steven Blackledge, "Oversight is critical for confidence in stem-cell research," *San Francisco Chronicle* (June 30, 2005) http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2005/06/30/EDGOODGATU1.DTL.
3. For example, the co-chair of the campaign, Michael Goldberg, is now on the ICOC (see http://www.mdv.com/team_goldberg.htm). Two other ICOC members, Joan Samuelson and Keith Black, appeared in television ads (see http://www.yeson71.com/tv_radio.php). Several others publicly endorsed the measure. Among the CIRM staff, several of the early hires were directly recruited from the campaign. See Terri Somers, "5 with Prop. 71 campaign land jobs at new institute," *San Diego Union-Tribune* (February 4, 2005) http://www.signonsandiego.com/news/state/20050204-9999-1n4stemcell.html.
4. The campaign's standard presentation can be viewed at http://www.yeson71.com/documents/stemcellpresentation.pdf. See also the economic analysis sponsored by the campaign: Laurence Baker and Bruce Deal, "Economic Impact Analysis: Proposition 71, California Stem Cell Research and Cures Initiative" (September 14, 2004) at http://www.yeson71.com/documents/Prop71_Economic_Report.pdf and the *Official Voter Information Guide* at http://www.ss.ca.gov/elections/elections_viguide_pg04.htm.
5. In one ad, for example, Jeffrey Bluestone of the UC San Francisco Diabetes Center says, "When a 7-year-old girl comes up to me and she's scared, and she says, 'Will stem cells be an answer for me? Will they be a cure for me?' I'm absolutely confident in saying that, 'This will happen.'" Other researchers featured in ads include Irving Weissman, Lawrence Goldstein, Paul Berg, and Keith Black. Some of the campaign ads remain online at http://www.yeson71.org/tv_radio.php.
6. In the campaign-sponsored economic analysis, Baker and Deal summarize, "Proposition 71 is capable of paying for itself during the payback period alone with the possibility of continuing to generate billions of dollars in revenues and savings for the State of California for decades after that." (Supra note 4, p. 2)
7. Proposition 71 has a clause titled "Patent Royalties and License Revenues Paid To The State of California," stating that "The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the state of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements." See http://www.yeson71.com/initiative.php. For campaign promises, see note 5.
8. "State deserves a share of stem-cell benefits," *San Francisco Chronicle* (December 9, 2004) at http://sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2004/12/09/EDGSVA88PD1.DTL.
9. For example, see the agendas of the two meetings of the CIRM's IP task force, on October 25 and November 22, 2005 at http://www.cirm.ca.gov/meetings/2005/10/10-25-05.asp and http://www.cirm.ca.gov/meetings/2005/11/11-22-05.asp.
10. The interim report, *Policy Framework for Intellectual Property Derived from Stem Cell Research in California*, is at http://www.ccst.us/ccst/pubs/IP/IP%20Interim.pdf. The committee members are listed at http://www.ccst.us/ccst/projects/ip/iplist.html.
11. At the Joint Assembly Health and Senate hearings on "Implementation of Proposition 71: Options for Handling Intellectual Property Associated with Stem Cell Research Grants" (October 31, 2005), Merrill Goozner of the Center for Science in the Public Interest outlined a patent pool for CIRM-funded discoveries, and Jennifer Washburn of the New America Foundation discussed the benefits of separating the management of intellectual property rights from the educational institutions. See http://www.senate.ca.gov/ftp/SEN/COMMITTEE/STANDING/HEALTH/_home/PROP_71_IP_TRANSCRIPT.doc.
12. Ibid.
13. "Senators Runner and Ortiz Introduce Legislative Package to Protect Public's Investment In Stem Cell Research," press release (March 16, 2005) at

http://republican.sen.ca.gov/news/17/pressrelease3283.asp.

14. See the transcript of the Joint Assembly Health and Senate hearings on "Implementation of Proposition 71, the Stem Cell Research and Cures Act" (March 9, 2005) at http://www.sen.ca.gov/ftp/SEN/COMMITTEE/STANDING/HEALTH/_home/PROP_71_OVERSIGHT_TRANSCRIPT.doc.
15. Both arguments were made at the second meeting of the IP task force (November 22, 2005), transcript available at http://www.cirm.ca.gov/transcripts/.
16. The text of his July 27, 2004 speech is at http://www.pbs.org/newshour/vote2004/demconvention/speeches/reagan.htm.
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19. See the President's reports of the April 7 and September 9 meetings of the ICOC, http://www.cirm.ca.gov/meetings/2005/04/04-07-05.asp and http://www.cirm.ca.gov/meetings/2005/09/09-09-05.asp. A more detailed but still inadequate budget was approved on December 6, 2005. See http://www.cirm.ca.gov/meetings/2005/12/12-06-05.asp.
20. Andrew Pollack, "California's Stem Cell Program Is Hobbled but Staying the Course," *New York Times*, (December 9, 2005) at http://www.nytimes.com/2005/12/10/business/10stem.html.
21. See the items and the discussion at the July 12 ICOC meeting, http://www.cirm.ca.gov/meetings/2005/07/07-12-05.asp and http://www.cirm.ca.gov/transcripts/pdf/07-12-05.pdf. Recent contract totals are at http://www.cirm.ca.gov/meetings/pdf/2005/09/09/090905_item_13b.pdf.
22. "ICOC Approves First Stem Cell Grants In California," CIRM press release (September 9, 2005) at http://www.cirm.ca.gov/pressreleases/2005/09/09-09-05_ii.asp.
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24. The Greenlining Institute made these requests in a February 7, 2005 letter to Robert Klein, cited in the background paper for the March 9, 2005 "Implementation of Proposition 71, the Stem Cell Research and Cures Initiative" Legislative hearings, at http://www.senate.ca.gov/ftp/SEN/COMMITTEE/STANDING/HEALTH/_home/PROP_71_OVERSIGHT_BACKGROUND.doc.
25. The Lee-Halpern petition is at http://www.genetics-and-society.org/policies/california/leehalpern20050216icoc.html. The response from the CIRM is at http://www.genetics-and-society.org/policies/california/leehalpern20050318response.html.
26. In the United Kingdom, for example, the Chair, Deputy Chair, and at least half of the 21 members of its Human Fertilisation and Embryology Authority can neither be doctors nor scientists involved in related research. See http://www.hfea.gov.uk/AboutHFEA/FAQs. In Canada, the Assisted Human Reproduction Act passed in 2004 requires the governing board it establishes to include ethicists, women's health representatives, and legal scholars, among others. See http://laws.justice.gc.ca/en/A-13.4/2389.html.
27. California Nurses Association, "California Nurses Assn. Calls for Added Public Protections as Prop. 71 Policy Board Convenes," press release (December 17, 2004) at http://www.datawarehousingsurvival.com/content/view/2232/2/.
28. The first round of grants is listed on the CIRM press release, "ICOC Approves First Stem Cell Grants in California," (September 9, 2005) at http://www.cirm.ca.gov/pressreleases/2005/09/09-09-05_ii.asp. Note that the Gladstone Institute is part of UC San Francisco, and that Sherry Lansing is a regent of the UC system. The ICOC members are listed in Appendix 2; there is more detailed information at http://www.genetics-and-society.org/policies/california/icoc.html.
29. See the report by the Center for Genetics and Society on potential conflicts of interest on the ICOC at http://www.genetics-and-society.org/policies/california/conflicts.html.
30. Ibid.
31. See the transcript of the July 12, 2005 meeting of the ICOC in Irvine at http://www.cirm.ca.gov/transcripts/pdf/07-12-05.pdf.
32. Foundation for Taxpayer and Consumer Rights documents can be viewed at http://www.consumerwatchdog.org/healthcare/pr/?postId=220&pageTitle=Prop+71%27s+Stem+Cell+Oversight+Committee+Rife+With+Conflicts+of+Interest and http://www.consumerwatchdog.org/healthcare/pr/?postId=5209&pageTitle=13+of+16+Stem+Cell+Grantees+Have+Conflicts-of-Interest+With+Drug+and+BioTech+Companies%3B+.
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37. Supra note 1.
38. The bridge financing was approved as bond anticipation notes by the Finance Committee on May 9, 2005, online at http://www.cirm.ca.gov/meetings/2005/05/05-09-05.asp, and discussed at several of the ICOC meetings in the latter half of 2005. The plan for obtaining below-market rates was discussed at the July 12, 2005 meeting. See the meeting transcript at http://www.cirm.ca.gov/transcripts/pdf/2005/07-12-05.pdf.
39. This resistance is best seen in Dr. Hall's statements at the joint Assembly Health and Senate hearings on "Implementation of Proposition 71, the Stem Cell Research and Cures Act" (March 9, 2005) at http://www.sen.ca.gov/ftp/SEN/COMMITTEE/STANDING/HEALTH/_home/PROP_71_OVERSIGHT_TRANSCRIPT.doc.
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