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LEGISLATIVE COUNSEL'S DIGEST

Bill No.

as introduced, Alquist.

General Subject: California Stem Cell Research and Cures Act.

The California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 2, 2004, statewide general election as Proposition 71, establishes the California Institute for Regenerative Medicine (CIRM), the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC) composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute, including, but not limited to, establishing standards applicable to research funded by the institute. Existing law prohibits amendment of Proposition 71 by the Legislature unless the amendment is approved by the voters, or the amendment is accomplished



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by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses, and only if the amendment enhances the ability of the institute to further the purposes of the grant and loan programs.

Existing law specifies the appointment process for the members of the ICOC, including the chairperson and vice chairperson who are employees of the ICOC, and provides that the chairperson and vice chairperson serve 6-year terms. Existing law defines the duties of the chairperson and the president of the ICOC and limits the total number of authorized employees of the CIRM to 50.

This bill would reduce the terms of the chairperson and vice chairperson to 4-year terms, would require their terms to be staggered, and would require the CIRM, under the guidance of the ICOC, to create a succession plan addressing changes in leadership in the CIRM and ICOC, as specified. The bill would make prescribed changes to the duties of the chairperson and president of the ICOC and would eliminate the 50-employee maximum for the CIRM.

The bill would also require the CIRM, under the guidance of the ICOC, to create a transition plan to address the expiration of current bond funding and to submit that plan to the Governor, the Controller, and the Legislature.

Existing law requires the Citizen's Financial Accountability Oversight Committee, chaired by the Controller, to review the annual audit and financial practices of the CRIM.

This bill would also require the Controller, under the guidance of the committee, to annually commission a performance audit of the activities of the CIRM and the ICOC, as specified.



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Existing law contains provisions relating to the extent to which requirements relating to the disclosure of public records applied to records of the CIRM.

This bill would require the ICOC to disclose, in all meeting minutes, a summary of vote tallies, including each board member's votes and refusals, and would require the ICOC to amend all past minutes to include this summary.

The act provides that the ICOC shall establish standards that require that all grants and loan awards under the act shall be subject to intellectual property agreements that balance the opportunity of the state to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to ensure that essential medical research is not unreasonably hindered by the intellectual property agreements.

This bill would require that intellectual property standards that the ICOC develops include a requirement that each grantee and the licensees of the grantee submit to the CIRM for approval a plan that will afford uninsured Californians access to any drug that is, in whole or in part, the result of research funded by the CIRM, and that the plan require that the grantees and licensees provide drugs to state and local government funded programs at one of the 3 benchmark prices in the California Discount Prescription Drug Program, provided for pursuant to existing law, except when the ICOC adopts a waiver, as specified. The bill would also require all revenues received from the intellectual property agreements to be deposited in the General Fund.

Existing law establishes the procedure by which grant and loan applications are processed and scored by the 15 scientist members of the Scientific and Medical Research Funding Working Group.



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This bill would remove the 15 member limit and would require all grant applications received by the ICOC to be sent to the Scientific and Medical Research Funding Working Group prior to any other process, unless the process is only to determine completeness of the application.

Vote: 70%. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.



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