

California stem cell research unit is admired but needs better governance

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Washington, DC

The California Institute for Regenerative Medicine has done a good job overall but should make several changes to enhance its viability, credibility, and operations, says a new report.¹

California voters approved the creation of the institute and authorized a \$3bn (£1.9bn; €2.3bn) bond issue in 2004 to fund stem cell research. The purpose was to assure the state's leadership in the emerging field by promoting research, jobs, and, ultimately, stem cell based treatments. It inspired a handful of other states to fund other research activities.

The institute commissioned the report into its work and governance, which was conducted by the Institute of Medicine and released on 6 December.

Harold Shapiro, president emeritus of Princeton University, who chaired the committee that wrote the report, said in a conference call with reporters that the committee had a "great deal of admiration, even wonderment," at how the institute came into existence as "a genuine social innovation."

The report's strongest recommendations are in the area of governance, which threatened to "undermine respect for its decisions," Shapiro said. "We think it is extremely important to separate independent oversight and the setting of strategic priorities from management."

The report also criticizes provisions that set aside seats on the board for specific institutions in the University of California system and for representatives from specific disease groups. It urges that they be replaced "with more independent members." The Institute of Medicine believes that the current arrangement is rife with potential for conflicts of interest.

The report questions "whether the scientific goals and current strategic plan are realistic, given the level of resources and time," Shapiro said. The institute "ought to consider even greater focus on tools, technology, and regulatory issues that will cut across all initiatives in developing cell based therapies."

A committee member, Terry Magnuson, vice dean for research at the University of North Carolina, Chapel Hill, said, "Our recommendations are not suggesting scaling back on clinical trials. It is raising the question of whether their net is too broad, [with] 37 diseases, multiple disease teams, and the expense of going into clinical trials."

The report notes that substantial advanced clinical development of cell based therapy is likely only with industry support. It believes that one impediment to such collaboration is the institute's lack of harmonization with rules governing federally funded research and treatment of intellectual property rights.

Federal provisions of the Bayh-Dole Act largely grant intellectual property rights to whoever conducts the research, but the institute seeks to retain a stake in ownership as a way to generate future revenue.

At the time of its enactment some people criticized this provision of Bayh-Dole and thought that the government should retain an economic stake in the research it funded. The *BMJ* asked why harmonization should not be in the direction of the institute's guidance.

Shapiro acknowledged the argument and stated that his own belief was "that harmonization is more important than which particular set of parameters we use."

Earlier external reviews had suggested some similar organizational changes, but the institute had not taken them up. Partly this was because many of the changes would require putting them to the voters again. That may occur in a few years if the institute decided to seek authorization for a second round of bond funding.

1 Institute of Medicine. The California Institute for Regenerative Medicine: science, governance, and the pursuit of cures. www.nap.edu/catalog.php?record_id=13523.

Cite this as: *BMJ* 2012;345:e8398

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