



JOHN CHIANG
California State Controller

February 20, 2013

To the People of California:

I am pleased to present the eighth annual report of the Citizens Financial Accountability Oversight Committee (CFAOC) to the California Institute for Regenerative Medicine (CIRM).

Proposition 71, passed by voters in November 2004, created CIRM to implement a \$3 billion stem cell research program. It is this committee's responsibility to ensure that those public funds are spent efficiently and effectively on lifesaving medical research. The CFAOC was created by Proposition 71 to provide financial oversight and recommendations to CIRM. The CFAOC must meet annually to review the finances of CIRM and issue an annual report.

Nine years ago, Californians showed their overwhelming support for stem cell research when they approved Proposition 71. Not only did California voters support stem cell research, they also said they were willing to pay for it – and committed more than \$3 billion in public funds, which will be closer to \$6 billion with bond financing, to pursue this promising research. I, too, believe stem cell research holds the key to cures for chronic and life-threatening diseases that affect millions of Americans. The members of this committee not only have the opportunity, but the obligation, to provide expert fiscal review and guidance to the Institute for Regenerative Medicine. We must ensure CIRM's fiscal practices are sound and that we fiercely protect the investment of public funds as we continue to make inroads into this revolutionary field of science and medicine.

Sincerely,

JOHN CHIANG
California State Controller

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Committee Overview

History of the Citizens Financial Accountability Oversight Committee

The Citizens Financial Accountability Oversight Committee (CFAOC) was created by Proposition 71, which was approved by voters in November 2004. Proposition 71 charged the CFAOC with reviewing the financial practices and performance of the California Institute for Regenerative Medicine (CIRM) and advising CIRM on its financial practices.

Scope

The CFAOC's six-member board, chaired by the California State Controller, must annually review the financial practices and performance of CIRM. As a part of its evaluation, CFAOC members review CIRM's annual financial audit, the State Controller's evaluation of that audit and the financial practices of CIRM.

Committee Members

The Honorable John Chiang, Chair
California State Controller

Controller John Chiang was elected in November 2006 to serve as California's Chief Fiscal Officer.

The Controller is the chair of the Franchise Tax Board and, during even-numbered years, the State Lands Commission. He serves on 81 boards and commissions including CalPERS and CalSTRS, the nation's first- and second-largest public pension funds.

As Controller, Chiang has moved swiftly to ensure California is on the road to prosperity while meeting its obligations to workers and retirees. Upon assuming office, Chiang immediately hired an independent actuary to determine, ahead of schedule, the costs of post-employment benefits as the first step in crafting California's long-term plan to meet the State's accounting and healthcare commitments.

The Controller brings extensive experience and fiscal leadership to the State Controller's Office. Chiang was first elected to the Board of Equalization in 1998 where he served two terms, including three years as chair. He began his career as a tax law specialist with the Internal Revenue Service and previously served as an attorney in the State Controller's Office.

Chiang is the son of immigrant parents, and graduated with honors from the University of South Florida with a degree in Finance. He received his law degree from the Georgetown University Law Center. Chiang and his wife, Terry Chi, live in Torrance, California.

Daniel Brunner

Retired, Appointed by the State Treasurer

Daniel Brunner has more than 30 years experience in health care law, policy and corporate management in both the public and private sectors. Mr. Brunner co-founded Affordable Health Care Concepts in 1983. The Sacramento-based firm, which developed highly customized PPO networks on the West Coast, was the first to introduce the concept of competitive bidding among hospitals for patient services. It was acquired by First Health in 1987. Through January of 2005, he served as Executive Vice President of First Health and as a member of its Board of Directors.

Mr. Brunner served as General Counsel for the California Governor's Office of Special Health Care Negotiations and was the Director of the Legislative Office at the Western Center on Law and Poverty, General Counsel and Deputy Director of Legal Affairs in the State Department of Benefit Payments and was on the faculty at UCLA and USC law schools.

Mr. Brunner earned a bachelor's degree in accounting at UCLA. He obtained his law degree from California Western University and is a member of the California Bar. In addition, he served on the boards of directors of the Sacramento Theatre Company and Capitol Public Radio. He also serves on the board of visitors of the University of California, Davis, School of Medicine.

Dr. James Kovach *CEO and President of Athleticcode Inc., appointed by the ICOC Chair*

Dr. James Kovach is currently the CEO and founder of Athleticcode, a fitness company using genetic testing and performance data that athletes can use to develop personalized training programs that reduce injury. He serves as the Principal Investigator of the NFL Concussion Study, in which more than 100 former National Football League players have undergone confidential genetic testing of APOE, a gene associated with late-life cognition issues in individuals who have suffered multiple concussions.

Dr. Kovach also serves as Manager of Healthcare System and Physician Outreach for SKS Investments, LLC, where he helps identify hospital and healthcare systems to partner with in developing medical office and life sciences research space.

He served as President and Chief Operating Officer of the Buck Institute for Age Research in Novato, California, in 2005-2010. In 1998-2005, Dr. Kovach was Executive Vice President and Chief Operating Officer of Athersys, Inc., a publicly-traded biotechnology company located in Cleveland, Ohio. He has also directed the Office of Technology Management at the Case Western Reserve University School of Medicine in Cleveland.

Dr. Kovach spent seven years as a middle linebacker in the NFL, playing for the New Orleans Saints and the San Francisco Forty-Niners and attending medical school in consecutive off-seasons. He received his Bachelor of Science degree in biology from the University of Kentucky in 1978, where he graduated cum laude. He received his Doctor of Medicine Degree from the University of Kentucky in 1984. He obtained his law degree from Stanford University in 1990, and practiced as a corporate attorney.

Dr. Loren G. Lipson

Retired, appointed by the State Controller

Dr. Loren G. Lipson is a Professor Emeritus of Medicine at the Keck School of Medicine at the University of Southern California. A resident of Pasadena, Dr. Lipson has been a recognized leader in the field of medicine for 40 years. He has been appointed to academic posts at some of the country's most prestigious universities, including the Harvard Medical School and the USC School of Medicine, where he served as Chief of the Division of Geriatric Medicine, Department of Medicine, from 1984-2004.

Dr. Lipson currently serves as a Geriatric Medicine and Long Term Care consultant to the U.S. Department of Justice, Civil Division; U.S. Department of Health and Human Services, Office of the Inspector General; California Department of Justice's Bureau of Medi-Cal Fraud and Elder Abuse; California Department of Social Services; and the New Mexico Department of Justice, Medicaid Fraud Control Unit.

He was director of two USC Teaching-Nursing Home Programs, the Hollenbeck Home in Los Angeles and the Atherton Baptist Home in Alhambra.

A graduate of Johns Hopkins University School of Medicine, Dr. Lipson received his undergraduate degree in Chemistry from the University of California, Los Angeles.

Jim Lott

Executive Vice President, Hospital Association of Southern California, appointed by the Senate President Pro Tem

Jim Lott is the Executive Vice President of the Hospital Association of Southern California where he is responsible for health care policy development, advocacy, and communications for hospitals serving Los Angeles, Orange, San Bernardino, Riverside, Santa Barbara and Ventura counties.

Prior to his move to Los Angeles, he served for five years as the President and Chief Executive Officer of the Hospital Council for San Diego and Imperial counties.

Mr. Lott served for ten years as Staff Director and Chief Consultant to the Senate Committee on Health and Human Services of the California Legislature. In that capacity, he was one of the principal architects of the health care finance reforms adopted by the California Legislature in 1982. Later, he worked on President Clinton's Health Care Reform Task Force.

Mr. Lott received his undergraduate degree from Cal State L.A., his MBA degree from the University of Redlands, and has achieved candidate status for his doctorate in Education-Organizational Leadership at Pepperdine University. He serves on the boards of the Claremont Universities Consortium, the Los Angeles Economic Development Corporation, and L.A. Care Health Plan, for which he serves as chairperson.

Dr. Gurbinder Sadana

Physician, Appointed by the Assembly Speaker

Dr. Gurbinder Sadana is a long-time private practice physician and specialty consultant with offices in Pomona.

He has been in private practice in Pomona since 1983, and is a specialty consultant and advisor on asthma and related disease. He is also Medical Director of Critical Care Services at the Pomona Valley Hospital Medical Center in Pomona.

Dr. Sadana is a fellow of the American College of Chest Physicians and a member of the Society of Critical Care Medicine. He serves on the Board of Directors of the Pomona Valley Hospital Medical Center Foundation.

His Board Certifications include American Board of Internal Medicine, American Board of Internal Medicine/Critical Care Medicine, and American Board of Internal Medicine/ Pulmonary Medicine.

Dr. Sadana graduated from Gauhati Medical College in Gauhati, Assam, India in 1969, and he has completed extensive post-graduate education including earning a Diploma in Chest Diseases from the University of Delhi, New Delhi, India.

**Oversight of the
California Institute
for Regenerative
Medicine**

When Proposition 71 created CIRM, it also established two structures for providing oversight of the Institute and the taxpayer bond money. The Independent Citizens Oversight Committee (ICOC) consists of 29 members who are appointed by statewide elected officials and Legislative leaders. The ICOC is the board that governs CIRM. ICOC members include scientists, physicians, business people, university administrators and patient advocates. Proposition 71 provided that the Chair and the Vice Chairperson of ICOC shall be full- or part-time employees of the Institute.

The Citizens Financial Accountability Oversight Committee (CFAOC) is chaired by the State Controller and is responsible for reviewing CIRM's annual financial audit, the Controller's review of that audit and the financial practices of CIRM.

Eighth Annual Meeting

Meeting Details

The eighth annual meeting of the Citizens Financial Accountability Oversight Committee (CFAOC) was held on February 20, 2013, at the SCAG Board Room, 818 W. 7th Street, 12th Floor, in Los Angeles. Five of the six members were in attendance.

Financial Presentations

On February 20, 2013, the Committee heard presentations regarding the independent audit of California Institute for Regenerative Medicine (CIRM); audit response by CIRM; the State Controller's Office's review of that audit; a status update of CIRM's financial performance; current budget, update of grants awarded; the grants process; IOM report; and CIRM's response to the IOM report.

Independent Audit

Shelly Walker-Davey from Macias, Gini & O'Connell (MGO) presented the audit findings for year ending June 30, 2012. MGO did not identify any deficiencies in internal controls over financial reporting. Expenses for FY 2011-2012 were \$239,502,000, of which \$226,927,000 was for grants and \$12,575,000 was for operations. This reflects a decrease in state operations of \$644,000 over 2010-2011. CIRM ended the fiscal year with a fund balance of \$66,043,166. The primary source of revenues is bond revenue and investment earnings. This year CIRM also received \$1,933,000 in interest on loans.

CIRM's net assets at the end of June 30, 2012, were \$89,742,000. In FY 2011-2012 CIRM received \$50.8 million in General Obligation (GO) bonds. CIRM has received \$1.23 billion in bonds to date, and anticipates requesting commercial paper funds of approximately \$100 million to meet its funding needs through June 20, 2012. (Prop. 71 authorizes issuance of not more than \$350 million in bonds annually over a 10-year period for a total of \$3 billion.) To date, CIRM has awarded \$1.7 billion and has about \$990 million left to be awarded. CIRM anticipates awarding funds until 2017 and running out of bond funding by approximately 2020.

The MGO audit report for FY 2011-2012 can be found online at

http://www.sco.ca.gov/Files-EO/CFAOC/Item_5_CIRM_2011-12_Audit.pdf

State Controller's Office Review

David Supan, Audit Manager, Financial Audits Bureau, with the State Controller's Office (SCO), reported on their review of the MGO audit, emphasizing that the objective of the review was to determine whether the audit was performed in accordance with generally accepted auditing standards, government auditing standards, and the California Business and Professions code. SCO found that the audit was performed in accordance with audit standards and requirements, and did not identify any exceptions.

The SCO report can be found online at http://www.sco.ca.gov/Files-EO/Item_5_MGO_Report_Jan_2013.pdf

Status Update of CIRM

Chila Silva-Martin, CIRM's Director of Finance, presented on the final expenditures for the 2011-12 fiscal year, current financial status and the 2012-2013 expenditures through December 2012. Ms. Silva-Martin was appointed to her current position in August of 2012.

Budget

Ms. Silva-Martin reported that CIRM had allocated \$10.3 million for salaries and benefits, but had spent only \$9.3 million, mostly due to unfilled positions. There was a million dollar savings in employee expenses due to several high-level vacant positions for a majority part of the fiscal year. For all other expenses, \$8.2 million was budgeted with \$6.2 million spent, for total expenditures of \$18.502 million for the year – \$3.1 million under budget.

Member Kovach asked about the grant review variance. Last year, CIRM convened clinical development advisory panels and budgeted \$125,000 based on their spending for grant reviews. CIRM only convened three of the panels and the cost were significantly less than budgeted. CIRM also spent less on grant reviews due to the hard work of CIRM staff.

Ms. Silva-Martin reported savings on several of their contracts, attributed to costs that did not materialize at the anticipated level or that they did not materialize at all. The majority of these savings came from their contract with Alliance Management, which provides support for the collaborative funding function.

Member Lipson asked Ms. Silva-Martin to speak about their legal contracts and in-house counsel. Chairman Thomas explained that in certain instances CIRM needed outside counsel for specific expertise. Their principal expenditure for outside counsel is Mr. Harrison, who represents the board and performs functions on an hourly basis throughout the year. Ms. Silva-Martin reported \$500,000 is spent on outside legal contract.

Ms. Silva-Martin reported grant disbursements through December 2012 have totaled \$79 million as compared to the previous fiscal year, when

they totaled \$109.8 million. The current cash availability is \$70.5 million since December, and the majority of that money is made up of commercial paper. The shift toward commercial paper is due to its short-term funding which provides a lower cost for the state. Through the fiscal year 2011-12, CIRM was funded with bond proceeds and received \$50.8 million from the October 2011 bond proceeds.

Ms. Silva-Martin compared the budget for the current fiscal year to the year which ended June 2012, flagging some of the key variances: salaries and benefits are \$1.8 million higher for the current fiscal year. Employee expenses are up due to an additional eight positions added. Review meetings and workshop expenditures are also up. This fiscal year, CIRM held seven different various grant review meetings compared with two in the previous year.

For the current year, CIRM projects expenditures of \$14.3 million, which leaves about \$104.3 million to carry CIRM through the remainder of the year. Currently, CIRM has awarded \$1.8 billion and has about \$990 million left to be awarded in grants. In conclusion, CIRM has spent \$68 million in general and grant administration support. There is a balance of \$1.1 million to support operational costs for the remainder of the year.

Committee Discussion

CFO Position

Matthew Plunkett, the first CFO hired by CIRM, came on board in December 2011 and left in July 2012. The position remains vacant. Chairman Chiang asked for update on the CFO position. Chairman Thomas reported that Dr. Plunkett felt that there was not enough work to employ a CFO at CIRM, and went back to the private sector. After Dr. Plunkett's departure, Ms. Silva-Martin took over the internal financial matters and hired a fellow to tackle business development issues. Chairman Thomas reported that CIRM is not currently seeking another CFO.

Donated Funds

Between 2005 and 2007, CIRM raised \$5.47 million, but has raised very little since. The audited statement shows only \$1,000 raised in FY 2010, \$2,000 in FY 2011, and \$21,630 in FY 2012 from Bob Klein for a current total of \$5.8 million. This information, including the donor list, is not readily available on CIRM's website because donors were never asked if CIRM could make it public.

Chairman Chiang asked for an update from last year's discussion on greater transparency of funds donated and posting this list on their website. Ms. Silva-Martin reported that she was unaware of this commitment. For FY 11-12, there is one donation for approximately \$21,000. This donation was used to allow staff to attend the annual ISSCR meeting.

Chairman Chiang asked if CIRM plans to disclose their donor list on their website. Ms. Silva-Martin committed to disclosing the donor list on their website.

Loan Policy

Dr. Feigal presented on the status of the loan program. CIRM allows industry the flexibility to accept either a loan or a grant. This option allows industry to state their preference. Chairman Chiang asked about the difference between loans and grants.

Mr. Harrison explained that there are different policies governing grants versus loans. Loans require a repayment under certain circumstances while grants come with revenue sharing provisions. The revenue sharing provision is one-tenth of one percent of commercial revenues per one million of grant awards - this is known as a royalty.

There are two types of loans from which the loan recipient can select: (1) Product-Backed loans, where payback includes interest and is predicated on success of the product being developed and are forgivable if the program fails; and (2) Company-Backed loans which the recipient is obliged to pay back, regardless of results. For Company-Backed loans, the loan recipient can choose whether to provide warrants at a certain level depending on the company's profits and financing, or pay a risk premium which is a multiple of the principal amount of the loan. Loans are taken out by for-profit companies

Member Lipson inquired about the provision where Californians benefit from the research grant or the loan. Mr. Harrison reemphasized the revenue sharing provisions and explained the two additional provisions: the preferential pricing provision and the access provisions. The preferential pricing provision applied to publically funded programs, whereas the access provision requires that a successful CIRM grantee or loan recipient develop an access plan to the product for Californians who are unable to afford insurance. Thus, enabling Californians otherwise without access, the access to the products developed with CIRM funds.

Member Lipson also inquired about the possibility for Californians to benefit from the loan interests. Under Prop 71, interest and repayment of principal on loans goes back to CIRM to grant new awards. However, if the interest comes after the award period, CIRM would be able to directly use those funds. This is an issue that the subcommittee is currently tackling. He also asked about the number of companies that applied for grants and how many got them. CIRM stated that there are around 14 different companies and 24 different research awards that have received approximately \$166 million.

Loan Termination

Dr. Feigal updated the committee on the two terminated loans. The first was to Geron in 2011, which was repaid in full with interest when the company decided not to pursue the research project. The second was to iPieran for \$5.6 million which was forgiven in accordance with regulations. The current standing loans are with Viacyte and Capricor, two disease research teams. The Viacyte loan is working on a therapeutic approach for diabetes while the Capricor is working on a therapeutic approach for cardiovascular disease.

Intellectual Property Revenues

Member Brunner inquired about CIRM's intellectual property rights. Mr. Harrison assessed that it is currently premature to estimate the revenues from intellectual property. Mr. Harrison went over the revenue sharing formula which applies to both for-profits and not-for-profit companies. Non-profits have a license revenue sharing obligation while companies with a commercialized product have a royalty sharing obligation. A royalty sharing obligation is one-tenth of 1 percent for each \$1 million of CIRM funding. In addition, there is an ongoing obligation for revenues over \$500 million of an additional 1 percent.

CIRM Response to the Performance Review

Mark Steranka, Director of Planning and Policy for Moss-Adams presented their performance audit and recommendations. Alexandra Campe from CIRM walked the council through the 24 recommendations. Ms. Campe committed to completing all of Moss Adams recommendations by June 30, 2013.

Currently, CIRM has completed 13 of the 24:

1. Grants Management System (GMS) IP module was released in October 2012 to gather data from grantees. This allowed CIRM to gather the full set of information in a more consistent manner from the Technology Transfer offices.
2. GMS IP module includes specific questions regarding commercialization activity.
3. A communication plan was completed in February 2013. The priorities set in the plan provide a better use of staff resources to focus on building stronger, more direct ties to the patient community by bringing that work in-house.
4. In November 2012, the Office of Administrative Law approved change to Grants Administration Policy (GAP) to require a Grant Outcome Closeout Survey.
5. The GMS incorporated milestones and requirements in the project management software, Mingle. Oversight of milestones and requirements are ongoing.
6. CIRM created bond forecasting procedures. The use of single reference file which is updated regularly by the Bond Finance Unit and Science Office has increased efficiency of staff workflow. The bond forecasting procedures enhanced strategic cash flow forecasting for the Institute.
7. Approved a checklist modified to ensure the required information is retained in a procured file maintained by the Contracts Administrator.
8. The SCO system access was completed in July 2012 with limited secured access to fiscal information.
9. A formal business plan was developed that addresses CIRM's strategic goals to engage with industry.
10. CIRM has a new website which has been integrated with the GMS. The GMS provides automatic updates to the CIRM website about new applications, funding, and progress reporting.

These automated features save several days per month of staff time and will provide the public with more accurate, timely and comprehensive information.

11. A management program was completed to integrate new employees faster with orientation information.
12. An Independent Citizens Oversight Committee (ICOC) Board Code of Conduct was adopted on May 24, 2012.
13. Forms have been developed to collect COI, confidentiality and financial disclosure information from the Grants Working Group.

IOM Report

Professor Eisenberg who served on the Institute of Medicine's (IOM) CIRM Review Committee and a professor of law at the University of Michigan Law School updated CFAOC on IOM recommendations. The IOM recommendations include:

1. Separate operations from oversight. CIRM management and staff should be focusing on operations and the ICOC focusing on oversight. The board should focus on strategic planning, oversee financial performance and legal compliance, assess the performance of the president and the board, and develop a plan for transitioning CIRM to sustainability. The board should oversee senior management, but should not be involved in day-to-day management.
2. Majority of the board members should be independent from personal, professional or institutional interest that might compete or conflict with the interest of CIRM and the people of California.
3. ICOC could benefit from more industry representation.
4. The current working groups should report to CIRM management rather than to the ICOC. The Chair and other ICOC members should be prohibited from serving on the working groups.
5. CIRM should revisit its conflict of interest to recognize conflicts arising from nonfinancial interests such as the potential for conflicts arising from an individual's interest in a specific disease.

CIRM Response to the IOM Report

Chairman Thomas responded that his plan addressed the IOM recommendations. Member Lipson asked specifically about CIRM's response to conflict of interests. Member Lipson raised the issue around deans of medical schools participating as board members while receiving grants worth \$10 - \$80 million.

Chairman Thomas explained their peer review group process is conflict free. This process is made up of stem cell experts from around the world with no connection with California. After the peer review process, the board takes a vote on the various potential projects. Prior to discussion and voting, board members are given a list of grant proposals where they

have conflicts and they are not allowed to participate in the discussion of those grant proposals. Deans of medical schools on the board are not allowed to vote on their own projects.

In terms of addressing the perception of conflict issue, Chairman Thomas recommended removing members from institutions from the board. However, this option would require legislation and maybe an additional ballot measure. Option two is to remove these members out of the discussions pertaining to voting on grants, strategic plan, and transition.

Chairman Chiang asked for further elaboration on recommendation to eliminate dual executives and overlapping responsibilities. Chairman Thomas felt that all scientific operations should be delegated to the president. Whereas government relations, bond financing, public communications should be the responsibility of the President.

Member Kovach inquired about the appeals process. Currently, the only appeal process is based on a conflict of interest. When applicants send letters to the board or to appear at public meetings, there is an extraordinary petition policy. This policy requires the applicant submit their appeal in writing to CIRM staff at least five days before a board meeting.

Committee Actions

The committee adopted the transcript of the January 28, 2012 CFAOC meeting. (2/20/13 minutes, p. 5)

Public Comments

No public comment was made at the February 20, 2013 meeting.

**Citizens Financial Accountability Oversight Committee
to the California Institute for Regenerative Medicine
c/o State Controller's Office
Post Office Box 942850
Sacramento, California 94250-5874
<http://www.cfaoc.ca.gov>**