

Proposition 71: Californians Pledge Three Billion Dollars to Support Stem Cell Research

Background on Proposition 71

On November 2, 2004, California voters issued a historic mandate for stem cell research by passing Proposition 71, the California Stem Cell Research and Cures Initiative. Supported by 59% of California voters, Proposition 71 will infuse \$3 billion dollars into stem cell research at California universities and research institutions over the next 10 years.

The passage of Proposition 71 brings about several immediate changes. First, Proposition 71 creates a state constitutional right to conduct stem cell research. Second, Proposition 71 establishes a state agency, the California Institute for Regenerative Medicine, to direct and oversee California's stem cell research program, the largest effort of its kind in the world. Proposition 71 also expressly prohibits the funding of human reproductive cloning; instead, priority funding is given to pluripotent stem cell and progenitor cell research that is unlikely to receive federal funding.

Beginning in 2005, up to \$3 billion dollars in bonds may be issued and sold over a 10-year period, subject to an annual limit of \$350 million. If less than \$350 million in bonds is issued in any year, the remaining permitted amount can be carried over to one or more subsequent years. Proceeds from the bond sales, after repayment of start up costs, will be deposited into the California Stem Cell Research and Cures Fund and allocated according to specific guidelines.

Hierarchy and Timeline for Implementation of Proposition 71

The California Institute for Regenerative Medicine is the agency primarily responsible for carrying out the purposes of Proposition 71. To effectuate Proposition 71's mission, the Institute is charged with making grants and loans for stem cell research and facilities and establishing regulatory standards and oversight bodies for research and facilities development. The Independent Citizen's Oversight Committee (ICOC) is the Institute's governing body. Members of the ICOC are appointed by various university and state officials. The ICOC is composed of representatives from California universities, including the University of California, non-profit research institutes, California commercial life science entities, and various disease advocacy groups. On December 17, 2004, the State Treasurer and State Controller convened a special meeting to swear-in ICOC members. At this meeting, the Chairperson and Vice-Chairperson of the ICOC were elected by the newly sworn-in ICOC members, bringing the total composition of the ICOC to 29 committee members. (see page 2 for a list of the Members of the ICOC)

One of the ICOC's first tasks will be the election of a President for the Institute. The ICOC may also authorize up to 50 employees to staff the Institute. In addition to making appointments, the ICOC's responsibilities include overseeing the Institute's operations, developing long-term strategic plans

for the Institute, and making final decisions on research standards and grant awards.

To assist the ICOC in making its final decisions, the ICOC will establish three working groups, each with specific responsibilities. The Scientific and Medical Accountability Standards Working Group is charged with numerous tasks, including the recommendation of scientific, medical and ethical standards to the ICOC. It is composed of 19 members, including five ICOC members, nine scientists, and four medical ethicists. The Scientific and Medical Research Funding Working Group is responsible for recommending interim and final criteria for funding research applications and for

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awarding research grants and loans. It is composed of 23 members, including seven ICOC members and 15 scientists. Lastly, the Scientific and Medical Facilities Working Group is responsible for recommending interim and final criteria for funding facilities and equipment applications and for awarding such grants and loans. This working group is composed of 11 members, including six members from the Scientific and Medical Research Funding Working Group and four real estate specialists. The ICOC Chairperson will serve as the final member of all three working groups.

To facilitate a speedy start, Proposition 71 imposed fairly rigid deadlines on the creation and establishment of the ICOC. The proposition called for appointments to the ICOC to be completed within 40 days following the passage of Proposition 71. It also required the State Controller and Treasurer to convene a special meeting of the ICOC within 45 days following the passage of Proposition 71 so the ICOC can elect a chairperson and vice-chairperson. Within 30 days following the first meeting of the ICOC, the ICOC must select members for the working groups.

The deadlines that Proposition 71 imposes on its working groups are less firm. However, Proposition 71 provides some built-in deadlines that can be triggered as the working groups accomplish certain milestones. For example, after the Scientific and Medical Research Funding Working Group recommends interim standards to the ICOC, and these standards are adopted by the ICOC, the Scientific and Medical Research Funding Group Working Group must recommend its first grant awards within 60 days following the issuance of such standards.

Issuance and Sale of Bonds

Proposition 71 authorizes the issuance and sale of up to \$3 billion dollars in general obligation bonds for stem cell research. To facilitate this process, Proposition 71 establishes a committee, the California Stem Cell Research and Cures Finance Committee, to

Elected and Appointees Members of the Independent Citizens Oversight Committee

ICOC Chairperson: Robert N. Klein, II, J.D., Prop 71 campaign committee, President, Klein Financial Corp., elected by a quorum of ICOC members on December 17, 2004

ICOC Vice Chairperson: Edward Penhoet, PhD, President, Gordon and Betty Moore Foundation, co-founder, Chiron and Renovis, former Dean, UC Berkeley School of Public Health, elected by a quorum of ICOC members on December 17, 2004

University of California Medical School Chancellors' Appointments:

UCD: Claire Pomeroy, M.D., M.B.A., incoming VC, Human Health Sciences, Dean, School of Medicine

UCI: Susan V. Bryant, PhD, Dean, School of Biological Sciences

UCLA: Gerald S. Levey, M.D., VC, Medical Sciences, Dean, School of Medicine

UCSD: Edward W. Holmes, M.D., VC, Health Sciences, Dean, School of Medicine

UCSF: David A. Kessler, M.D., J.D., VC, Medical Affairs, Dean, School of Medicine

Other California Universities:

UC Berkeley: Chancellor Robert J. Birgeneau, PhD, appointed by Lt. Governor Bustamante

CalTech: President David Baltimore, PhD, appointed by Treasurer Angelides

Stanford: Medical School Dean Philip Pizzo, M.D., appointed by State Controller Westly

USC: Medical School Dean Brian Henderson, M.D. appointed by Governor Schwarzenegger

Nonprofit CA Research Institutions:

Burnham Institute: CEO John C. Reed, M.D., PhD, appointed by State Controller Westly

Cedars-Sinai Medical Center: Keith L. Black, M.D., Dir., Maxine Dunitz Neurosurgical Institute, Dir. Neurosurgery, appointed by Governor Schwarzenegger

City of Hope: CEO Michael Friedman, M.D., appointed by Treasurer Angelides

Salk Institute: President Richard A. Murphy, PhD, appointed by Lt. Governor Bustamante

CA Life Sciences Commercial Entities:

Michael Goldberg, M.B.A., Bd. Member, Genomic Health (Redwood City), appointed by Treasurer Angelides

Ted W. Love, M.D., CEO, President, Nuvelo Inc. (Sunnyvale), appointed by Controller Westly

Tina Nova, PhD, CEO, President, Genoptix Inc. (San Diego), appointed by Lt. Gov. Bustamante

Gayle Wilson, member, Bds. of Directors, Gilead Sciences, Inc. (Foster City), Chela Financial and Ralph M. Parsons Foundation; Member Bd. of Trustees, CalTech; former First Lady, appointed by Governor Schwarzenegger

Disease Advocates:

AIDS/HIV: Jeff Sheehy, member, Survive AIDS, Deputy Dir., Communications, UCSF AIDS Research Institute, HIV/AIDS advisor to SF Mayor Gavin Newsom, appointed by prior Senate pro Tem John Burton

Alzheimer's: Leon J. Thal, M.D., Director of Alzheimer's Disease Research Center, Professor and Chair of Neurosciences, UC San Diego, appointed by Governor Schwarzenegger

Cancer: Sherry L. Lansing, Chairman, CEO, Paramount Pictures, Chair, Stop Cancer; UC Regent; appointed by Controller

Type I Diabetes: Francisco Prieto, M.D., President, Sacramento-Sierra Chapter, American Diabetes Association, physician, Sutter Medical Group, Elk Grove, appointed by Treasurer Angelides

Type II Diabetes: Phyllis Preciado, M.D., Clinical Instructor, UCSF-Fresno Medical Education Program, Dept. of Family and Community Medicine, Diabetes management program, Fresno Chapter President, California Latino Medical Association, appointed by Lt. Gov. Bustamante

Heart Disease: Janet Wright, M.D., Medical Director Cardiology, Enloe Medical Center, Chico, member, American Heart Association, appointed by Treasurer Angelides

Mental Health: Jonathan Shestack, L.A., founder, Cure Autism Now, appointed by Speaker Nunez

Multiple Sclerosis: David Serrano Sewell, J.D., Deputy City Attorney, San Francisco, appointed by Lt. Gov. Bustamante

Parkinson's: Joan Samuelson, J.D., founder and President, Parkinson's Action Network, appointed by Controller Westly

Spinal Cord Injury: Oswald Steward, PhD, Chair and Director, Reeve-Irvine Research Center for Spinal Cord Injury, UC Irvine, Prof. Anatomy and Neurobiology, appointed by Governor Schwarzenegger

oversee the sale and issuance of bonds. Composed of several state officials, ICOC members and the ICOC Chairperson, the Finance Committee is charged with the responsibility of issuing bonds and determining the amount of bonds to be issued in each year. The Finance Committee may issue up to \$350 million in bonds per calendar year; if less than \$350 million is issued in any given year, the remainder may be carried over to one or more subsequent years.

Allocation of Funds

Proceeds from the sale of bonds go towards direct repayment of interim debt incurred by the Institute; the remainder is deposited into the California Stem Cell Research and Cures Fund. A portion of the funds are earmarked for the costs of issuing and administering interim debt and bonds, as well as payment for interest on bonds during the first five years of Proposition 71's implementation. The remaining funds are allocated between grants and grant oversight. Proposition 71 sets a global cap of \$180 million dollars on institute operating and general administration costs. Of the remaining funds available for grants, 90% is allocated to research grants and 10% is allocated to grants for research facilities and equipment. With respect to the amount available for research grants, Proposition 71 imposes restrictions on the amount of research funding that may be allocated per calendar year. In Year 1, 5.6% of the funds available for research grants may be allocated; this percentage increases to 9.4% for Years 2-3, 11.5% for Years 4 - 9, and 7.5% for Year 10. In any single year, a grantee can receive no more than \$60 million dollars in research funding; however, this limitation is considered separately for each new proposal without regard to prior funding.

What Types of Research Projects Will Receive Priority Funding Under Proposition 71?

Currently, federal policy prohibits the federal funding of research on human embryonic stem cell lines that are not listed on

the NIH Human Embryonic Stem Cell Registry; according to the NIH, there are 22 human embryonic stem cell lines that federally supported researchers may purchase. Because Proposition 71 is designed to close this funding gap, priority will be given to research that is unlikely to receive federal funding, with an emphasis on pluripotent stem cell and progenitor cell research. Research categories that are currently funded by the National Institutes of Health will not be funded under Proposition 71. In some cases, funding can also be provided for other types of research that may lead to new types of cures or treatments of diseases and injuries. The Institute is not allowed to fund research on human reproductive cloning.

Who recommends and awards research grants? What criteria will be used to determine who will receive research grants?

The Scientific and Medical Research Funding Working Group is responsible for recommending guidelines for evaluating research grant applications to the ICOC. Additionally, the Working Group must evaluate and recommend applications to be funded. Proposition 71 offers some guidance as to what criteria the Working Group should use in evaluating grant applications. These criteria include: (1) applicant's record of achievement in pluripotent stem cell and progenitor cell biology; (2) the quality of the research proposal; (3) the potential for achieving significant research or clinical results; (4) the timeliness of results, (5) the importance of the research objectives; and (5) the innovativeness of proposed research. The Working Group may choose to recommend, and the ICOC may adopt, additional criteria for evaluating grant applications. The 15 scientist members of the Scientific and Medical Research Funding Working Group will score grant and loan applications for scientific merit based on these criteria and recommend prospective grantees to the ICOC.

Once the ICOC receives these recommendations, it makes the final decision on grant

awards. All ICOC actions require a majority vote of a quorum. The ICOC must award all grants, loans and contracts in public meetings.

Who recommends and awards grants for research facilities and equipment? How are grantees selected?

The Scientific and Medical Facilities Working Group is charged with the task of recommending guidelines for evaluating applications for facilities grants to the ICOC. It must also recommend grant awards. To guide the Working Group, Proposition 71 establishes some baseline criteria for evaluating such applications. First, applicants must be not-for-profit entities. Second, all funded facilities and equipment must be located solely within California. Third, grantees must secure matching funds from outside sources in an amount equal to at least 20% of the grant award; among applications of equivalent research merit, priority will be given to the applicant who provides higher matching fund amounts. The Scientific and Research Facilities Working Group may waive the matching fund requirement in extraordinary cases. Priority is given to facilities that will be available for research within two years after the grant award. The Working Group may recommend, and the ICOC may adopt, additional criteria for evaluating facilities grants.

Proposition 71 also requires its grantees to comply with various standards. For example, grantees must achieve certain facility milestones and establish timetables for achieving such milestones. Additionally, grantees must comply with the reimbursable building cost standards, competitive building leasing standards, and capital equipment cost standards ultimately adopted by the ICOC.

What legal issues should prospective grantees be aware of?

There are a number of intellectual property issues that prospective and future grantees should consider. Proposition 71 requires the ICOC to establish standards requiring all

grant and loan awards to be subject to intellectual property agreements that would allow California to share in patents, royalties, and licenses resulting from funded projects. While Proposition 71 requires the ICOC to adopt such standards, it offers little guidance as to what standards the ICOC should adopt. Instead, Proposition 71 calls upon the ICOC to balance between 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.”¹

In addition to this vague language, the newly formed ICOC has already come under political pressure to guarantee that the state recoups its investment, at least in part, through intellectual property revenues. On December 6, 2004, State Senator Deborah Ortiz, a proponent of Proposition 71, introduced legislation to ensure that California will reap the benefits of its funding. Entitled the “Proposition 71 Public Accountability Act,”² Senator Ortiz’s proposal would explicitly require the State to receive a share of royalties commensurate with its role of providing funding for the research. Political pressure has also come from other fronts. For example, in convening the special meeting of the ICOC on December 17, 2004, Steve Westly, the State Controller and Chair of the Institute’s Financial Accountability Oversight Committee, called upon the ICOC to develop creative royalty sharing agreements that would allow Californians to “benefit from the best possible deals.”³

Aside from licensing schemes and royalty-sharing arrangements, grantees must navigate through the thicket of patent rights that currently exist in the stem cell field. For example, the University of Wisconsin and Geron Corporation, a company based in Menlo Park, California, have taken strong positions with respect to their stem cell patents and claim broad patent rights to any commercial products developed with stem cells. Given the emergence of such

claims, grantees will need to carefully consider their positions and if necessary, enter into the appropriate intellectual property arrangements.

In addition to intellectual property issues, grantees should be aware of Proposition 71’s indemnity provisions. Under Proposition 71, the ICOC may sue and be sued. Proposition 71 calls upon the ICOC to establish standards that require grantees to indemnify and hold the Institute harmless against any and all losses and liabilities, arising from research conducted by the grantee pursuant to the grant. Alternatively, grantees may be required to name the Institute as an additional insured and submit proof of such insurance.

Attention should also be given to the public and financial accountability standards that the administrative bodies of Proposition 71 are required to follow. For example, Proposition 71 requires the Institute to issue a public annual report that discloses a variety of information, including the grantees for the prior year, the number and dollar amounts of research and facilities grants and a summary of research findings, including promising research areas. The ICOC is also required make all grants, loans and contracts in public meetings and adopt all governance, scientific, medical and regulatory standards in public meetings. Additionally, the records of the ICOC and its working groups must comply with the California Public Records Act. While the public meeting and public record requirements of Proposition 71 carves out exceptions for sensitive matters, including confidential intellectual property, work product, and prepublication research data, grantees need to be aware of these requirements.

Please contact members of Cooley’s Life Sciences Group with any questions you may have regarding the issues discussed in this Alert. ■

Notes

¹ Cal. Health and Safety Code § 125290.30(h).

² The Proposition 71 Public Accountability Act calls for other additional requirements. For example, the Act would require grantees to make treatments available and affordable for state programs and low-income residents. It also calls for the state to recoup its legal and administrative costs associated with patent and licensing associated with grants. With respect to the ICOC, the Act requires members to disclose economic and other interests in the same manner as other public officials. The Act also requires the ICOC to ensure that its working groups abide by open meeting laws. The validity of this legislation is likely to be challenged by the ICOC, since Proposition 71 includes a provision prohibiting amendments during the first three calendar years of the proposition’s implementation.

³ Letter to the ICOC from Steve Westly, December 17, 2004.