

[NewStandard Home](#) [Non-Printer Version](#) [More Environment and Health Articles](#) [Browse Archive](#)

# Stem-cell Research Blasted from New Angle

## Patient advocates call funding hand-out to firms at expense of poor

by Michelle Chen

**A new controversy is gripping stem-cell science as California funds efforts with what critics consider little regard for ensuring the products of publicly funded research will benefit the public as a whole.**

**May 8** – Despite a court victory over conservative fundamentalists, California's plunge into the highly publicized, relatively unexplored realm of stem-cell research still faces criticism, and not just from the religious right. Groups that support stem-cell research are warning that the state's massive research-funding plan is not immune to narrow interest groups that could undermine the potential public-health benefits.

Critics caution the government against rushing to fund projects without first implementing strong protections for patients and consumers.

"The thing that we're most interested in is making sure the public-benefit promises that were made actually are kept, and that just this doesn't end up being a way of dumping a lot of money in biotech's pockets with no direct benefit for the people," said John Simpson of the consumer-advocacy group Foundation for Taxpayer and Consumer Rights (FTCR).

With \$3 billion in taxpayer bonds earmarked for stem-cell research at its disposal, California is now poised to dole out an initial \$300 million in funds under Proposition 71, a ballot initiative approved by voters in 2004. The agency charged with managing the initiative, the California Institute for Regenerative Medicine (CIRM), is currently crafting policies to govern the distribution and use of the grant money over the next decade.

The FTCR has called on the state to enact policies to promote accountability among businesses and institutions receiving the grants, to regulate prices for treatments developed with CIRM funding and to give the state a major share of the profits from state-supported medical discoveries.

But some proponents of Proposition 71 say such criticisms might be premature, arguing that the first priority should be getting the money into the hands of researchers and providing commercial incentives for the pharmaceuticals industry.

"Even if there was no direct payback to the state... the main thing is to try to advance this research [for] some cures," said Bernard Siegel, executive director of the Genetics Policy Institute, which advocates for publicly funded stem-cell research. "That's the ultimate payback."

Don Reed, with the California-based advocacy group Alliance for Stem Cell Research, argued that the state should not regulate companies in a way that might deter them from investing in the development of stem-cell treatments – including therapies that he hopes might alleviate the spinal-cord injury that left his son paralyzed. "I don't care if someone gets rich off this," he said. "I want the corporations to get rich off this, so they can be encouraged to take up the research."

But the FTCR argues that who gets rich off of Proposition 71 is closely linked to how equitably the fruits of the research will be distributed. The group argues that the state has an obligation to regulate pharmaceutical companies and make stem-cell-based therapies affordable for patients who would otherwise be priced out of expensive healthcare treatments.

So far, CIRM has rolled out a formal intellectual-property policy only for nonprofit grantees, such as academic institutions, and has not yet issued a policy for profit-making companies. Under CIRM's proposed nonprofit guidelines, the state will receive 25 percent royalties from treatments developed using CIRM funds, once profits

from a treatment exceed \$500,000. The cost of treatments distributed through healthcare programs for low-income people would be pegged to federal Medicaid prices. In addition, the government would have "march-in" rights to take over a license for a treatment if certain conditions of the grant were violated, such as a general requirement "to satisfy health or safety needs."

But the FTCR says CIRM has not gone far enough to protect patients from market manipulation. Although some for-profit corporations and other Proposition 71 supporters have urged the state to minimize restrictions on businesses seeking to capitalize on the research money, the FTCR is calling for tighter regulations for both for-profit and non-profit grantees.

The organization has recommended that the government's march-in rights be enhanced to explicitly allow the state to intervene if prices exceed a reasonable cost to consumers. The FTCR is also pushing for a lower royalty threshold of \$100,000, and for a state-run "patent pool" – a free exchange of intellectual property that enables other researchers and institutions to build on CIRM-funded discoveries. The open system would provide an alternative to exclusive patent rights, which allows a single entity to control the marketing and distribution of a treatment.

"There's not much point in discovering something if nobody can afford it, particularly when all the Californians paid for it," Simpson commented.

To tighten government control over Proposition 71 funds, State Senator Deborah Ortiz has proposed legislation to firmly regulate the CIRM's activities. The bill, SB 401, would provide a state profit-share of up to 50 percent for CIRM-supported patents and would require that the state receive royalties on a scale comparable to revenues accrued through similar research sponsored by the University of California. It would also require CIRM's scientific advisors to disclose to a state auditor any financial ties to institutions or companies involved with stem-cell research in California.

Some critics of Proposition 71 suspect that underlying agendas may influence the decisions of CIRM's 29-member governing board, euphemistically known as the Independent Citizens' Oversight Committee (ICOC). Fifteen members are leaders of academic, financial or research institutions; ten are patient advocates, representing people with specific diseases such as diabetes and AIDS; and four members represent pharmaceutical companies.

The FTCR fears that because the board's membership represents academic and private research centers and corporations that stand to benefit from the grant funds, overlap between the funding institution and the beneficiaries could skew its decision-making.

Marcy Darnovsky, associate executive director of the bioethics advocacy group Center for Genetics and Society, warned that in its current form, the ICOC's policies and funding process will be "controlled by a governing board that is dominated by people who represent institutions that are going to be receiving the money."

In response to conflict-of-interest concerns, CIRM officials have issued guidelines ostensibly designed to keep the decision-making process "objective." Although board members could be affiliated with grantee institutions, they would be required to disclose any financial, personal and professional connections that might influence administrative decisions. Similarly, scientific advisers commissioned to review grant applications would not be able to consider requests from institutions with which they have ties.

In public statements, CIRM's leaders have also stressed that the agency's ongoing rulemaking process is taking into account not only the recommendations of institutional stakeholders but also public input gathered through filed comments and open hearings.

But critics say that the ICOC still lacks crucial perspectives from constituencies that might be uniquely affected by the still-evolving research on stem cells, including low-income communities and people of color – and especially women, who could be impacted by the bioethics issues related to egg donations for embryonic stem-cell development.

"Certainly," Simpson said, "there's a place at the table for some people who are interested in how taxpayers' money is spent without having a vested interest in receiving it."

http://newstandardnews.net (online) or display newstandardnews.net (print), and carry this notice. For more information or commercial reprint rights, please see the TNS [reprint policy](#).