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April 15, 2005

The Honorable Deborah Ortiz
 California State Senate
 State Capitol, Room 5114
 Sacramento, CA 95814

RE: SCA 13 (Ortiz & Runner)

Dear Senator Ortiz:

On behalf of the California Healthcare Institute (CHI), whose more than 250 members include our state's premier life sciences companies and academic research institutions, I am writing to express concern over your measure – SCA 13. This measure seeks to change the California Stem Cell Research and Cures Act, passed by the voters as Proposition 71 in November 2004. Your measure will require the governing board of the new California Institute for Regenerative Medicine, the Independent Citizens Oversight Committee (ICOC) to be subject to certain conflict of interest rules, as well as the state's open meeting laws. Your measure also requires the state to recoup the full amount of its legal and administrative costs incurred with respect to patenting and licensing activities related to biomedical research funded by taxpayer dollars.

In November 2004, voters passed Proposition 71 by an overwhelming 59-41 percent margin. The new California Institute for Regenerative Medicine (CIRM), created by Proposition 71, will make loans and grants for stem cell research over a ten-year period from \$300 million per year in state-backed bond sales. These bonds will be sold by the state and repaid with taxpayer money. In addition to your support for Proposition 71, you have historically been a strong supporter of embryonic stem cell research and we are grateful for your leadership in this area.

With respect to SCA 13, though, CHI has concerns about the timing of the measure as well as certain provisions that, however well-intentioned, would almost certainly interfere with the CIRM's progress and pose obstacles to funding the best stem cell research. The CIRM, during its first five months, has accomplished much: appointing all 29 members of the Independent Citizens' Oversight Committee

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University of California and other leading research institutions on these complex issues. Accordingly, CHI believes the requirement that the state recoup the full amount of its legal and administrative costs incurred with respect to patenting and licensing activities related to biomedical research funded using tax-payer dollars is premature.

CHI remains deeply committed to legislation that promotes the discovery of new medical technologies for patients with unmet medical needs, recognizing also the need for oversight and guidelines. We thank you for the opportunity to share our concerns and we look forward to working with you in the future on this critically important topic.

Sincerely,

A handwritten signature in black ink that reads "David Gollaher". The signature is written in a cursive, flowing style.

David L. Gollaher, Ph.D.
President & CEO

CC: Senator George Runner
Members, Senate Health Committee
Peter Hansel, Consultant, Senate Health Committee
Senate Republican Caucus
Kacy Hutchison, Governor's Office

April 19, 2005

The Honorable Deborah Ortiz, Chair
Senate Health Committee
State Capitol, Room 5114
Sacramento, CA 95814

Dear Senator Ortiz:

On behalf of the California Institute of Technology, Stanford University, the University of California, and the University of Southern California, we are writing to express concerns about Senate Constitutional Amendment (SCA) 13, your measure that would enact a number of provisions related to the implementation of Proposition 71 and to the conduct of stem cell research in California.

The passage of Proposition 71 last Fall positioned our state to be a world leader in a promising emerging field that we hope will lead to many important advances in the understanding and treatment of human disease. We agree that it is important that this significant research initiative be implemented in accordance with appropriate guidelines and standards to assure the public that the funds are being used responsibly and ethically to fund the best possible science.

In fact, the California Institute for Regenerative Medicine (the Institute) has already begun to develop and adopt rigorous interim standards and guidelines, and plans to hold public hearings before finalizing its interim standards. We believe that the Institute should be given time to complete this process, and that therefore the provisions of SCA 13 proposing specific standards are premature.

In addition, we have the following concerns about some of the specific proposals contained in SCA 13.

Peer Review. We are concerned that the rigor of the scientific review process will be weakened significantly if the scientific peer review meetings of the Institute's Working Groups are required to be open to the public. It is certainly important and appropriate for the meetings of the Institute's Independent Citizens Oversight Committee (ICOC) to be open to the public. In contrast, it is standard practice, widely accepted in the scientific community, to conduct scientific peer review of grant applications in private. Requiring such meetings to be conducted in public would discourage the candor necessary to ensure rigorous scientific review, and could discourage applicants from sharing with the review committee details of projects that might include proprietary or unpublished results. We believe a public meeting requirement for scientific peer

revenues be shared with the State in an amount sufficient for the State to repay its expenses in developing clinical treatments and in issuing bonds associated with funding the research. Typically, the State is not directly involved in developing clinical treatments or in patenting and licensing associated with funded research; these provisions in SCA 13 raise questions about whether there is an intent that the State assume a greater role in such activities. With respect to recouping expenses associated with issuing bonds, it is unclear how a state entity would determine what bond costs are associated with any particular research project (since bonds are not issued to fund individual research projects, but are sometimes issued to provide funding for programs or buildings that may encompass many projects).

Senator Ortiz, thank you for the opportunity to comment on SCA 13. We appreciate that you have been a longstanding supporter of stem cell research. Despite our concerns about several specific aspects of your bill, we recognize that your general goal is one that we all share -- ensuring that the groundbreaking stem cell research initiative that California is undertaking is conducted in a way that makes our state a model and a leader for the nation.

We would be pleased to work with your office to elaborate on our concerns, or to provide research expertise from our respective institutions should there be specific areas about which you may have questions.

Sincerely,



President David Baltimore
California Institute of Technology



President John L. Hennessy
Stanford University



President Robert C. Dynes
University of California



President Steven B. Sample
University of Southern California

cc: Senator George Runner



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April 4, 2005

Linda L. Conte
 Office of the General Counsel
 Ethics Division
 Department of Health and Human Services
 Room 700-E, Hubert H. Humphrey Building
 200 Independence Avenue, SW
 Washington, DC 20201

Dear Ms. Conte:

I write to you on behalf of the Association of American Universities (AAU) to comment on the Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of the Department of Health and Human Services (5 CFR parts 5501 and 5502, *Federal Register*, February 3, 2005, p. 5543). AAU is composed of 60 of the leading U.S. and two Canadian research universities; its U.S. members perform 60 percent of federally funded university research and grant nearly half of all Ph.D. degrees awarded nationally.

AAU supports the effort of the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) to address activities by some NIH employees that have threatened NIH's reputation as "the jewel in the crown" of biomedical research and the federal government. NIH is the most prestigious biomedical research agency in the world, and the scientific and patient communities and the American public must have complete confidence in the operations of NIH—in both its intramural scientists' conduct and its grant-making programs that provide funding to the extramural biomedical research enterprise.

As an association of research universities, AAU does not have standing to comment on HHS regulation of its civil service employees. However, we do believe that the new and significantly tighter financial disclosure requirements should be considered carefully. In developing such standards, NIH should evaluate their prospective impact on the agency's ability to recruit and retain the best scientific talent. Recent responses to the newly implemented reporting and divestiture requirements suggest that they are harming NIH's capacity to attract and retain such highly-qualified individuals. NIH should implement standards that allow it to maintain public confidence in its operations, but it should avoid standards that exceed requirements for public accountability and impair its ability to attract the exceptional talent that the agency needs for its critical mission.

AAU also notes that HHS would allow NIH employees, with prior approval, to teach at a university, participate in continuing medical education, and edit scientific journals or textbooks. This section of the new regulations, while it may benefit from some modifications, recognizes that a critical element of the scientific process is free and open exchange among scientists in a variety of academic and research settings. We applaud NIH for allowing these types of activities and strongly encourage development of an approval process that does not hinder or delay such scientific exchange.

Thank you for allowing us to comment.

Sincerely,

Nils Hasselmo
 President, Association of American Universities

NH/FPW/kb