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January 15, 2008

VIA EXPRESS MAIL
RETURN RECEIPT REQUESTED

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Re: Petition for Adoption of Regulation Defining “California Supplier” to Further the Purposes and Objectives of Health and Safety Code Section 125290.30(i) [Enacted at the November 2004 General Election]

Dear Mr. Tocher:

On behalf of our client, a California-headquartered life sciences corporation, we are petitioning the California Institute for Regenerative Medicine (CIRM) and the Independent Citizen’s Oversight Committee (ICOC), charged with the governance of the institute, for the adoption of a regulation establishing a definition – that of “California Supplier” - critical to furtherance of the purposes and objectives of Health and Safety Code Section 125290.30(i). This statutory section was approved by the voters of California at the November 2004 General Election as an integral component of the California Stem Cell Research and Cures Act. Our proposed definition is attached hereto as Exhibit “1.”

Authority

Pursuant to Health and Safety Code Section 125290.4(j), the CIRM is required to “Adopt, amend, and rescind rules and regulations to carry out the purposes and provisions of this chapter, and to govern the procedures of the ICOC. Except as provided in subdivision (k), these rules and regulations shall be adopted in accordance with the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1, Chapter 4.5, Sections 11371 et seq.).”

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1. The Voter-Approved Mandate.

As approved by the voters at the November 2004 General Election, there is established an express, statutory “Preference for California Suppliers.”

Specifically, “*The ICOC shall 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 of more than 50 percent of such purchases from California suppliers.*” (Health & Safety Code Sec. 125290.30(i))

The drafters, and the voters, have established a comprehensive charge – “to the extent reasonably possible” – “to ensure” – that CIRM grantee purchases of goods and services from California suppliers achieve a goal of more than 50 percent of grantee purchases of goods and services. However, the drafters did not present the voters a specific definition of a vitally necessary term – California Suppliers. That work now falls, appropriately, to the ICOC and CIRM as required by the terms of Health and Safety Code Section 125290.4(j).

2. The Express Intent of the People of California.

Section 3 of the voter-approved Act, affirmatively declared that the express “...intent of the people of California in enacting this measure...,” in pertinent findings, was to:

- **“Benefit the California economy by creating projects, jobs, and therapies that will generate millions of dollars in new tax revenues in our state.”** (emphasis added) An obvious key to achieving the stated intent of the People is fulfillment of the California Supplier mandate.

- **“Advance the biotech industry in California to world leadership, as an economic engine for California’s future.”** This broadly stated goal must certainly be read to encompass not only California’s domestic life sciences industry that may become CIRM grantees, but also California entities and businesses that will provide critical and essential support – in the form of goods and services – for those grantees. The California Supplier mandate is in furtherance of achieving the creation of the “economic engine” envisioned.

- **“Improve the California health care system and reduce the long-term health care cost burden on California...”** The practical and commercial aspects of the research funded by the Act naturally and necessarily entails use of California business entities within, and supporting, the state’s health care system. Business revenues for those entities (California Suppliers) is an obvious key to improvement of the state’s health system, making both purchases and provision of health care more manageable in this state.

- **“Protect and benefit the California budget...”** The general fiscal condition of the state, and the maintenance of its creditworthiness, is essential to the eventual success of Prop. 71.

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Utilizing Prop. 71 bond proceeds in fulfillment of the California Supplier mandate, recycles and recirculates voter-approved and generated funds for the overall protection and benefit and stability of the state's budget.

3. Contemporaneous Mandates for the Benefit of California in the Act.

The California Supplier mandate in voter-enacted Health & Safety Code Section 125290.30(i) is consistent with the overall objective of advancing California economic interests stated and re-stated liberally throughout the Act, but, perhaps, most pointedly in the establishment of the Scientific and Medical Facilities Working Group. (Health & Safety Code Section 125290.65)

•“*Four real estate specialists. To be eligible to serve on the Scientific and Medical Research Facilities Working Group, a real estate specialist shall be a resident of California....*” (*Id.*, (a)(2)) (emphasis added)

•“*The Scientific and Medical Research Facilities Working Group shall perform the following functions:...* ¶¶ (C) The requirement that all funded facilities and equipment be located solely within California.” (*Id.*, (b)(1)(C)) (emphasis added)

•“*The Scientific and Medical Research Facilities Working Group shall perform the following functions:...* ¶¶ (E) *The requirement that grantees shall pay all workers employed on construction or modification of the facility funded by facilities grants or loans of the institute, the general prevailing rate of per diem wages for work of a similar character in the locality in which work on the facility is performed....*” (*Id.*, (b)(1)(E)) Obviously, the foregoing is an economic mandate that is only applicable in, and potentially enforceable in, California, in conjunction with the mandate for location of CIRM-funded facilities and equipment in California.

4. The Express Definition of a California “Life Science Commercial Entity” in the Act.

The unequivocal definition of “Life Science Commercial Entity” approved by the voters for clarification of Article XXXV of the California Constitution, and as used throughout the Act, provides,

“*Life science commercial entity*” means a firm or organization, headquartered in California, whose business model includes biomedical or biotechnology product development and commercialization.” (Health & Safety Code Section 125292.10(o); Emphasis added.) This reference captures the essence of how a California Supplier may be defined, and this essential reference to a California-based entity represents an excellent basis on which to build a necessary definition of California Supplier. Clearly, an entity that meets the above definition and which, in turn, proposes to be a supplier of goods and services to recipients of grants from the CIRM, should be assured of being accorded a “California Supplier” preference. This definition, and

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Petitioner's proposed definition, are clearly consistent, coordinated, and articulate well in this integrated statutory construct. The mechanics of the preference – what entities qualify for that status - are appropriately to be set forth in implementing and clarifying regulations in furtherance of both the Act's broad and specific objectives.

5. The "Objective" Representations of Economic Benefit Presented to the Voters by the Legislative Analyst.

In 1941, the California Legislature established the office of the Legislative Analyst by a Joint Rule of the Senate and Assembly, giving the office the mission to ". . . ascertain facts and make recommendations . . . concerning the state budget . . . with a view to reducing the cost of the state government and securing greater efficiency and economy." The Legislative Analyst's Office (LAO) in California was the first office of its kind in the nation. Later enacted statutes accorded the Analyst's Office the job of reviewing Initiatives and Ballot Measures presented to the voters of California. The Office prepares fiscal analyses of all proposed initiatives (prior to circulation) and analyses of all measures that qualify for the statewide ballot.

The Legislative Analyst produced the following estimate for California voters of the net fiscal state fiscal impact of Proposition 71:

•"Summary of Legislative Analyst's Estimate of Net State and Local Government Fiscal Impact:

¶....

• Unknown potential state and local revenue gains and cost savings to the extent that the research projects funded by this measure result in additional economic activity and reduced public health care costs." (Excerpt, Official Title and Summary; Proposition 71, November 2004)(emphasis added)

The potential state and local revenue gains and costs savings represented to the People of California are fully dependent on implementation of "research projects funded by this measure (resulting) in additional economic activity...." The scope and breadth of that "economic activity," as analyzed and presented to the People, includes the California Supplier mandate of the purchase by grantees of goods and services totaling "*more than 50 percent of such purchases from California suppliers.*"

As expanded upon in her Official Analysis, the Legislative Analyst makes the matter clear that the analysis presented to the voters is dependent on the basic assumption of comprehensive implementation of the Act:

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“Other Potential Fiscal Effects. If the measure were to result in economic and other benefits that would not otherwise have occurred, it could produce unknown indirect state and local revenue gains and cost savings. Such effects could result, for example, if the added research activity and associated investments due to the measure generate net gains in jobs and taxable income, or if funded projects reduce the costs of health care to government employees and recipients of state services. The likelihood and magnitude of these and other potential indirect fiscal effects are unknown.” (Excerpt, Analysis by the Legislative Analyst; Proposition 71, November 2004)

Mandated purchases of goods and services from California Suppliers are fairly clearly “benefits that would not otherwise have occurred” without the enactment of the Act. Avoiding, mitigating or obviating the mandate reduces both the “likelihood and magnitude” of the potential direct and indirect fiscal effects of the Act presented to the voters at the November 2004 election.

6. The “Subjective” Representations of Economic Benefit Presented to the Voters by the Proponents.

“By making California a leader in stem cell research and giving our State an opportunity to share in royalties from the research, 71 will generate thousands of new jobs and millions in new state revenues.” (Excerpt, Argument in Favor of Proposition 71, November 2004)

“71 PROTECTS CALIFORNIA’S BUDGET. Prop. 71 is a good investment. Studies led by a Stanford University economist project that 71 will generate millions in new state revenues from royalties and new jobs, and that new medical treatments and cures can REDUCE CALIFORNIANS’ HEALTH CARE COSTS BY BILLIONS.” (Excerpt, Rebuttal to Argument Against Proposition 71, November 2004)(Emphasis in original.)

Simply, the subjective representations of the myriad economic benefits for California from the enactment of the Act, presented to voters at the November 2004 General Election by proponents, were, and remain, completely dependent on the full implementation of the Act, including the California Supplier mandate. Realization of the projections and representations is dependent on grant expenditures pursuant to the Act that reach beyond the researchers and research entities, themselves, but that also include distribution of bond proceeds/grant expenditures to businesses and entities that qualify as California Suppliers. Clarifying that qualification is an administrative necessity.

7. Further Arguments in Support of the Adoption of the Proposed Regulation

First, CALIFORNIA COMPANIES CAN PROVIDE THE NEEDED GOODS AND SERVICES. California is home to a significant portion of the \$17 billion global life science tools and technologies industry. As such, a variety of California companies can provide the goods and services needed to conduct CIRM-funded research, without creating any research-

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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.

If even 10% of the total CIRM funding is spent on goods and services (and that number could easily exceed 20%), the terms of this Preference provision will affect \$300 million in California taxpayer money. Given that California companies can meet the needs of CIRM-funded researchers, Petitioners ask, “why 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?”

Second, AN EQUIVOCAL OR WATERED-DOWN PREFERENCE WILL REDUCE STATE ECONOMIC BENEFITS. Without an explicit goal concerning purchasing from California Suppliers, CIRM grantees will face a vague requirement with no clear definition of what constitutes a good faith effort. The clearer the definition of a California Supplier, against which a “good faith effort” standard may apply, the easier actual achievement may be measured, and the greater the economic benefit that will accrue to California workers and California communities.

Appreciate that if only 10% of the total CIRM funding is spent on California Supplier goods and services (and that number could easily exceed 20%), the terms of this Preference provision would affect \$300 million in California taxpayer money. Given that California companies can readily meet the needs of CIRM-funded researchers, Petitioners, again, ask “why 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?”

Third, THE FULL SUPPLIER PREFERENCE IS CONSISTENT WITH ICOC POLICY AND PROPOSITION 71 INTENT. Other policies and practices of the CIRM explicitly favor California research institutions, California facility locations, and California residents. The ICOC has been diligent in ensuring the maximum economic benefit to the state of California and its taxpayers in other areas, and there is no reason to dilute that effort here.

Fourth, CALIFORNIA VOTERS APPROVED THE FULL PREFERENCE – NOT A DILUTED VERSION. The Proposition language said that the ICOC would “ensure that grantees purchase goods and services from California suppliers to the extent reasonably possible, with a goal of making more than 50% of such purchases from California suppliers.” Simply put, guiding grantees, with specificity, to defined California suppliers facilitates achievement of the “more than 50%” goal. Failure to do so may significantly dilute the requirement, and meaningfully change the provision voters approved. Moreover, the official estimate of state economic benefits provided to voters prior to the November election explicitly relied on the “more than 50%” goal in its assessment. Furtherance of that goal will enhance CIRM’s credibility with those who voted in favor Proposition 71 *as written*.

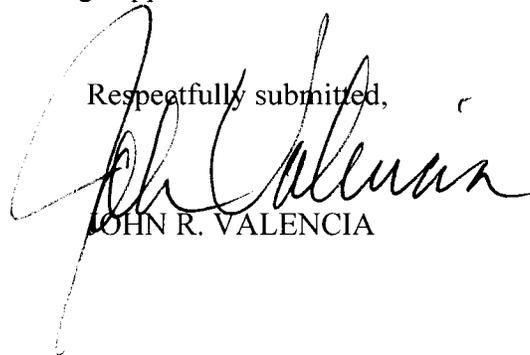
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Fifth, THE FULL REQUIREMENT CAN BE READILY IMPLEMENTED. The full California Supplier Preference can be achieved with minimal administrative burden on the part of grantees – certainly at no more burden than many other provisions contained in existing, and proposed, Grants Administration policies adopted to date by the ICOC, or pending before the agency. Petitioners appreciate that flexibility is necessary, but to require grantees to make a “good faith effort” to “as reasonably possible” make more than 50% of their purchases from a rich array of California Suppliers still provides a great deal of flexibility. It is also worth noting that recipients of many state and federal contracts are required to purchase some of their goods and services from specified entities (e.g. small and emerging businesses, veteran-owned businesses, disabled vendor-owned businesses, etc.) so many, if not most, of CIRM’s grant recipients will have the necessary accounting systems already established, or systems that are readily adaptable to track and report on the California Supplier preference.

Conclusion

In light of the substantial evidence warranting adoption of this regulations, we respectfully submit that such is warranted by the respective bodies. CIRM and the ICOC can implement the requirement in a manner that neither burdens grantees nor limits their research potential – all while ensuring that CIRM funding supports the California biomedical community, and the larger California economy.

Respectfully submitted,



JOHN R. VALENCIA

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Exhibit (1)

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Exhibit "1"

17 Cal. Code of Regs. §100XXX (to be determined)

As used in Section 125290.30(j), and generally whenever referenced, "California Suppliers" means (a) a sole proprietorship, partnership, joint venture, corporation, or other business entity the owner(s) or policymaking officer(s) of which are domiciled in California and (b) whose permanent, principal office or place of business is located in California and (c) from which the supplier's trade or business is directed or managed.

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