



JOHN CHIANG
California State Controller

April 4, 2011

To the People of California:

I am pleased to present the sixth 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.

Seven 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 CIRM. 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

John Chiang was first elected in November 2006 to serve as Controller of the State of California. He was elected to serve a second term in November 2010.

Since taking office in January 2007, Controller Chiang took immediate action to make the State's finances more transparent and accountable to the public and to weed out waste, fraud and abuse of public funds.

He has led efforts to reform the State's public pension systems, helped local governments navigate difficult economic times, protected California's precious natural resources, returned more than \$1.6 billion in unclaimed property to the rightful owners, and launched financial and tax assistance seminars for California's working families, seniors, small businesses and non-profit organizations.

The Controller's aggressive audits have in identified \$3 billion in taxpayer dollars that were denied, overpaid, subject to collection, or resulted in revenues, savings and cost avoidance.

As the State's chief fiscal officer, Chiang 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.

The son of immigrant parents, Chiang 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 Athleticode Inc., appointed by the ICOC Chair

Dr. James Kovach is currently the CEO and founder of Athleticode, 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.

Sixth Annual Meeting

Meeting Details

The sixth annual meeting of the Citizens Financial Accountability Oversight Committee was held on January 28, 2011, at the Metropolitan Water District, 700 N. Alameda Street, in Los Angeles. All six members were in attendance. The Committee welcomed Dr. James Kovach, the newest member who replaced Dr. Daniel Hollander.

Financial Presentations

On January 28, 2011 the Committee heard presentations regarding the independent audit of CIRM; the State Controller's Office's review of that audit; a status update of CIRM's financial performance and grants awards process. The Committee heard a presentation from CIRM on the "Report of the External Advisory Panel," and discussed the new provisions laid out for CIRM in SB 1064 (Alquist), Chapter 637.

Independent Audit

Russel Robertson, with the independent audit firm Macia, Gini & O'Connell (MGO), presented MGO's audit covering Fiscal Year 2009-10. CIRM ended Fiscal Year 2009-10 with net assets of \$495,807,268, compared to \$294,677,818 in the prior fiscal year. CIRM's cash and investments balance was \$427,621,888, an increase of \$59,278,203 from the balance of the prior fiscal year. General revenues were \$275,717,525 for Fiscal Year 2010, representing a decrease of \$234,306,823 from the

prior year. Expenses for Fiscal Year 2010 were \$144,588,965, a \$6,097,272 decrease from the prior year.

The audit offered a clean opinion, meaning the financial statements present fairly the financial position of the governmental activities and the major fund of CIRM as of June 30, 2010. The audit did not identify any deficiencies in internal controls on financial reporting.

(1/28/11 minutes, p. 6-8)

The MGO audit report for FY 2009-10 can be found online at <http://www.sco.ca.gov/Files-EO/CFAOC/CIRM - 2009-10 Audit.pdf>

State Controller's Office Review

Caroline Baez, Manager, Financial Audits Bureau, with the State Controller's Office (SCO), reported on the SCO's review of the MGO audit. She emphasized 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. The SCO found that the audit was performed in accordance with audit standards and requirements.

(1/28/11 minutes, p. 12-13)

The SCO report can be found online at

<http://www.sco.ca.gov/Files-EO/CFAOC/Controller response to audit review report S11CRM001.pdf>

Status Update of CIRM

Chila Silva-Martin of CIRM presented the final overview of CIRM's 2009-10 operating budget and reported on the 2009-10 budget expenditures through December 31, 2010. She explained that CIRM spent roughly 95 percent of its budget and left \$660,000 of the total budget in savings for Fiscal Year 2009-10. For the July through December reporting period of FY 2010-11, CIRM had an overall budget of \$6.8 million, of which it spent \$6.2 million through December 31, 2010.

Dr. Lipson asked for an explanation of the considerable increase of \$1.4 million for salaries and benefits compared to the prior year. Ms. Silva-Martin mentioned that there were some previous year vacancies that were filled in 2009-10. She also explained that benefit costs increased as CIRM employees began to vest into the PERS retirement system. Dr. John Robson, Vice President of Operations for CIRM, added that \$400,000 went to benefits for employees that were vested and the other increase was due to filling three positions, one of which was for the Vice President for Research and Development, which is an expensive position.

Chair Chiang questioned the size of the contract budget, particularly in light of the lift on the employee cap. Dr. Robson responded that the 50-person cap was just lifted on January 1, 2011. He stated that most of the contracts were for software developers building the grants management system. Mr. Lott asked why the grants management system is being built now, as CIRM has been established for six years. Dr. Robson gave a quick history on the previous methods for tracking grants from the use of excel spreadsheets to commercial database products, but these did not satisfy CIRM's needs. Dr. Lipson then questioned the other outside contacts CIRM has in other areas such as communications and legal. Dr. Robson gave a description of the level of service and necessity for the outside contracts. The Communications contracts provide a number of services including website support and educational outreach, as the internal communications team at CIRM is too small to support everything. Mr. Art Torres, Vice Chair of CIRM, validated the need for such large outside legal contracts due to the number of lawsuits CIRM faced in the early years and because decisions made by the board need to be reviewed by an outside objective counsel. Chair Chiang asked for details on the \$649,000 that was allocated for other operating expenses. Ms. Silva-Martin stated that the money was distributed for office furniture, office supplies, minor equipment, maintenance, IT support, and communications costs. Dr. Robson also explained that \$180,000 was spent on an external review of the scientific programs and progress the organization made since 2006. There was also a later discussion on the use of an outside PR firm. Dr. Alan Trounson, President of CIRM, explained that CIRM has received a lot of negative publicity and it is important to have the use of an external PR firm to educate the public, provide daily news clips, and help formulate responses to criticism when the need arises, and that other state agencies don't have the capacity to provide the kind of services CIRM needs due to their own personnel needs. Mr. Torres explained that CIRM recently decided to hire their own communications staff and move away from such heavy reliance on external firms.

Dr. Robson gave an overview of the 6 percent administrative limit placed on CIRM in Proposition 71. This means CIRM has \$180 million, or 6 percent of the \$3 billion for administration funds. He explained that it is a tough balancing act to spread out the money. To date, they have spent about \$40 million of the \$180 million, and anticipate that once they start slowing down awarding grants, their administrative fees will decrease because CIRM will not have a need for as many personnel positions. CIRM anticipates being able to build up to 60 employees with some outside contracts and maintain that until at least 2016, when the grant awarding will begin to decline. Dr. Brunner asked whether money could be used for grants if CIRM does not use the full 6 percent. Dr. Robson stated that the left over administrative money could be used for grants.

Dr. Kovach asked about the use of CIRM funds in the future. Dr. Robson stated that CIRM would always be funding basic research. He emphasized that as CIRM has moved out of the startup phase, it needs to shift its focus more on clinical issues. In terms of loans and grants, Chair

Chiang asked what the return to CIRM is. If companies have developed a product with CIRM grants, CIRM will receive some royalties, which will go straight to the General Fund. However, on loans given out by CIRM, the repayment goes directly to CIRM and can be recycled to give out more grants. Chair Chiang asked if the Governor's plan to not sell any bonds would impact the awarding of grants. Dr. Trounson stated that it would not affect any grants until the middle of next year. At this time CIRM has only one loan in 380 projects, but the board has decided to make the loans more attractive to the business sector. The grants that are in the clinical trial all will involve loans, and those loans will return the money with interest to CIRM. James Harrison of CIRM explained that these loans are difficult because they are trying to solicit companies that would not normally get loans from any bank. He said it is called the "Valley of Death," where companies have a great idea, but it is too new and uncertain, making it difficult to obtain funding for the early phases. CIRM is pursuing product-backed loans, a loan where repayment of the principal and interest is contingent upon success of the CIRM-funded project. They would be required to pay up to 500 percent of the principal of the loan back to CIRM in addition to the principal and interest. Another loan is a company-backed loan, where the company is required to repay the loan regardless of whether the product that CIRM has funded is successful or not. The money does not go back to pay bonds, but it is recycled to pay for more grants. Chair Chiang asked if the Governor's plan to not sell any bonds would impact the awarding of grants. Dr. Trounson stated that it would not affect any grants until the middle of next year.

(1/28/11 minutes, p. 14-54)

Committee Discussion

Discussion of SB 1064

Mr. Torres started by saying that CIRM took very seriously the transcript from last year's meeting and tried to implement all of the recommendations from the Committee that it could. The remainder of the recommendations CIRM adhered to were in SB 1064 (Alquist). CIRM is working on establishing parameters for the performance audit, and plans to review 2010 and 2011. They have adopted the Intellectual Property (IP) provisions that were in SB 1064 and also recommended by the Committee last year. These IP requirements include codifying the existing CIRM regulations regarding IP standards that require grantees to submit plans to provide low-income Californians access to drugs that are entirely or partly a result of CIRM-sponsored research, and requiring all revenues received from the IP agreements to be deposited in the state General Fund. They have not done anything with the 50 person cap yet, as that was just lifted at the beginning of January. CIRM acknowledged that they will also publish the ICOC vote tallies and conflicts of interest in the minutes of the ICOC meetings. Mr. Torres added that they began posting their financial

disclosures (Form 700s) on the CIRM website and will post on a quarterly basis, which was a recommendation of the Committee last year.

Mr. Torres pointed to efforts they are making to become as transparent as possible in the selection of the next Chair. A survey has been provided to the Board members to evaluate themselves to determine what type of Chair they really want and what qualities they want the Chair to possess. Once the survey is completed they will report the results to the Controller. Mr. Lott asked if CIRM would be clarifying the division of labor between the president and chairperson to ensure these positions are separate. Dr. Trounson stated that the new chairperson may want to do things differently than Mr. Klein but that the boundaries of the two positions seemed clear. Mr. Lott expressed concern that there was not enough separation between the two. Dr. Trounson explained that the ICOC is not a conventional board, and that he believes there is distinct clarity of these positions.

Presentation of CIRM’s “Report of the External Advisory Panel”

Dr. Trounson explained that the purpose of the review was set up in the 2006 strategic plan to have an outside assessment in the third and seventh year. This external review was of the third year of operations. The goal was to look at CIRM’s progress in its programs, and its effectiveness, in accomplishing the overall mission, and to recommend changes in the funding priorities. The panel was made up of stem cell experts from around the world. The ICOC will review and finalize its response and post it to its website in mid-March.

The review panel provided the following feedback in their report: First, maintain focus on meaningful scientific excellence. Dr. Trounson’s interpretation is that CIRM ensure that the scientific integrity of the grants review is maintained and improved. Second, sustain fundamental discovery, meaning maintain strong basic science discovery and training programs, which CIRM will continue. Third, have a path from fundamental to transcriptional research. CIRM’s interpretation is to take the clinic translational medicine, product development, and healthcare delivery to the people of California. Dr. Trounson said CIRM is trying to take a proactive approach on these matters. The panel directed CIRM to look at their current portfolio, narrow it to programs that will be successful, and move forward with those. CIRM also will focus on the projects that have the greatest chance of clinical success. The panel felt CIRM’s major weakness was a lack of industry engagement. They wanted CIRM to be more engaged with the biopharmaceutical industry. Mr. Lott questioned how CIRM can

prevent conflicts of interest, and Dr, Trounson assured the Committee that they are as transparent as possible. CIRM wants to meet the interests of California.

There was a discussion on how the grant selection process works and whether there are conflicts for board members choosing grants that benefit their organizations. Dr. Lipson brought up the question, saying he asked about this last year and it was not addressed. Dr. Trounson explained that companies and academics can both apply and they go through the same process, and grants are awarded based on the one that has the best science. To prevent favoritism, the process is blind, meaning the board members do not know what organizations each application represents. Any person that may present a conflict of interest for any application will be excluded from participating in that grant review.

Committee Actions

The Committee took no action at the meeting on January 28, 2011.

Public Comments

No public comment was made at the meeting on January 28, 2011.

**Citizens Financial Accountability Oversight Committee
to the
California Institute for Regenerative Medicine**

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