To: ICOC Members
From: Nancy J. Koch
Re: Biosimilars Legislation
Sbj"t.: FTC Report on Exclusivity
Date: June 15, 2009

On Thursday, June 11, 2009, the Federal Trade Commission ("FTC") released a report entitled "Emerging Health Care Issues: Follow-on Biologic Drug Competition." The report addressed the impact of establishing an accelerated regulatory pathway for follow on biologics ("FOB") with particular focus on how a statutory exclusivity period would affect competition. The FTC concluded that FOB market entry would neither divert significant market share from Innovators nor drastically reduce prices for their products. Thus, the FTC argued that the current patent law system coupled with market based pricing would adequately protect biologic product innovation. Lengthy market exclusivity periods (like those proposed by Representative Eshoo in H. R. 1548), according to the FTC, are not necessary and could actually dampen innovation. A copy of the full FTC report is available at http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf. Though the FTC Report is quite lengthy, it contains a useful Executive Summary at pages i through x.

FTC Reasoning: The FTC approached the question of whether market exclusivity was necessary to promote innovation by trying to predict the competitive impact presented to a biologics Innovator by a FOB. FTC acknowledged that the complicated nature of biologics (compared to traditional chemical drugs) makes them much more costly and time consuming to develop. Similarly, FTC accepted that there would be significant economic advantages to a FOB applicant permitted to reference clinical trial and related data generated by an Innovator. Nonetheless, FTC concluded that the competition presented by a FOB would be more like the competition between two branded pharmaceutical products than it would be like the competition between a branded pharmaceutical drug and a generic drug under the Hatch Waxman regime. To support that conclusion, FTC cited the high barriers to entry involved with biologics, the relatively few competitors expected to bring FOBs to market and the fact that payor/insurance incentives and requirements to substitute generic drugs would not apply to biosimilars.

Based upon this prediction, FTC reasoned that notwithstanding entry of a FOB, an Innovator could still maintain most of its market share and not be forced to reduce prices by more than 10 to 30%. Thus, Innovators could reasonably expect to make profits and recoup their investment costs for many years after the FOB entered the market. The FTC noted that the existing patent system protects Innovators and saw no reason why the existing laws would not adequately protect and motivate biologic

Innovators. Further, the FTC argued that creating an exclusivity period for biologics could actually dampen innovation because companies would target "scarce R&D dollars toward developing low-risk clinical and safety data for drug products with proven methods of action rather than toward new inventions to address unmet medical needs." Report at p. 27.

External Reactions to FTC Report: Representative Waxman hailed the FTC's report, saying: "The report completely disposes of the drug industry's argument that they need 12 to14 years of exclusive marketing, indeed that they need any additional exclusivity, to sustain innovation. " According to Mr. Waxman, "This is good news for consumers, who will have early access to affordable versions of life-saving drugs without compromising future breakthroughs." His full statement is available at: http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1659:chairman-waxmans-statement-on-ftc-report-on-follow-on-biologic-drug-competition&catid=155:statements&Itemid=55>.

BIO issued a rebuttal to the FTC report challenging many of the FTC's assumptions, decrying its narrow policy perspective and charging that the FTC failed to understand the conditions needed to drive biomedical breakthroughs. The biotechnology sector, according to BIO, plays a critical role not just in advancing medical technology but also in driving the American economy. BIO renewed its call that Congress strike an appropriate balance between spurring innovation and safely increasing access to biomedical technologies. BIO's full statement is available at: http://bio.org/healthcare/followonbkg/FTC_biosimilars_report_rebuttal.pdf.

Finally, in light of the FTC report, the FDA has been asked by the House Energy and Commerce Committee to update its position concerning FOBs. The FDA's last policy statement on this matter came during the Bush Administration. Some speculate that the Agency's position may shift under the Obama administration.

Impact on CIRM's Position: The ICOC endorsed H.R. 1548, the "Pathway for Biosimilars Act of 2009" which would create a 12 to 14 year exclusivity period. At its next meeting, the ICOC will have another opportunity to consider both H.R. 1548 and a competing piece of legislation, Representative Waxman's H.R. 1427 which would establish a 3 to 5 year exclusivity period. Anticipating that discussion, it may be useful to call to the ICOC's attention a few aspects of the FTC Report:

1. The FTC's report predicts the future. Hence, the FTC itself identified several forces which could impact the competitive environment and presumably would affect the FTC's analysis. Specifically, the FTC drew attention to: a) potential changes in technology (for instance if it became routine to more accurately characterize and compare biologics); b) the occurrence of biosimilar safety issues (which could undermine confidence in FOB's); c) expansion of health insurance coverage and changes in payor and reimbursement strategies (which could mandate use of biosimilars as is the

case with generic chemical drugs). See Report at p. 24. These are significant qualifiers to the accuracy of the FTC's predictions.

2. The Report makes almost no distinction between Big Pharma and small to mid size biotech companies. In fact, the Report assumes that FOB competitors will be Big Pharma organizations. See Report at p. 14 and 15. This ignores the role played by small and mid sized biotechnology companies in developing biotech products. different economic situations faced in today's market by well financed Pharma companies compared to smaller biotech organizations.
3. Similarly, the FTC report makes little mention of how difficult it is for smaller companies to obtain financing. In fact, the Report ignores the different economic situations faced in today's market by well financed Pharma companies compared to smaller biotech organizations. The Report assumes that basic science is paid for by the government and then developed into commercial success by Big Pharma. See Report at p. 28, f.n. 101. ("While government funds are used on a variety of novel scientific research, corporate funding typically is incremental innovation to support its pre-existing core business, and to "advance its established products and process technologies to better serve existing markets.'). That analysis sidesteps the financially daunting circumstances faced by smaller companies.

For CIRM, this last point is particularly significant. Even if the FTC's prediction were generally correct, stem cell research and the market for stem cell therapies would seem to fall outside the Agency's analysis:

First, CIRM is focused on a technological field still in its nascent stage. We do not face a market where the fundamentals have long been established and all that remains to accomplish are minor advances and improvements. In our field, the money required and the development timeframes are comparatively vast;

Second, the majority of commercial entities in the SC filed are small or emerging companies. Data exclusivity for these entities is key to their ability to obtain financing. This is a very different financial circumstance from the Big Pharma circumstance assumed in the FTC report; and

Third, since early in the Bush Administration, federal funds have not been available for eSC research. Even in the Obama administration, the Dickey-Wicker Amendment continues to bar federal support of eSC work. Though that could change in the future, the history of no government funding is significant to understanding the economic circumstances faced by commercial entities in this field.