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BY ELECTRONIC MAIL TO NONPROFITIPREGS@CIRM.CA.GOV

Mr. C. Scott Tocher  
Interim Counsel  
California Institute for Regenerative Medicine  
250 King Street  
San Francisco, CA 94107


Dear Mr. Tocher:

California Healthcare Institute (CHI) welcomes this opportunity to comment on the California Institute for Regenerative Medicine’s (CIRM) third set of proposed changes to regulations addressing Intellectual Property Policy for Non-Profit Organizations (IPPNPO). CHI represents the full biomedical sector of the California economy; our members include more than 250 of California’s leading life sciences companies, universities, and academic research institutions.

As the advocate for California’s statewide biomedical research and development community, CHI appreciates the time and effort the Independent Citizens’ Oversight Committee (ICOC) has directed towards the development of an intellectual property policy that conforms to the purpose and intent of Proposition 71, the California Stem Cell Research and Cures Act (Prop 71). We especially appreciate the consideration given to comments provided by stakeholders, such as CHI, in the development of this important policy.

Nevertheless, CHI remains opposed to the requirement, as revised, that would permit exclusive licensing only if “licensees will agree to provide to patients whose therapies and diagnostics will be purchased in California with California funds or fund of any political subdivision of the state the therapies and diagnostics at a cost equal to that resulting from the provisions of Title 42, United States Code section 1396r-8, subdivisions (c)(1)(A)-(B) and subdivision (c)(2).”

Because commercialization is essential for the development and production of new medicines, CHI has long argued that the goal of the IPPNPO should be to minimize barriers to technology transfer. CHI understands that Prop 71’s language requires CIRM-funded research to provide “an opportunity for the state to benefit from royalties, patents, and licensing fees that result from the research.” However, we

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1 Proposed Title 17 of California Code of Regulations, section 100306(d), as revised
3 Text of Proposition 71, Sec. 3, Purpose and Intent
also note that Prop 71 specifically requires that such opportunities be balanced “with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.”

In their present form, requirements included in Section 100306(d) of the IPPNPO, we believe, will hinder medical research and product development by creating a **substantial disincentive** to commercial interest in licensing CIRM-funded inventions. Specifically, this provision would discourage commercial collaboration, technology transfer and licensing by (a) increasing the administrative complexity of licensing agreements involving CIRM-funded technologies in comparison to the mainstream of academic-industry transactions, which derive from federally-funded research, and (b) increasing investors’ financial risk by imposing state price regulation on downstream products. In short, we argue that the consequences of this provision would be to make industry and investors significantly less likely to consider licensing CIRM-funded technologies. The long-term result is likely to be fewer “life-saving regenerative medical treatments and cures” – the core purpose of Prop 71.

Beyond the general policy arguments against this provision, CHI suggests that the proposed new language remains impractical. It incorrectly implies that manufacturers provide patients with drugs directly, suggesting that the federal Medicaid drug rebate statute is the sole driver of “cost.” The real cost to a state government (or other entity) purchasing a drug on a patient’s behalf cannot be ascertained simply by reference to federally-mandated Medicaid rebates. Accordingly, any attempt to codify a therapy’s “cost” by in terms of a single component of this complex system misunderstands and oversimplifies the realities of drug distribution and reimbursement. Moreover, the proposed statutory citations do not apply to diagnostics or inpatient therapies. They apply only to “outpatient covered drugs” which are essentially all products regulated as drugs not delivered in the inpatient setting. In summary, the revised language fails to address CHI’s previous comments on this particular provision, may in fact be a further step in the wrong direction, and, we suggest, reinforces our conviction that IP policy is an inappropriate vehicle for addressing health care access and pricing issues.

For the reasons detailed above, CHI urges the deletion of this provision.

As CHI’s previous comments have suggested, the IPPNPO should include a “trigger” or threshold function that would limit its access and pricing provisions to resultant products for which CIRM funding is a significant and substantial portion of a product’s overall development costs. Such a trigger should apply to CIRM funding whether it involves an invention developed by a company in part through direct CIRM funding to the firm or part of an invention licensed by a company from a CIRM grantee. The principle for the trigger, we suggest, should be the proportion of CIRM funding in the total cost of bringing a resultant product to market, not the process by which CIRM funding is provided. To be clear, we believe that the provisions of Section 100306(d) will deter commercial and

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4 Prop 71 language establishing California Health and Safety Code, Division 106, Part 5, Chapter 3, Section 125290.30(h)  
5 Text of Prop 71, Sec. 2, Findings and Declarations  
6 August 22 and September 15 letters from D. Gollaher as well as public comments during September 21 IP Task Force meeting  
7 As included in the proposed Intellectual Property Policy for For-Profit Organizations (IPPFPO)
private investor licensing interest even with the adoption of a threshold function, but urge the ICOC to consider it as an improvement over the current construction.

We also continue to suggest that consideration should be given to those cases in which federal funding for an invention exceeds CIRM funding. In those instances, CHI suggests that approaches normally used in managing federally funded inventions should preempt CIRM IP regulations and requirements and preclude the triggering of these pricing and access provisions.

Conclusion

CHI appreciates this opportunity to comment on the revised CIRM Intellectual Property Policy for Non-Profit Organizations. We believe that a strong IPPNPO will advance CIRM-funded stem cell research and, ultimately, treatments for millions here in California and worldwide. This, in turn, will improve California’s health care system, benefit the California economy, and further stimulate the state’s biotechnology industry. We hope that the ICOC will give careful consideration to our comments and incorporate them into the final IPPNPO.

In summary, to promote technology transfer and commercial collaboration on CIRM-funded inventions and to limit barriers to stakeholder participation in research, licensing, and commercialization, CHI suggests that the ICOC:

- Remove provisions in Section 100306(d) that refer to Medicaid pricing.
- Limit pricing and access requirement provisions in Section 100306(d) to those resultant products for which CIRM funding was a substantial source of overall product commercialization funding.
- Affirm that in cases where federal funding for an invention exceeds CIRM funding that federal IP policy and relevant federal law would preempt CIRM IP requirements and preclude the triggering of pricing and access provisions.

We look forward to continuing to work with the ICOC as it finalizes this policy, and we would be happy to further discuss these comments in additional detail.

Thank you for your attention to this important matter.

Sincerely,

David L. Gollaher, Ph.D.
President and CEO
CHI – California Healthcare Institute