

**ICOC Legislative Subcommittee
Background Information on Legislation
June 20, 2008**

General Background: This year marks the first legislative session where the statutory provisions of Proposition 71 may be amended by a 70% or more vote of each house of the Legislature and with the Governor's approval. Thus far this session there are two bills that propose to amend CIRM governing statutes: AB 2381 and SB 1565.

In addition there are two other bills that address policy issues which may be of sufficient interest to the ICOC to review and to consider taking a watch, support or oppose position: AB 2663 and AB 2296.

I. AB 2381 (Mullin)

This bill would add to state statute a definition for "California supplier" for use by the California Institute for Regenerative Medicine (CIRM). In its present form, this definition is identical to the language proposed in a petition filed by Invitrogen before the ICOC at its meeting in March. At that time the ICOC decided to vet the definition with interested parties for the purposes of beginning a regulatory process for public review, comment and amendment. At the May ICOC meeting an alternate definition was discussed and the ICOC agreed to use this definition and solicit input from grantees and other interested parties. Since CIRM has the legal authority to adopt interim regulations for up to 270 days prior to formal filing with the Office of Administrative Law, the ICOC voiced its intent to adopt an interim regulation at its June 2008 meeting.

When AB 2381 was heard in Assembly Health Committee, the author acknowledged that CIRM has begun a regulatory process related to the same issue. He stated that he will drop this bill should CIRM successfully adopt a definition for "California supplier" in the regulatory process. His bill is a "placeholder," needed only if the regulatory process fails to result in a timely definition being adopted.

AB 2381 is now in Senate Health Committee and will be heard June 25, 2008. The ICOC Meeting is to be held on June 26 & 27, 2008 in San Francisco.

Should the ICOC support, oppose or watch AB 2381 given that our current policy assumes this issue will be addressed in regulation rather than statute?

II. SB 1565 (Kuehl and Runner)

SB 1565 is currently in Assembly Health Committee set for hearing on June 17, 2008 and will also be heard by the Assembly Judiciary Committee.

This bill proposes to add to state statutes two different policies related to the work of CIRM:

1. Amends into statute a different version of CIRM intellectual property policies as it relates to the approval of and pricing associated with access plans currently required from both non-profit as well as for-profit grantees.

In March of 2008 the final CIRM regulations were approved addressing intellectual property policies for for-profit grantees (regulations governing nonprofit grantees were approved in 2007).

In an effort to address outstanding concerns of some legislators about a few of the elements in these regulations, at the March ICOC meeting CIRM was directed to initiate an amendment process to these regulations to clarify CIRM's role in approving access plans. The process also will seek public comment on language in the regulations that links the pricing of products under these access plans to pricing benchmarks used in the CalRx program.

SB 1565 appears to tie the price for **any and all** commercialized products to the lowest pricing based on the current benchmarks of the CalRx program in effect at this time. Any change to that price over time, given any new circumstances, need for flexibility in order to leverage commercialization on products for "orphan diseases" or even for time itself would require a change in statute with more than 70% vote of both houses of the Legislature as well as approval by the Governor. Any change would further be delayed by a minimum of one year in order to enact authorizing statute.

Should the ICOC support, oppose or watch legislation that establishes prices fixed in statute as well as places policies already part of state regulations into statute?

2. SB 1565 also proposes to strike out a provision in Proposition 71 that requires a 2/3rds super-majority of the members of the grants working group to fund research that does not involve pluripotent or progenitor cell research.

Current law provides funding priority for pluripotent and progenitor cell research that is not receiving timely or sufficient federal funding. The law also provides that CIRM may fund other [stem cell and](#) stem cell-related research if two-thirds of a quorum of CIRM's Grants Working Group recommends to the ICOC that the proposal is a vital research opportunity ("a substantially superior research opportunity vital to advance medical science"). CIRM has not yet taken a position on this provision, but in practice, the two-thirds threshold has not prevented CIRM from funding a research proposal.

The question is if this amendment to Proposition 71 furthers the purposes of the initiative, a requirement for any amendment to the proposition.

3. SB 1565 also requests the Little Hoover Commission conduct a study of the governance structure established by Proposition 71. A report would be required by July 2, 2009, on the results of this study including any recommendations of ways to “better ensure public accountability and reduce conflicts of interest consistent with the purposes of Proposition 71.”

The Little Hoover Commission has indicated already has the authority to do such a study and it can undertake this study within existing resources; therefore, there is no need for a statute.

Should the ICOC support, oppose or watch this aspect of SB 1565?

III. AB 2296 (Mullin)

This bill establishes causes of action for civil damages and injunctive relief for actions taken against persons or property used in animal research. It also establishes crimes associated with obstructing or interfering with research facilities or programs engaged in what the bill defines as “animal enterprises.”

The bill is sponsored by the University of California whose research institutions are concerned with several incidents of attacks against property and the privacy of research personnel by those who advocate changes or prohibition of animal research in the state. The proposed language is patterned on current laws that seek to protect the free exercise of providing and receiving human reproductive health services.

Should the ICOC support, oppose or watch this legislation?

IV. AB 2663 (Dymally)

This bill establishes a policy to provide Medi-Cal coverage for the health service costs associated with participation in any clinical trial involving stem cell research. Currently the state provides similar coverage for patients enrolled in cancer research clinical trials. California also provides coverage for the hospitalization and treatment of persons with serious mental disorders as well as HIV patients participating in clinical trials.

The author does not intend to move this legislation this year but introduced the language so that interested parties can look at how clinical trials involving stem cell research are expected to be financed in the future and to consider ways to assure that Californians who need access to stem cell clinical trials have some way to be assured that their publicly financed health insurance will cover the costs of their health care during the trials.

Should the ICOC consider any role for CIRM to assist in analyzing the issues associated with access for publicly financed patients who may benefit from stem cell research clinical trials in the future?