ANALYSIS OF SENATE BILL NO. 1064	
Intent:	
Stated Intent: "to further enhance the ability of the institute to manage this investment made with public funds by addressing public concerns regarding oversight and transparency."	Proposition 71 provides that the Legislature may only amend the statutory terms of Proposition 71 "to enhance the ability of the institute to further the purposes of the grant and loan programs created by the measure."
Terms of Chair and Vice Chair:	
Proposed Amendment to Section 125290.20(a)(6): Reduces terms of Chair and Vice Chair from six years to four years, and requires that terms be staggered.	The terms proscribed in Proposition 71 were intended to provide continuity across the administrations of the appointing authorities. Currently, the terms of the Chair and Vice Chair run simultaneously (i.e., December 17, 2004 through December 17, 2010.) Although the proposed amendment provides for the terms to be staggered, it does not provide a mechanism by which that could be accomplished. Furthermore, given the complex issues facing the Board (including conflict of interest laws, open meeting laws, peer review procedures, scientific issues (from basic to translational to clinical), FDA issues, intellectual property issues, ethical standards, biotech collaboration, etc.) and the steep learning curve, a four-year term does not provide sufficient time for an individual to acquire the knowledge necessary to lead the Board. In addition, a two-year overlap will limit the time available to the Chair and the Vice Chair to coordinate on a range of complex issues, including those cited above.
Jurisdiction of CFAOC:	
Proposed Amendment to Section 125290.30(c): Expands the jurisdiction of the Citizens' Financial Accountability Oversight Committee ("CFAOC") to include commissioning an annual performance audit of CIRM and the board from a certified independent auditing firm.	CIRM is already subject to audit by the Legislature and the Controller, both of which have already conducted performance audits of CIRM. In 2006, when the agency was still in the process of developing its policies and procedures, the Bureau of State Audits, at the direction of the Joint Legislative Audit Committee, conducted a

ANALYSIS OF SENATE BILL NO. 1064	
Audit shall include a review of the policies and procedures established by the Board to determine whether: (1) the structure is suitable for administering CIRM; (2) the policies and procedures comply with relevant laws, regulations, and best practices; and (3) CIRM is complying with the policies and procedures. Policies and procedures to be audited include, but are not limited to: (1) the strategic policies and plans developed by CIRM and the Board; (2) policies and procedures for the issuance of contract and grants, including a review of a sample of contracts and grants; and (3) policies and procedures relating to protection or treatment of intellectual property rights. Requires Controller to review the audit and include that review in the Controller's annual report. Requires CIRM to pay all costs associated with the annual audit.	performance audit of CIRM at a cost of more than $200,000. The cost to CIRM also exceeded $200,000 and consumed hundreds of hours of staff time. The BSA made several suggestions in its report, and in response, CIRM implemented those suggestions. The Controller also conducted an audit of CIRM's conflict policies and procedures and found that CIRM was in compliance. CIRM is in the process of commissioning an independent scientific review of its performance, as required by CIRM's scientific strategic plan, which was adopted by the Board in 2006. This review is expected to be completed by the end of 2010.
Public Records:	
Proposed Amendment to Section 125290.30(e): Requires CIRM to post a summary of vote tallies and "disclosure of each board member's votes and refusals [sic]."	Since CIRM's inception, each meeting of the Board and its subcommittees has been transcribed and a copy of the transcript has been posted on CIRM's website. CIRM also posts minutes of its Board meetings. In addition, since May of 2009, CIRM has posted a summary of the vote tallies and recusals for each board meeting, along with the minutes. CIRM has posted such tallies for all meetings dating back to January 1, 2008, and has incorporated this policy going forward. It appears that this provision applies only to meetings of the Board, but it is not explicit.

ANALYSIS OF SENATE BILL NO. 1064	
Intellectual Property Agreements:	
Proposed Amendment to Section 125290.30(h): Provides that all revenues received through intellectual property agreements be deposited into the General Fund.	CIRM's regulations require that intellectual property revenues arising from CIRM-funded research be deposited into the General Fund. (17 Cal. Code Regs., tit. 17, § 100608.)
Succession Planning:	
Proposed Amendment to Section 125290.40: Requires Board to create succession plan addressing changes of leadership on the Board and in the agency. The plan must include: (1) a statement of commitment to prepare for leadership change; (2) a statement of commitment to assess leadership needs before beginning a search; (3) an outline of succession procedures, including: (a) a timeframe for making "the interim appointment"; (b) a timeframe for appointing a board transition committee; (c) a description of the role of the transition committee, including communicating with stakeholders, identifying a transition management consultant, and conducting an organizational assessment and designing the search plan; and (4) strategies to ensure knowledge transfer.	The Board began discussing succession planning in 2009 and the Evaluation Subcommittee intends to discuss the topic, including the ideal qualities for Chair and Vice Chair, at its upcoming meeting. The proposed amendment would require the Board to develop a timeframe for "interim appointments" but it does not explain what an "interim appointment" is or how the Board could affect the timeframe given that it does not have the power to appoint members. Under Proposition 71, the Governor, the Controller, the Treasurer, the Lieutenant Governor, Senate President Pro Tem, and the Assembly Speaker make appointments, not the Board. (The Board elects the Chair and Vice Chair from nominations submitted by the four constitutional officers.) It is also not clear whether the requirement to design a search plan applies to the leadership of CIRM or the Board. As discussed above, the Board does not make appointments or nominations so it is not clear how the required "search plan" would apply.
50-Employee Cap:	
Proposed Amendment to Section 125290.45(b)(1): Eliminates 50-employee cap.	CIRM remains committed to the 6% limit on its administrative expenses but is challenged by the 50-employee cap. The agency is in the process of examining alternatives for addressing the challenges posed by the 50-employee cap.

ANALYSIS OF SENATE BILL NO. 1064	
Role of Chair:	
Proposed Amendment to Section 125290.45(b)(1)(A): Provides that Chair's role is to provide leadership to the Board and does not include the day-to-day management of CIRM. Eliminates Chair's responsibility to supervise annual report and "public accountability" requirements and to lead intellectual property negotiations. Provides that President's role is to manage day-to-day operations of agency and adds the responsibility for "leading negotiations for intellectual property agreements, policies, and contract terms" to the President's duties.	Under current law, the Chair has the responsibility for supervising the preparation of the annual report and compliance with "public accountability requirements." Under Proposition 71, these requirements include public meeting laws, public records laws, conflict of interest laws, and CIRM's intellectual property regulations. Proposition 71 was designed to ensure that the person responsible for providing oversight of the public accountability requirements would be a person nominated by the Constitutional Officers and elected by the Board. The proposed amendment does not address who would carry out this oversight function in the absence of the Chair. Current law also provides that the Chair is responsible for CIRM's intellectual property policies and agreements and that the President is responsible for executing the agreements. The separation of authority to negotiate and authority to execute was intended to provide an additional layer of review, thereby protecting the public interest. The amendment would transfer responsibility for negotiations to the President, but it is not clear whether the President's authority would include adopting intellectual property policies or whether this power would remain with the Board.

ANALYSIS OF SENATE BILL NO. 1064	
Grants Working Group:	
Proposed Amendment to Section 125290.60(c)(1): Strikes "15" from the provision that states s that only the 15 scientist members of the Grants Working Group score applications for scientific merit.	Under current law, the Grants Working Group is comprised of 15 scientist members, seven patient advocate members, and the Chair of the Governing Board (23 members). Although it appears that the author's intent is to remove the 15-scientist limit, the limit would remain under the proposed amendment. Removing the 15-scientist cap on review would not significantly affect the GWG's capacity to review more grant applications or enhance CIRM's ability to make grants and loans. The real limiting factor for review is time. Increasing the number of GWG members at a review will not speed up the rate at which each application is reviewed. In fact, it may increase that review time to accommodate discussion by additional members. This could result in a slower rate of review and discourage members from participating.
Pre-Application Review:	
Proposed Amendment to Section 125290.60(c)(2): Requires all "grant applications" be sent to the Grants Working Group for peer review "prior to any other review process, unless the process is only to determine completeness of the application."	Pre-application review is an important tool employed by CIRM to ensure that it is funding the best scientific and medical proposals. Pre-application review applies only to those Requests for Applications that are expected to be reissued every 12-18 months. Pre-applications are reviewed by external and internal reviewers against stated criteria. Those proposals determined to be the most promising, competitive and responsive are invited to submit a full application. Applications that are deferred can reapply in subsequent rounds of the RFA or in response to other more suitable RFAs for the proposed research. CIRM has utilized other tools to ensure that the Grants Working Groups is not overwhelmed by applications, including limiting the number of applications submitted by each institution. In response

ANALYSIS OF SENATE BILL NO. 1064	
	to a survey, the leaders of California's stem cell programs unanimously supported the pre-application process over other alternatives. CIRM also conferred with major stem cell biotech companies who agreed that pre-application review is the preferred model. The Board will be examining the process to see how it can be improved or whether there are other alternatives to accomplish the same goals.
Intellectual Property – Access and Pricing:	
Proposed Addition of Section 125290.80: Requires CIRM's intellectual property regulations to include a requirement that each grantee and licensee submit a plan to ensure that uninsured Californians have access to any drug that is, in whole or in part, the result of CIRM-funded research. Requires grantees and licensees to provide drugs to California state and local government funded programs at one of three CalRX prices, as the program exists on December 31, 2010. Provides that the Board can waive the pricing requirement, after holding a public hearing, when the drug is used to treat an orphan disease and the Board determines that the pricing requirement would impede development of the drug or the grantee commits to provide expanded access to a class of patients who would not otherwise receive access to the drug and the Board anticipates that the benefits of the waiver will exceed the benefits of the pricing requirement.	Under Proposition 71, the Board has the responsibility to adopt intellectual property regulations that strike a balance between the opportunity for Californians to obtain a return on their investment and the need to assure that the policies CIRM adopts do not unreasonably hinder medical research. After undertaking extensive fact-gathering and numerous public hearings, the Board's Intellectual Property Taskforce recommended intellectual property regulations to the Board, which adopted them at a public meeting. These regulations include access plans and pricing requirements. Given the uncertainties surrounding health care in California and nationally, however, it is critical that the Board maintain the flexibility necessary to address changing circumstances. Placing these requirements in statute would prevent the Board from responding to such changes to ensure that the interests mandated by Proposition 71 are appropriately balanced. Similarly, the proposal would lock in the current version of CalRX, even if the Legislature amends the law to improve it in the future. CIRM previously addressed these same issues in connection with SB 1565, which included similar provisions and which the Board opposed. (*See* Continuing Concerns Re SB 1565 (Attachment A) and Board Resolution 2008-02 (Attachment B).

ANALYSIS OF SENATE BILL NO. 1064	
Transition Planning:	
Proposed addition of Section 125291.90: Requires CIRM, under the guidance of the Board to create a plan addressing the expiration of bond funding by January 1, 2014. Requires plan to be transmitted to the Governor, the Controller, and the Legislature within 30 days of completion.	CIRM has already begun to consider strategies relating to the expiration of bond funding. For more than a year, CIRM, led by the Chair's Office, has been exploring the potential for a loan program and federal guarantees to extend the funding available to the agency. CIRM has also developed matching fund programs that have leveraged CIRM's resources. The proposal also appears to misapprehend the bond financing provisions of Proposition 71, which impose no time limit on the issuance of bonds. Instead, it authorizes the issuance of up to $350 million per year, with any unutilized balance to be available for issuance in subsequent years. Proposition 71 was designed to provide flexibility in order to accommodate delays (e.g., litigation) and to permit the Board to fund only those proposals that are scientifically meritorious, rather than being bound to expend all funds within a defined time period. In fact, the Board has, at times, funded under the established budget for an RFA.

Attachment A

CONTINUING CONCERNS REGARDING SB 1565
Waiver Language Cannot Anticipate All Reasons in the Future

We greatly appreciate Senator Kuehl's efforts to address our concerns regarding the potential unintended consequences that could flow from placing a rigid pricing mechanism in statute. Assuming we reach agreement to strike Section 1 of SB 1565 as amended June 9, 2008, we are prepared to work on resolving our opposition to Section 2.

We offered as examples of the need for flexibility and the authority to waive the pricing policy proposed in SB 1565 only based in part on the case of orphan diseases as examples of how a strict application of the CalRx program to drugs and therapies derived in whole or in part from CIRM-funded research could affect our ability to ensure that therapies are available to the patients who most desperately need them. Pricing mechanisms need to be designed to reflect the patient population the therapy needs to reach. While we are in total agreement that California public purchasers should receive at least the same level of pricing as the lowest available commercial rate, we nonetheless believe that we need flexibility to adapt pricing mechanisms to fit the patient population waiting for the therapy as the facts present themselves in each case:

Alzheimers disease:
The age of onset for Alzheimers disease varies. Most patients are diagnosed later in life, when they are often already covered by the Medicare program. But there is a group of "early onset" patients diagnosed in their 40s and 50s where health insurance availability can be extremely problematic. These specific patients have to wait for two years to be eligible for Medicare. Our concern about the pricing mandate of SB 1565 is that it does not allow for a pricing adjustment to fit a subset of patients such as those afflicted by early onset Alzheimers.

Battin's disease:
Current stem cell research aimed at this orphan disease has already presented serious financial challenges to the company involved in attempting to develop a therapeutic product for this disease which today results in the death of young children. If pricing plays a role in the financing solution for that therapeutic product, we need to be able to make such a decision. On balance, bringing the therapeutic product to market outweighs the incremental savings which would result from a one-size-fits-all pricing policy. For example, what if a health care provider helps fund part of the clinical trials for this disease or some other orphan disease and receives special commercial pricing in exchange? We have e a continuing need to be creative in recruiting private funding and stretching California's extremely valuable research dollars.

These are only two examples of which we are aware today where the policy in SB 1565 would not allow for customization to the specific facts of the case. There are other factors that can influence pricing decisions as well. As the members of the California Legislature know better than most, ensuring access in our current health care system is an enormously complex challenge. When coupled with nascent and cutting edge medical research, the challenges posed by trying to anticipate and address all of the issues that

Attachment A

could arise in the future are insurmountable. For that reason, the ICOC determined that SB 1565 is premature and voted on June 27, 2008 unanimously to oppose it.

Indeed, Senator Kuehl's recent efforts to address our concerns underscore the complexity of trying to anticipate and address these issues before they arise. For example, the proposed language recognizes that some uninsured individuals will not qualify for any public program. However, it is possible that individuals who receive government funded health care or who are privately insured may not qualify for treatment due to a cap on coverage or may be unable to obtain access to a specialist or team of specialists who provide the therapy due to reimbursement rates.

By attempting to specify the precise conditions pursuant to which the ICOC could grant a waiver, the proposed amendments will undoubtedly fail to address other situations in which a waiver would be equally justified. Again, our concern is that the only way these shortcomings could be addressed would be by future legislation, and given the 70 percent threshold for amendments to Proposition 71, it may prove impossible to change the law to accommodate a therapy derived from human embryonic stem cells.

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 polices 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, in its current form, is premature and unnecessary and would interfere with the flexibility required in this new field of research and therefore opposes the bill.

6. In order to permit CIRM to continue to work with the Legislature, the Independent Citizens' Oversight Committee delegates to the Legislative Subcommittee authority to respond on the Board's behalf between Board meetings as events require.

This resolution shall take effect immediately upon its approval.

Date Approved: June 27, 2008

Signed: _____

Robert N. Klein
Chair, Independent Citizens' Oversight Committee