BILL ANALYSIS

SENATE THIRD READING
SB 1565 (Kuehl)
As Amended July 14, 2008
70% vote

SENATE VOTE :40-0

HEALTH 16-0 JUDICIARY 10-0

Ayes:	Dymally, Nakanishi, Berg, Carter, De La Torre, Caballero, Emmerson, Hancock, Hayashi, Hernandez, Huff, Jones, Lieber, Ma, Salas, Silva	Ayes:	Jones, Tran, Adams, Evans, Feuer, Keene, Krekorian, Laird, Levine, Lieber

APPROPRIATIONS 16-0

Ayes:	Leno, Walters, Caballero, Davis, DeSaulnier, Emmerson, Furutani, Karnette, Krekorian, La Malfa, Lieu, Ma, Nakanishi, Nava, Sharon Runner, Solorio

SUMMARY : Requires the intellectual property (IP) standards of the California Institute for Regenerative Medicine's (CIRM) Independent Citizen's Oversight Committee (ICOC) to include a requirement that each grantee and the licensee of the grantee submit a plan for CIRM's approval that will afford uninsured Californians access to any drug that is entirely or partly the result of CIRM-funded research, as specified. Revises the vote threshold necessary for CIRM funding of certain research proposals. Requests the Little Hoover Commission (LHC) to study the existing governance structure of the ICOC and CIRM, as specified. Specifically, this bill :

1)Requires the IP standards that the ICOC develops to include a requirement that each grantee and licensee submit a plan to CIRM that will afford uninsured Californians access to any drug that is entirely or partly the result of CIRM-funded research.

2)Directs the ICOC to require the plan to be submitted before a drug is placed into commerce, and requires CIRM to approve the plan after a public hearing and public comment period.

3)Requires the plan to require each CIRM grantee and licensee to provide drugs resulting from CIRM-funded research to publicly funded programs in California at one of the three benchmark prices in the California Discount Prescription Drug Program (Cal-Rx).

4)Provides that this bill does not preclude any public agency from obtaining prices that are lower than those in Cal-Rx, as specified.

5)Permits the CIRM to waive the requirement in 3) above under specified circumstances relating to providing access to drugs for rare diseases with small patient populations and expanding access generally.

6)Changes the vote threshold necessary for CIRM funding of certain research proposals from two-thirds to a simple majority of a quorum of the members of CIRM's Scientific and Medical Research Funding Working Group (Working Group) and clarifies that the Legislature affirms that the underlying purpose of the ICOC and CIRM is to give priority to stem cell research that has the greatest potential for development of therapies and cures.

7)Requests the LHC to study the governance structure of the California Stem Cell Research and Cures Act (Act), including the membership and relative roles of the ICOC and CIRM.

8)Requires the LHC, if it conducts the study, to report to the Legislature by July 1, 2009, on the results of the study and recommend ways that the governance structure of ICOC could better ensure public accountability and reduce conflicts of interest, consistent with the purposes of the Act.

EXISTING LAW :

1)Establishes the Act approved by voters as Proposition 71 in November 2004.

2)Establishes CIRM to award grants, loans or contracts for stem cell research and research facilities. Establishes the ICOC to oversee operations of CIRM and includes within the functions of the ICOC the responsibility to render final decisions on research standards and grant awards.

3)Requires the ICOC to establish standards to make all grants and loans subject to IP agreements that balance public benefit with the need to assure that essential medical research is not unreasonably hindered by the agreements.

4)Prohibits certain research proposals from being funded by CIRM except when at least two-thirds of a quorum of the Working Group recommend to the ICOC that such a proposal is a vital research opportunity.

5)Prohibits any amendment to Proposition 71 by the Legislature unless approved by the voters or accomplished by a bill introduced after the first two full calendar years and approved by a vote of 70% of both houses.

FISCAL EFFECT : According to the Assembly Appropriations Committee, no direct public fiscal impact to codify pending CIRM regulations and no direct fiscal impact to the LHC 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 : The author believes that Proposition 71 lacks the provisions necessary to ensure that therapies emerging from the state's stem cell research investments are available to uninsured Californians, as well as to programs that serve low-income Californians, at the best available prices. In order to ensure that the neediest Californians benefit from groundbreaking stem cell research funded by taxpayer dollars, the author contends that statutory provisions are needed to require grantees and licensees to submit a plan to afford uninsured Californians access to new drugs prior to

commercialization, and require these drugs to be sold to public programs at the best available prices. Additionally, the author asserts that changing the voting requirements for funding of other stem cell-related research from two-thirds to a simple majority of a quorum of CIRM's working group members reflects the latest scientific breakthroughs involving non-embryonic stem cell research and makes certain that the most promising research is funded, regardless of the source of the stem cells. Lastly, the author asserts that, given the ICOC/CIRM's unique formation as a public entity, the public's investment of $3 billion in bond funds, and the close-knit nature of the scientific community, the ICOC and CIRM warrant a high level of scrutiny by an independent body, such as the LHC, to ensure public trust and confidence and protect the integrity of the ICOC and CIRM from real or perceived conflicts of interest.

To date, CIRM has adopted regulations pertaining to IP requirements for nonprofit organizations, such as universities and research institutions, and for for-profit organizations, such as biotechnology companies. At the March 12, 2008, meeting of the ICOC, revised IP draft regulations were issued for grants to for-profit organizations to include language similar to this bill by requiring grantees to submit plans to afford uninsured Californians access to a drug resulting from CIRM-funded research, prior to the time the drug is brought to market, and requiring the plans to be subject to CIRM approval after a public hearing and opportunity for public comment is held. The proposed revisions also indicate that if Cal-Rx is repealed, benchmark prices must be based on the Cal-Rx benchmark prices on the last day the program is in effect.

Cal-Rx was created pursuant to AB 2911 (Nunez), Chapter 619, Statutes of 2006, to require the Department of Health Care Services (DHCS) to use manufacturer rebates and pharmacy discounts in order to reduce prescription drug prices and improve the quality of health care for eligible Californians. DHCS is required to consider three different benchmarks in negotiations with drug manufacturers: the lowest price offered to private payers; the Medicaid best price; or, the average manufacturers' price minus 15%.

Current federal funding for human embryonic stem cell research is restricted to research involving stem cell lines created prior to 2001. Current state law, pursuant to Proposition 71,

establishes a high priority for CIRM funding for embryonic stem cell research that cannot or is unlikely to receive timely or sufficient federal funding and permits CIRM to fund other stem cell-related research proposals if two-thirds of a quorum of the members of its Working Group recommend to the ICOC that the proposal is vital to advancing medical science. This bill changes the two-thirds voting threshold to a simple majority. The author indicates that the change in the voting requirement is intended to make certain that 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.

The University of California (UC) is concerned that any effort to codify in statute IP provisions related to Proposition 71 is premature at this time. As a major research university engaged in stem cell research and a recipient of Proposition 71 funding, UC points out that CIRM's IP policy was the result of broad consultation with the public and various stakeholders, and carefully balanced the need to foster university-industry partnerships with the important goal of ensuring that scientific advances in stem cell diagnostics and therapies benefit the public. UC states that CIRM's approach to IP includes novel treatments of IP that have not yet been tested on the state or national level and, therefore, the policy should be given the chance to be tested and the flexibility to be modified if it turns out that it is not adequately serving the public interest before it is codified in statute or significant changes are made. UC asserts that CIRM should be permitted to establish a track record to assure prospective industry partners that CIRM's policies support commercialization of products and encourage success in these risky research endeavors.

CIRM states that this bill is premature and unnecessary and is opposed to this bill unless it is amended to remove the provision that changes the two-thirds vote requirement to a majority vote and to give CIRM greater flexibility to establish a waiver mechanism through the Administrative Procedure Act (APA), which would provide for adoption of regulations to implement the waiver after notifying the Legislature and conducting a public hearing. CIRM contends that eliminating the current two-thirds vote requirement for funding of non-embryonic-related research eliminates the priority that

Proposition 71 places on human embryonic stem cell research and thwarts the will of Californians who approved Proposition 71 in order to address the federal funding gap that exists for this type of research. With respect to the public pricing requirement in this bill, CIRM asserts that providing for a waiver process pursuant to the APA would permit CIRM to assess changes in medical technology and in the health care sector prior to defining the scope and contours of the waiver and would provide an opportunity for the Legislature and the public to comment on the proposed waiver mechanism before it is adopted. Lastly, CIRM remains concerned that by attempting to specify the precise conditions under which CIRM could waive pricing provision, this bill will fail to address other situations in which a waiver would be equally justified.

Supporters, including Consumer Watchdog (formerly the Foundation for Taxpayer and Consumer Rights), California Common Cause, Health Access, California Nurses Association and California Alliance for Retired Americans, state that this bill will help ensure that the taxpayers of California will have affordable access to the fruits of the research they are funding and will help make CIRM and the ICOC more responsive and accountable to the public. They note that Californians saw great promise when Proposition 71 was adopted, that they would have access to drugs and products that could cure or slow the progression of numerous diseases and conditions and, therefore, they should have access to this promise whether they are insured or uninsured. Furthermore, supporters point out that too often public funds are used to develop medical treatments that are then unaffordable to the most vulnerable people in our society and this bill ensures that every taxpayer in California paying for research funding by CIRM has access to any medical care that is developed.

Groups representing the life sciences community, including the California Healthcare Institute and BayBio, contend that this bill discourages commercial collaboration and industry participation in research opportunities by codifying proposed IP regulations prematurely and increasing investors' financial risk by imposing state price regulation on products resulting from CIRM-funded research. Consumer advocacy groups that support cutting-edge medical research in this area, including Californians for Cures, oppose the provision modifying the vote requirement for funding proposals that involve non-embryonic

stem cell lines, arguing that it is a poison pill that removes the existing priority established for embryonic stem cell research and inappropriately assumes that alternative therapies are viable and timely. Opponents contend that while recent advances in alternative therapies are exciting, they are still unproven and the vast majority of the scientific community agrees that embryonic stem cell research remains the gold standard.

Analysis Prepared by : Cassie Rafanan / HEALTH / (916) 319-2097 FN: 0006182