

June 12, 2008

The Honorable Sheila Kuehl  
The Honorable George Runner  
California State Senate  
State Capitol, Rooms 5108 and 5097  
Sacramento, CA 95814

RE: Senate Bill 1565  
CHI Position: Oppose, as amended June 9, 2008

Dear Senators Kuehl & Runner:

On behalf of the California Healthcare Institute (CHI), whose more than 250 members include our state's premier life sciences companies and academic research institutions, I am writing in opposition to SB 1565, legislation that would require intellectual property standards that are developed by the Independent Citizens Oversight Committee (ICOC) of the California Institute for Regenerative Medicine (CIRM) to include a requirement that each grantee and the licensees of the grantee submit to the CIRM for approval a plan that will afford uninsured Californians access to any drug that is, in whole or in part, the result of research funded by the CIRM, and would require that any plan subject to approval require that the grantees and licensees thereof sell drugs at a price that does not exceed any benchmark price in the California Discount Prescription Drug Program.

As the advocate for California's statewide biomedical research and development community, CHI, in 2006 and 2007, endeavored to help the ICOC develop their intellectual property policies for non- and for-profit organizations. During these processes, CHI submitted detailed comments regarding concerns with the pricing and access requirements that were eventually included as part of the final policies. Based on a CHI survey of biotech companies in California, we believe these provisions will create a significant disincentive for firms to commercialize inventions funded with CIRM money. And without industry participation, basic stem cell science cannot be developed into treatments for patients.

Because commercialization is essential for the development and production of new medicines that can be used by Californians and others, CHI believes that the basic goal of intellectual property policies should be to *minimize* barriers to transferring technologies from basic research laboratories to the private sector. During the past thirty years, California biotechnology companies have licensed hundreds of inventions from academic institutions. The lesson from this collective experience is that stakeholders – researchers and research organizations, industry and other licensees, and venture capital investors – value transparency and predictability in licensing and technology transfer agreements. Investment in biotechnology is inherently very risky. Any aspect of a technology transfer contract that increases risk, particularly by adding an element of uncertainty, makes it

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less attractive to potential partners and investors and thus reduces the prospects for successful commercial collaboration.

CHI strongly believes that a stated purpose of Prop 71 – to “improve the California health care system and reduce the long-term health care cost burden on California through the development of therapies that treat diseases and injuries with the ultimate goal to cure them” assumes that CIRM-funded research and resulting innovation will directly address these goals. The provisions in your measure would discourage commercial collaboration, technology transfer and licensing by (a) reducing the rate of return on CIRM-related deals in comparison to other academic-industry transactions, and (b) increasing investors’ financial risk by imposing state price regulation on downstream products. Considering biotechnology’s long product lead times, future price regulation makes it all the more difficult to project return on investment.

Experience at the federal level confirms these concerns. During the early 1990s, technology transfer and licensing policies at the National Institutes of Health (NIH) attempted to incorporate “fair pricing” requirements, with poor results. According to a report by the Congressional Research Service (CRS)

Prior to 1995, NIH had included what was known as a “fair pricing clause” in its cooperative research and development agreements [CRADA] and many licensing arrangements. In 1989, the Public Health Service (PHS) instituted a policy addressing the pricing of products resulting from a government-owned patent licensed by NIH on an exclusive basis to industry or an invention jointly developed with industry under a CRADA and then licensed exclusively to the collaborator. ...

The clause was removed in 1995 at the request of Dr. Harold Varmus, Director of NIH, after a review of the situation and several public hearings. He concluded that the evidence indicated “...*the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public.*” While sharing concerns over the “potential inaccessibility” of drugs due to costs, “*NIH [agreed] with the consensus of the advisory panels that enforcement of a pricing clause would divert NIH from its primary research mission and conflict with its statutory mission to transfer promising technologies to the private sector for commercialization.*” A study by the Department of Health and Human Services Inspector General found that companies viewed the clause as a major problem in the NIH CRADA approach. Opponents of the clause argued that the *uncertainty of the pricing clause exacerbated a process already fraught with risk.* According to industry sources, *not knowing what the determination of “fair” pricing would be at the end of a long and expensive research, development, and commercialization process was a strong deterrent to entering into cooperative arrangements.* Many of the pharmaceutical and biotechnology companies declined to undertake

CRADAs. Some firms even declined opportunities for joint clinical trials with NIH in anticipation of future price control demands.<sup>1</sup> (emphasis added)

Despite CHI's disagreement over the inclusion of pricing and access requirements in the IP policies, we have a greater concern with policymakers enacting legislation at this point. We believe that codifying IP provisions in statute will deny the ICOC the flexibility it may need to amend its IP policies in the event they prove to be inadequate. CIRM has just begun to issue research grants and it will likely be several years before any discoveries from this research move to the commercialization stage. Thus, the ICOC may not know for some time whether the IP policies it has adopted are effective and will need flexibility to change its IP policies as the situation warrants.

CHI and the biomedical community support the goals of the CIRM to invest in promising research that can be commercialized creating therapies and medicines that will benefit patients around the globe. We strongly believe that industry participation is critical to this success. We look forward to discussing this with you further.

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra Pizarro". The signature is fluid and cursive, with a long horizontal stroke at the end.

Sandra Pizarro  
Vice President – State Government Affairs

CC: Chair & Members, Assembly Health Committee  
Cassie Rafanan, Consultant, Assembly Health Committee  
Almis Udrys, Assembly Republican Caucus