

**RESOLUTION NO. 2008-02**

**A RESOLUTION OF THE INDEPENDENT CITIZENS’  
OVERSIGHT COMMITTEE TO OPPOSE SB 1565 (KUEHL/RUNNER)**

WHEREAS, the California Legislature is currently considering a bill that would have an effect on the operations and policies of the California Institute for Regenerative Medicine;

WHEREAS, the Independent Citizens’ Oversight Committee, the governing board of the CIRM, is committed to working with the Legislature to advance stem cell research, to ensure that California taxpayers benefit from their investment in this vital research, and to guarantee that therapies and cures developed through research funded by Proposition 71 are made available to all members of the California public;

WHEREAS, the Independent Citizens’ Oversight Committee has already taken several actions to advance these common interests: (1) the Board has adopted intellectual property regulations that: (a) provide for a return to the State General Fund; (b) require each grantee and licensee to submit a plan to CIRM that will afford uninsured Californians access to any drug or therapy that is entirely or partly the result of CIRM-funded research; and (c) require each CIRM grantee and licensee to sell drugs resulting from CIRM-funded research, and that are purchased with public funds, at a price provided in the California Discount Prescription Drug Program (Cal-Rx); (2) the Board has approved grants involving adult and cord blood stem cell research; and (3) CIRM has cooperated with extensive performance and financial audits conducted by the Bureau of State Audits, the Controller, and external auditors, and has addressed all of the issues raised in the audits;

WHEREAS, Section 8 of Proposition 71 permits the Legislature to amend the law after three years with a 70 percent vote of the membership of both houses, provided that the amendment enhances CIRM’s ability to further the purposes of the grant and loan programs created by Proposition 71;

WHEREAS, this provision provides an opportunity for the Legislature to adopt legislation to further the purposes of Proposition 71, while at the same time affording the Independent Citizens’ Oversight Committee sufficient time to adopt policies and standards through a deliberate, thorough, and public process;

WHEREAS, SB 1565 would amend various provisions of Proposition 71, to: (1) require the CIRM’s intellectual property policies 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; (2) require each CIRM grantee and licensee to sell drugs resulting from CIRM-funded research, and that are purchased with public funds, at a price that does not exceed *any* benchmark price in the California Discount Prescription Drug Program (Cal-Rx); (3) revise the vote threshold necessary for CIRM funding of certain research

proposals; and (4) request the Little Hoover Commission (LHC) to study the existing governance structure of the ICOC and CIRM;

WHEREAS, to date, no products have been commercialized as a result of CIRM-funded research and CIRM is continuing to evaluate and implement its intellectual property policies to meet the requirement in Proposition 71 that the ICOC adopt policies that balance the opportunity of the State to benefit from royalties and license fees arising from CIRM-funded research with the need to assure that essential medical research is not unnecessarily impeded;

WHEREAS, SB 1565 is premature because it attempts to solve a problem that does not exist and it interferes with CIRM's on-going process to adopt and implement intellectual property policies that strike the balance required by Proposition 71;

WHEREAS, SB 1565 could also restrict CIRM's ability to negotiate agreements to commercialize products, including but not limited to, customized access methodologies to reach subsets of patient populations such as Alzheimer's disease or ALS by imposing a one-size-fits-all pricing mandate;

WHEREAS, current law provides funding priority for pluripotent and progenitor cell research that is not receiving timely or sufficient federal funding and also provides that CIRM may fund other 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");

WHEREAS, in practice, the two-thirds threshold has not prevented CIRM from funding a single research proposal, and CIRM has funded research involving adult and cord blood stem cell research;

WHEREAS, the Bureau of State Audits, the Controller, and external auditors have performed extensive financial and performance audits of CIRM and CIRM has addressed all of the issues raised by these audits;

WHEREAS, the Little Hoover Commission already has the authority to study CIRM if it chooses to do so, and CIRM will cooperate if the LHC chooses to conduct of study of CIRM;

WHEREAS, SB 1565 is premature and unnecessary because: (1) CIRM has already adopted intellectual property regulations that address the concerns expressed in SB 1565 while providing CIRM with the flexibility to address changes in the fast-developing field of stem cell research; (2) the two-thirds vote required to fund adult and cord blood stem cell research has not posed a barrier to the funding of such research; and (3) the LHC could conduct a study of CIRM without legislation;

WHEREAS, SB 1565 would interfere with the ICOC's public process for the implementation of policies that will address the concerns expressed in SB 1565;

BE IT RESOLVED, by the Independent Citizens' Oversight Committee as follows:

1. The Independent Citizens' Oversight Committee is committed to working with the Legislature to advance stem cell research, to ensure a return to California taxpayers and to provide a strong and effective intellectual property program to protect the interests of the State of California and its citizens.
2. The Independent Citizens' Oversight Committee has adopted strong policies in this area and is in the process of implementing these policies pursuant to the Administrative Procedure Act.
3. The Independent Citizens' Oversight Committee believes that the Legislature should allow the Institute time to implement its policies and to respond to changed circumstances, as necessary, to ensure that CIRM meets the mission approved by California voters.
4. The Independent Citizens' Oversight Committee is committed to working with the Legislature to address any concerns after these policies have been implemented and to address any concerns identified by the audits.
5. The Independent Citizens' Oversight Committee believes that SB 1565 is premature and unnecessary and would interfere with the flexibility required in this new field of research and therefore opposes the bill.

This resolution shall take effect immediately upon its approval.

Date Approved: \_\_\_\_\_

Signed: \_\_\_\_\_

Chair, Independent Citizens' Oversight Committee