



July 9, 2009

The Honorable Dianne Feinstein
United States Senate
331 Hart Senate Building
Washington, DC 20510

Dear Senator Feinstein:

We are writing to thank you for meeting with us yesterday to discuss an issue of critical importance to California's biotechnology innovators -- legislation to enact a pathway at the U.S. Food and Drug Administration (FDA) for the approval of follow-on biologics, or biosimilars, and in particular, the importance of maintaining the bi-partisan compromise agreement (S 1695, attached) crafted and unanimously reported out of committee last Congress by HELP Committee Chairman Kennedy, then-Senator Clinton, and Senators Enzi and Hatch.

As we discussed, the crux of the debate surrounds the period of data exclusivity -- the number of years after approval of a new biologic product that must pass before the FDA can rely upon the clinical data and other information generated by the innovator to approve a biosimilar product. The California biotechnology industry has for some time endorsed 14 years of data exclusivity as optimal and appropriate for a biosimilar regime. This position is based on a number of studies indicating that: 1) between 12.9 and 16.2 years is needed for innovator biologic products to cover costs [see attached paper "Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition" by Duke University Economist Henry Grabowski, and in particular Fig. 6, pg 8] and 2) traditional drugs, on average, are on the market for 13.5 years before encountering generic competition [see attached paper "Generic Competition and Market Exclusivity Periods in Pharmaceuticals" by Grabowski and Kyle, and in particular Fig. 3, pg 5].

That period is further supported by a recent paper by Deloitte, "Avoiding No Man's Land: Potential Unintended Consequences of Follow-On Biologics," (attached) which provides a first-of-its-kind overview comparing and contrasting the pharmaceutical industry and Hatch-Waxman generics pathway with the science, business and investment model of the biotechnology industry. Importantly, the Deloitte paper suggests that unlike under Hatch-Waxman, where generic drugs brought significant price competition but continued pharmaceutical innovation was maintained primarily through protections offered by patent rights, under a follow-on biologics regime, data exclusivity, not patent protections, will be key to promoting continued investment and innovation.

Following a major hearing (March 8, 2007) on the issue and numerous meetings with stakeholders from the biotechnology and generic industries and others, Chairman

Kennedy and Senators Clinton, Enzi and Hatch reached a compromise agreement providing for 12 years of data exclusivity, a term which we have supported. As mentioned above, that legislation was unanimously reported out of HELP Committee.

Unfortunately, efforts are underway to walk away from that agreement and include language in healthcare reform legislation being marked-up at the HELP Committee that would provide for reduced data exclusivity periods of as few as nine (9) years. Proponents of these reduced periods point to increased Democratic majorities in the Senate as well as a recent Federal Trade Commission report on “Follow-On Biologic Drug Competition” that suggests that 12-14 years of data exclusivity is “too long to promote innovation.” However, the basis of that FTC report has already been questioned in failing to fully and comprehensively account for elements such as the risk that biosimilars will come to the market before patents expire and the true “cost of capital” in the biotechnology industry, as addressed in the recent letter from the California Institute for Regenerative Medicine (CIRM) and a forthcoming report by the National Venture Capital Association (executive summary attached).

In light of the critical importance of this issue to California’s biotechnology innovators, as well as the thoughtful, balanced compromise agreement reached in the form of S 1695 last Congress, we respectfully request that you urge members of the HELP Committee to maintain that agreement and its central provision of 12 years of data exclusivity.

Sincerely,



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