

BILL ANALYSIS

SENATE HEALTH  
 COMMITTEE ANALYSIS  
 Senator Sheila J. Kuehl, Chair

BILL NO: AB 2381  
 A  
 AUTHOR: Mullin  
 B  
 AMENDED: June 23, 2008  
 HEARING DATE: June 25, 2008  
 2  
 FISCAL: Appropriations  
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 CONSULTANT:  
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 Park/cjt  
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SUBJECT

Stem cell research

SUMMARY

Defines "California supplier" for purposes of the California Stem Cell Research and Cures Act (Act), as specified.

CHANGES TO EXISTING LAW

Existing law:  
 The California Stem Cell Research and Cures Act (Act), enacted by voters as Proposition 71 in November, 2004, establishes the CIRM (California Institute for Regenerative Medicine) to make grants and loans for stem cell research and research facilities. Existing law also establishes the ICOC (Independent Citizen's Oversight Committee) as the governing body for the CIRM. Existing law authorizes the sale of \$3 billion in general obligation bonds over 10 years for stem cell research and facilities in California, with a focus on research that does not qualify for federal funding.

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Existing law, from Proposition 71, requires the ICOC to establish standards that require all grants and loan awards to be subject to intellectual property agreements that balance the opportunity of the state to benefit from the patents, royalties, and licenses that result from research and therapy development, as well as clinical trials, with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.

Existing law also provides that the Legislature may amend the non-bond statutory provisions of the Act, to enhance the ability of the California Institute for Regenerative Medicine to further the purposes of the grant and loan programs created by that Act, with a 70 percent vote of each house, and compliance with specified procedural requirements.

Existing law requires the ICOC to establish standards to ensure that grantees purchase goods and services from California suppliers to the extent reasonably possible, in a good faith effort to achieve a goal that more than 50 percent of such purchases shall come from California suppliers.

This bill:  
 This bill would define "California supplier" to mean any sole proprietorship, partnership, joint venture, corporation, or other business entity that meets any of the following criteria:

- 1) The owners or policymaking officers are domiciled in California and the permanent, principal office or place of business from which the supplier's trade is directed or managed is located in California.
- 2) The business or corporation, including those owned by,

or under common control of, a corporation: a) has owned and operated a manufacturing facility or research facility located in California that researches, develops, builds, or manufactures products for life sciences research, continuously during the five years prior to submitting a bid or proposal to provide supplies to a CIRM grantee; b) has been licensed by the state on a continuous basis to conduct business within the state during the five years

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prior to submitting a bid or proposal to provide supplies to a CIRM grantee; c) has continuously employed California residents for work within the state during the five years prior to submitting a bid or proposal to provide supplies to a CIRM grantee.

3) The entity produces, builds, or manufactures a product or products in California and for the specific product or products that are used by CIRM grantees.

The bill would specify that a distribution or sales management office or facility does not qualify as a manufacturing or research facility for the purposes of qualifying as a California supplier.

#### FISCAL IMPACT

Unknown.

#### BACKGROUND AND DISCUSSION

##### Author's statement

The author writes that CIRM has initiated significant grant-making activities, and guidance is needed to assist grantees in their fulfillment of the preference for California suppliers. The author states that, by providing clear guidelines in this key expenditure area, expenditures of California voter-approved funds with California suppliers would generate critically important economic stimulation to the state's economy, and, potentially, vitally needed business transaction revenues in an otherwise dim state budget circumstance.

##### Proposition 71

In November 2004, California voters approved the Act, which authorizes the state to sell \$3 billion in general obligation bonds to provide funding for stem cell research in California. It establishes CIRM to award loans, grants, and contracts to research facilities and makes CIRM responsible for establishing regulatory standards for stem cell research and stem cell research facilities. The Act also creates and specifies the composition of the 29-member ICOC to govern CIRM. The ICOC is required to award all grants, loans, and contracts in public meetings and to adopt all governance, scientific, medical, and regulatory

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standards in public meetings.

Section 3 of Proposition 71, in describing the purpose and intent of the initiative, states, among other purposes, that it is the intent of the people of California in enacting this measure to benefit the California economy by creating projects, jobs, and therapies that will generate millions of dollars in new tax revenues in our state, and to advance the biotech industry in California to world leadership, as an economic engine for California's future.

##### California supplier

In January 2008, Invitrogen, the sponsor of the prior version of the measure, submitted a petition to CIRM to adopt by regulation a definition of a "California supplier." In the petition, the sponsor contended that the ICOC is mandated to establish a definition in order to achieve the goals of Proposition 71. According to Invitrogen, defining a California supplier to mean those companies that are headquartered in the state, whose principal owners or officers are residents of the state, and whose operations are directed from within the state, ensures that a variety of California companies are well-positioned to provide the goods and services needed to conduct CIRM-funded research.

Prior to the March 12, 2008, meeting of the ICOC, four

members of the Legislature sent correspondence to Robert Klein, Chairman of the ICOC, in support of the petition for CIRM to initiate rulemaking to develop a definition of "California supplier."

At the March 12th meeting, CIRM staff initially recommended denying the petition for several reasons, including that the ICOC has already carried out its statutory requirement to establish a standard for a preference for California suppliers that is incorporated in its existing and proposed grants administration policies, which states, "To achieve this goal [of 50 percent purchase from California suppliers], CIRM expects the grantee to purchase from California suppliers, to the extent reasonably possible, the goods and services it uses in its CIRM-supported research. The grantee must provide a clear and compelling explanation in its annual programmatic report for not

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purchasing more than 50 percent of its good and services from California suppliers." Additionally, staff indicated that new revenue and employment opportunities can also be achieved in California by including any supplier that makes sales taxable in the state, pays income tax in the state, employs residents of the state or has a brick and mortar location in the state; and, finally, that the sponsor's proposed definition may violate federal interstate commerce law. However, CIRM indicates that, during the meeting, the sponsor clarified that the petition was intended to initiate a rulemaking process rather than a demand to adopt a definition. As a result, the ICOC decided to adopt the sponsor's definition as an initial draft for the purpose of initiating a regulatory review process to finalize a formal definition.

On May 8, CIRM circulated a memo to "interested parties" announcing that the ICOC would consider adopting an interim regulation defining the term "California supplier" at its June 26-27, 2008, meeting. At that meeting, the ICOC will also consider authorizing CIRM to initiate a formal regulatory adoption process under the Administrative Procedures Act. The memo stated that the ICOC requests comment from the public and has authorized the following language to elicit feedback:

As used in Section 125290.30(i) and in CIRM policies and regulations, "California supplier" means any sole proprietorship, partnership, joint venture, corporation, or other business entity: (1) whose owners or policymaking officers are domiciled in California and whose permanent, principal office or place of business from which the supplier's trade is directed or managed is located in California; or (2) that employs at least one-third, with a minimum of 100, of its total employees in California; or (3) that produces, builds, or manufactures a product or products in California for the specific product or products which are used by CIRM grantees.

In correspondence provided by Invitrogen, on June 6, 2008, the company states:

Unquestionably, California companies can provide needed goods and services. California is home to a significant

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portion of the \$17 billion global life science tools and technologies industry. A variety of California companies can provide the goods and services needed to conduct CIRM-funded research, without creating any research-limiting constraints on grantees. Just as first rate research can be done within the California-only restriction on CIRM research grants, so, too, can world-class goods and services be obtained from California Suppliers?.

Given that California companies can meet the needs of CIRM-funded researchers, it's a good time to consider the question of why we would otherwise send hundreds of millions of California taxpayers' dollars outside the State, where it will do nothing to create California jobs, economic growth, or tax revenue?

Related legislation  
SB 1565 (Kuehl and Runner) of 2008 requests, among other

things, the ICOC to conduct a study of the governance structure of Prop 71 and provide recommendations on ways the governance structure of the ICOC could better ensure public accountability and reduce conflicts-of-interest, consistent with the purposes of Prop 71. Pending in the Assembly Judiciary Committee.

Prior legislation  
SB 340 (Battin) of 2005 would have required all revenues derived from patents, royalties, and licenses paid to the state as a result of intellectual property agreements entered into pursuant to Proposition 71 to be deposited into the state General Fund. Held in the Assembly Health Committee.

ACR 24 (Mullin), Resolution Chapter 111, Statutes of 2005, requests that the California Council on Science and Technology expand its study group on how the state should treat intellectual property made under state contracts, grants, and agreements to include contracts, grants, and agreements under Proposition 71 and that it expand the membership of the study group to include representatives from the ICOC.

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Arguments in support  
Becton, Dickson and Company (BD), a global medical technology company with operations in California employing 1,600 Californians in five facilities throughout the state, and ThermoFisher Scientific, which employs more than 1,200 people in 14 facilities throughout the state, write that they believe the definition provided by the current version of the measure will further the intent of Prop 71.

Correspondence provided by Millipore, an S&P 500 company with 6,000 employees worldwide, indicates that it supports the definition of "California supplier" proposed by BD, which is similar but not identical to the current measure. Headquartered in Billerica, Massachusetts, Millipore states that it has been qualified to conduct business in California since 1969, and has paid taxes to California in excess of \$650,000 and \$480,000 in tax years 2005 and 2004, respectively. It recently acquired additional California-based companies, and currently employs 382 people in three facilities throughout California.

Millipore's correspondence stated that, under the original proposal of the definition of California supplier in the measure, companies that made a small or modest contribution to California would be rewarded, while those making a large contribution would be penalized. For example, Company A has a small headquarters facility in California, and its CEO lives in the state. It has 101 of its 303 employees in California; while Company B is a global company that has 7,000 of its 100,000 employees in California, has major biotechnology and diagnostics facilities in the state and is a leader in the field. Company A would be included under the original definition of California supplier, while company B would be excluded.

#### COMMENTS

1. Definition of California supplier broad. In addition to other definitions, one provision allows a California supplier to be defined, independently, as an entity that produces, builds, or manufactures a product or products in California and for the specific product or products that are used by CIRM grantees. The author's staff indicates that this is an attempt to address inclusion of

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construction companies and recent facilities grantees. Staff recommends that this independent definition be more narrowly applied to facilities grantees.

Page 3, lines 8-10:

The entity produces, builds, or manufactures a product or products in California and for the specific product or products that are used by CIRM facilities grantees.

2. Fifty percent purchase rate from California suppliers is a goal, not a requirement under Prop 71. As indicated in its March 12, 2008, memo, CIRM staff stated that 50 percent is a goal and not a requirement. Additionally, there appears to be no penalty for not meeting that goal. Finally, given the high presence of life sciences companies in the state, 50 percent may not be a high threshold to meet. It is unclear why the definition of California supplier should not be more narrowly tailored in light of the circumstances. The author may wish to address.
3. Statutory definition of California supplier. While the ICOC has indicated that it will consider adoption of an interim regulation on the definition of supplier at its June 26-27, 2008, meeting, this measure would provide a statutory definition that would direct the ICOC in its adoption of a final definition.

PRIOR ACTIONS

Assembly Floor: 75-0  
Assembly Appropriations: 17-0  
Assembly Health: 13-0

POSITIONS

Support: Advanced Medical Technology Association  
Becton, Dickinson and Company  
ThermoFisher Scientific

Oppose: None

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-- END --