



JOHN CHIANG
California State Controller

April 7, 2009

To the People of California:

I am pleased to present the third 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. The CFAOC was created by Proposition 71 to “review the annual financial audit, the State Controller’s report and evaluation of that audit, and the financial practices of the institute.” The CFAOC must meet annually to review the finances of CIRM and issue an annual report.

Five 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,

Original signed by

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 76 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. 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. and his MBA degree from the University of Redlands. He serves on the boards of the L.A. Care Health Plan, Insure the Uninsured Project, the Los Angeles Economic Development Corporation and he is the Senate Appointee to the Citizens' Financial Accountability Oversight Committee for stem cell research in California.

Myrtle Potter

President & CEO, Myrtle Potter And Company, LLC, appointed by the ICOC Chair

Myrtle Potter's professional experience includes close to 30 years of successful operating and general management experience in large, global biotechnology, pharmaceutical and healthcare businesses. She served in executive roles at Genentech from 2000-2005, helping steer the company through one of the most profitable periods in its history.

While president of Commercial Operations and COO, Potter oversaw the successful launch of six products including the blockbuster Avastin™. Prior to Genentech, Potter was president of Bristol-Myers Squibb's multi-billion dollar U.S. Cardiovascular/Metabolics Business. During her tenure, this was the company's largest source of sales, growth and profits.

For the 14 previous years, Potter worked at Merck where she established the new pharmaceutical company, Astra/Merck, Inc. (now Astra Zeneca). She also led the marketing of the prescription drug Prilosec® and set it on course to become the largest pharmaceutical product in the world.

In 2005 Potter established a number of privately held real estate development businesses.

Potter has received numerous awards and honors during her career. In 2009 Ms. Potter was honored as an "Everyday Icon" by *Glamour* magazine and in 2008 she was named one of "50 Directors under 50" by *Directorship* magazine. In 2007 Legal Momentum, the legal defense fund for the National Organization for Women, named her "Woman of the Year". Potter was also featured in Business Week in 2007 as "An Entrepreneur to Watch". In 2006 she was named "Woman of the Year" by the American Diabetes Association and in 2005 and 2004 she was featured by *The Wall Street Journal* which listed her as one of its "50 Women To Watch." In 2003 and 2004 she was listed in *FORTUNE* magazine's "Top 50 Most Powerful Women In Business" list.

Potter has received numerous honors and accolades during her career, including recognition in 2006 by the American Diabetes Association as 'Woman of the Year'. In 2004 and 2005 *The Wall Street Journal* named her as one of its "50 Women To Watch." In 2003 and 2004 she was named to *FORTUNE*'s "Top 50 Most Powerful Women In Business" list and to *Time* magazine's list of "Global Influentials".

Potter serves as a member of the Board of Directors for Amazon.com, Medco Health Services and Eleuthera Properties Limited. She holds a Bachelor of Arts degree from the University of Chicago.

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.

Third Annual Meeting

Meeting Details

The third annual meeting of the Citizens Financial Accountability Oversight Committee was held on July 7, 2008, in the Board Chambers room of the County Administration Center at 1600 Pacific Highway in San Diego. Five of the six members were in attendance. Jim Lott was absent.

Financial Presentations

The Committee heard presentations regarding the independent audit of CIRM; the State Controller's Office's review of that audit; the 2007-08 SCO review of CIRM's Conflict-of-Interest Policies, Grant Administration, Administrative Expenses and Expenditures; CIRM's final

response to the BSA audit; and a status update of CIRM's financial statements, grants awards process, best practice considerations and intellectual property regulations.

Independent Audit

Anthony Neequaye with the independent audit firm, Macia, Gini & O'Connell (MGO) presented their audit covering Fiscal Year 2006-07. CIRM ended Fiscal Year 2006-07 with a net asset deficit of - \$22,203,251 compared to the end of the prior fiscal year deficit of - \$15,204,115. CIRM's cash and investments balance was \$180,152,735, an increase of \$177,501,161 from the balance of the prior fiscal year. CIRM had program revenues of \$411,107, which represents a slight increase of \$61,107 from the prior year. Additionally, general revenues were \$4,567,783 for fiscal year 2007 representing an increase of \$4,494,067 from the prior year. Expenses for fiscal year 2007 were \$11,978,026, a \$6,107,418 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, 2007. The audit did not identify any deficiencies in internal controls on financial reporting. MGO recommended that CIRM adopt formal policies for monitoring and reviewing compliance with debt service agreements and donor contribution requirements. CIRM agreed that a formal policy should be in place.

The MGO audit report can be found online at

<http://www.sco.ca.gov/eo/cfaoc/meetings/yr2008/index.shtml>

State Controller's Office Review

Carolyn Baez, Audit Manager with the State Controller's Office (SCO) reported on their review of the MGO audit. She emphasized that the objective of their review was to determine whether the audit was performed in accordance with generally accepted auditing standards set forth in *Government Auditing Standards (GAS)*. The SCO found that the audit was performed in accordance with the standards set forth in GAS.

The SCO report can be found online at

<http://www.sco.ca.gov/eo/cfaoc/meetings/yr2008/index.shtml>

The Chair inquired about a formal policy, recommended by the management letter, which should be in place for monitoring and reviewing donor contribution agreements. Ms. Baez reported that the SCO did not review any recommendations, other than to see if they were supported by the audit.

SCO Review of the Conflict-of-Interest Policies

In November 2007, the Chair directed his staff to perform a review to determine whether CIRM complied with the requirements of Proposition 71 as it relates to CIRM's conflict-of-interest policies, Grant

Administration, and Administrative Expenses and Expenditures. The scope of the audit was planning and performing review procedures.

Suzanne Goodwin-Stenberg, an Audit Manager at SCO, delivered the results of the audit. SCO found CIRM's Conflict-of-Interest policies and procedures to be adequate and properly followed, with the exception of specialists used by grant working groups who failed to sign post-review conflict-of-interest certification forms. She reported that SCO recommended specialists sign the post-review certification form regarding Conflict-of-Interest, regardless of the circumstances of the meeting. CIRM has since then implemented that recommendation.

The SCO report can be found online at

<http://www.sco.ca.gov/eo/cfaoc/meetings/yr2008/index.shtml>

CIRM's Final Response to BSA Audit

Tamar Pachter, General Counsel for CIRM, gave a summary of the scope of the BSA audit and a report on how CIRM has implemented the recommendations of the audit, one year later. The purpose of the BSA audit requested by the Joint Legislative Audit Committee in 2006, was to review the implementation of Proposition 71 and the performance, policies, and oversight of CIRM and the ICOC.

Pachter presented all fourteen recommendations and provided updates regarding actions taken by CIRM that were outlined in their one year, final response letter. CIRM reported, at one year, all recommendations were implemented or otherwise resolved.

CIRM's response to the BSA audit can be found online at

<http://www.sco.ca.gov/eo/cfaoc/meetings/yr2008/index.shtml>

Status Update of CIRM

Mr. Klein, the ICOC Chair, provided an update of CIRM's financial status. He stated that CIRM had just gone through a Controller's audit, which he emphasized as an important process in gaining public confidence. CIRM has now been audited by all three branches of government, and all three found CIRM in compliance with Proposition 71.

Klein reported that CIRM has awarded \$560 million in grants to date and discussed the awards process. The \$270 million in facilities grants required matching fund commitments which led to a total of \$1.15 billion in commitments.

Klein pointed to an economic analysis done by an economist at Stanford University School of Medicine who does cost-benefit studies for health care institutions, to show that CIRM was not just contributing to stem cell research but also financially to the state. The study showed that donor and institutional matching funds were 281 percent higher than

expected in the original projections. The result would be much higher tax revenues and more jobs than what was previously expected.

Dr. Penhoet reported on the development of the intellectual property policy. Both the non-profit and for-profit policies are before the Office of Administrative Law. The process was very public with extensive feedback from stakeholders. Both require that any company which develops a product based on CIRM funding must develop an access plan for uninsured Californians who cannot afford the product.

Lipson expressed concern about the facilities grants and how CIRM will ensure they are not used for work besides stem cell. He also questioned the relationships with outside scientists and how CIRM is protecting ideas of grantees from being taken by reviewers.

Committee Actions

The Committee formally approved a motion (5-0) to notice the Office of Administrative Law of the Committee's intent to comply with the Conflict of Interest Code pursuant to FPPC regulation 187512(c)(3). This code provides for the broadest economic disclosure as required by the Governor and the Legislature. It requires that Committee members file annual statements of economic interest that disclose all sources of income, all interest in real property and all investments.

Committee Discussion

SB 1565 (Kuehl and Runner)

The Committee heard a presentation and had a discussion about SB 1565. Lark Park, a staff consultant of the Senate Health Committee, gave the presentation, and addressed all concerns by the committee and public. The bill calls for a study of CIRM by the Little Hoover Commission and requires grantees and licensees to submit plans showing how uninsured Californians will have access to drugs developed with CIRM funding.

The Chair expressed his support for the bill and emphasized the importance of a transparent governance structure and assurance that low-income Californians have access to the drugs that are developed within CIRM. Member Potter agreed that the bill had a good mission, but encouraged the members of CIRM to continue to work with the legislative staff to fix the bill, because it does have flaws. Klein and other CIRM staff expressed their concerns about the bill.

SB 1565 (Kuehl and Runner) can be found online at <http://www.sco.ca.gov/eo/cfaoc/meetings/yr2008/index.shtml>

The Chair explained that at the last meeting concerns were presented regarding reports of Conflict-of-Interest rule violations by Dr. John Reed, an ICOC appointee. The Chair, at the time, made a request of the FPPC to investigate this issue, and as of the date of this meeting they had not received a response.

Public Comments

John Simpson, with Consumer Watchdog, addressed the CFAOC throughout the meeting. He said the fact that the SCO review of the independent audit found all procedures to be in compliance with Proposition 71, was a result of Proposition 71 having built in conflicts of interest. Simpson believes the problems to be inadequately addressed by the very structure of the board. Simpson also commented on the public process CIRM used to develop the intellectual property regulations and acknowledged that CIRM has improved the transparency of its process. He applauded the Chair for supporting SB 1565.

Don Reed, with Californians for Cures, also made some remarks at the meeting, regarding conflicts of interest. Commending the efforts of the ICOC, he stated that they do try to follow the letter of the law, and try to minimize conflicts of interest. Reed also expressed concerns about SB 1565 stating that he would like to see the ICOC maintain flexibility in pricing for orphan drugs, of which his son would be a recipient.

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

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