

Date of Hearing: July 16, 2007

ASSEMBLY COMMITTEE ON APPROPRIATIONS
Mark Leno, Chair

SB 1565 (Kuehl) - As Amended: July 14, 2008

Policy Committee: Health
Vote: 16-0
Judiciary 10-0
Urgency: No State Mandated Local Program:
No Reimbursable:

SUMMARY

This bill modifies several provisions of Proposition 71, which created the California Institute for Regenerative Medicine (CIRM) to provide funding for stem cell research. Specifically, this bill:

- 1)Codifies proposed CIRM regulations to add to intellectual property (IP) standards requiring grantees to submit plans to provide low-income Californians access to drugs that are entirely or partly a result of CIRM-supported research.
- 2)Requires grantees subject to #1, above, to provide drugs to publicly funded programs in California at one of three benchmark prices in the California Discount Drug Prescription Program. Authorizes CIRM to waive this pricing requirement under specified circumstances, including when a drug is related to rare diseases recognized by the federal Food and Drug Administration (FDA).
- 3)Reduces the vote threshold for funding of research proposals supported by federal funding (generally non-embryonic-related projects) from 2/3 to a simple majority vote.
- 4)Requests the Little Hoover Commission to evaluate the governance structure of CIRM.

FISCAL EFFECT

- 1)No direct public fiscal impact to codify pending CIRM regulations.
- 2)No direct fiscal impact to the Little Hoover Commission, as

this bill is permissive with respect to the Commission. The Commission will vote on whether this request will be filled within the current budget provided to the Commission.

COMMENTS

- 1)Rationale . This bill codifies IP regulations that have been proposed with respect to making sure publicly funded programs serving low-income Californians are able to access medications that may be discovered through CIRM-supported research. Recent amendments further clarify these pricing provisions. The California Discount Drug Program was created by AB 2911 (Nunez), Chapter 619, Statutes of 2006. In addition, this bill reduces a voting threshold from 2/3 to a simple majority for proposals that qualify for federal funding.
- 2)Proposition 71 was approved by voters in November 2004 to authorize the state to sell \$3 billion in general obligation bonds to provide funding for stem cell research in California. The issue was put before the voters to address federal restrictions on the use of human embryonic stem cells. CIRM, which is governed by the Independent Citizen's Oversight Committee (ICOC), is required to award grants and loans and to adopt governance, scientific, medical and regulatory standards in public meetings. Proposition 71 requires the ICOC to establish standards for IP agreements that balance public benefit with the assurance that medical research and private investment is not hindered by IP agreements.
- 3)Federal Funding Issues . Current federal funding for human embryonic stem cell research is restricted to research involving stem cell lines created prior to 2001. Part of the genesis and voter support of Proposition 71 was for California to establish a high priority for embryonic stem cell research that otherwise fails to garner federal funding.

The current and higher CIRM voting threshold of 2/3 for

federally supported projects ensures that the emphasis remains on embryonic-related projects, which many believe hold greater immediate scientific promise. This bill changes the two-thirds voting threshold to a simple majority. The author indicates the change in the voting requirement is intended to make certain the most promising research is funded, regardless of whether embryonic or non-embryonic stem cells are used. According to CIRM, the current two-thirds threshold has not prevented it from funding a research proposal to date.

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4)Concerns from Health Consumers and Scientific Community . A number of consumer and scientific groups have expressed concerns about the IP and voting provisions of this bill. The University of California indicates that codification of proposed IP regulations is premature and the bill requires IP strategies to be implemented that have not been tested on the state or national level. Premature action in this area, as well as proposed pricing changes that would result may risk reducing industry participation. The Californians for Cures, a public policy group supporting cutting-edge research in this area, is concerned about the change in the voting threshold. The group indicates the change defies the will of the voters who created Proposition 71.

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