



1750 Ocean Park Boulevard, #200, Santa Monica, CA 90405 - 4938  
Tel: 310-392-0522 • Fax: 310-392-8874 • Net: consumerwatchdog.org

Oct. 5, 2007

Mr. Scott Tocher  
Interim Counsel  
California Institute for Regenerative Medicine  
210 King St.  
San Francisco, CA, 94107

**Re: For-Profit IP Regulations**

Dear Mr. Tocher:

We remain concerned that the proposed Intellectual Property Regulations for For-profit Organizations lack an adequate provision to ensure that any drugs, therapies or treatments developed with CIRM funds will be affordable and accessible to all Californians. To ensure that the people who have paid for the research to develop these drugs have this affordable access, there must be a provision allowing for intervention by the state attorney general if the drugs are priced unreasonably.

This basic safeguard is lacking in the Intellectual Property Regulations for Non-profit Organizations as well.


A partial attempt to meet a goal of affordable access was intended by tying CIRM-funded drugs to the proposed California Discount Prescription Drug Program (Cal Rx). However, the flaw in that approach has been clearly demonstrated this summer. As part of the state budget accord, Gov. Arnold Schwarzenegger vetoed all funds to implement Cal Rx.

Clearly, any provisions in the IP policies that intend to implement favorable pricing must rely entirely on the IP regulations under CIRM's auspices and not on some outside scheme that is highly subject to political whim.

On a positive note, the added definitions and general editing of the proposed regulations help to clarify the regulations and remove ambiguity. Sadly, however, if the proposed regulations lack an essential provision – in this case a provision that guarantees affordable access for all Californians – it matters little how clear they are.

Thank you for your consideration.

Sincerely,

  
John M. Simpson  
Stem Cell Project Director