To: ICOC Members
From: Nancy J. Koch
Re: Biosimilars Legislation
Subject: Update
Date: June 10, 2009

At its June 17 and 18th meeting, the ICOC will have another opportunity to consider two proposed federal bills which would create a regulatory pathway for approval of biosimilars: H.R. 1548, the "Pathway for Biosimilars Act of 2009" introduced by Representative Eshoo; and H.R. 1427, the "Promoting Innovation and Access to Life-saving Medicines Act," introduced by representative Waxman. You will recall that the Board endorsed H.R. 1548 at its May 12, 2009 telephonic meeting. This memo summarizes recent developments concerning biosimilars legislation.

ICOC Process Background: Establishing a regulatory pathway for biosimilars was first considered by the ICOC in April, 2009. The Board received extensive briefing materials and engaged in a substantive discussion of the issues. During a specially noticed meeting of the ICOC held on May 12, 2009, the ICOC voted to endorse H.R. 1548 and delegated to its Legislative Subcommittee responsibility to continue monitoring relevant developments and adjust CIRM's position appropriately. To inform the Board regarding the latest developments and to permit further opportunity for discussion by the Board and the public, we have included consideration of federal biosimilar legislation (H.R. 1427 and H.R. 1548) on the Board's June agenda. Board Members will be free to consider public comment and additional motions, if a member so desires, relating to this item.

Summary of Legislation/Background Materials: ICOC members previously received copies of H.R. 1548 and H.R. 1427. Other materials, including an analysis prepared by the Congressional Research Service, also were made available to Board members and the public in connection with prior ICOC meetings. Staff will provide additional copies of any of these materials upon request. For your convenience, here are links to the materials previously provided:
http://www.cirm.ca.gov/sites/default/files/PDFs/042809_item_14a.pdf

http://thomas.loc.gov/cgi-bin/query/z?c111:h1427

http://thomas.loc.gov/cgi-bin/query/z?c111:h1548

In summary, both legislative proposals would establish a regulatory pathway for FDA approval of biologic pharmaceuticals similar to the one that currently exists for "generic" chemical pharmaceuticals. Each bill would facilitate entry of additional biologics to the market by allowing applicants to reference clinical studies performed by Innovators of "similar" biologics that had been found safe and efficacious by the FDA.

The competition presented by additional products is expected to result in lower prices for patients and providers.

To foster innovation, both bills would create an "exclusivity period" during which applicants could not reference studies performed by Innovators to support generic applications. The exclusivity period proposed by Representative Eshoo would range between 12 and 14 years. Under Representative Waxman's proposal, 3 to 5 years of exclusivity would be accorded. Both bills permit competitors to seek FDA approval using preclinical, clinical and manufacturing data which they generated themselves at any time (subject, of course, to applicable intellectual rights which may be held be the Innovator).

Developments Since May 2009: Here is a summary of relevant events since the ICOC last considered the biosimilars issue:

1. Currently, Representative Eshoo's legislation has 90 co-sponsors. Representative Waxman's competing legislative proposal has 11 co-sponsors.
2. On June 11, Representative Eshoo will hold a hearing on biosimilars at which the FTC will be the sole witness. Apparently, the FTC has generated a report on the biosimilars pathway, but the report is not yet publicly available. CIRM Staff will study this report upon release and provide the ICOC with germane portions.
3. Representative Waxman wrote to President Obama this week urging that biosimilars be considered as part of the overall health care reform issue. A copy of that letter is attached. Waxman further suggested that the FDA should move very quickly to implement the biosimilars regulatory pathway once legislation is enacted.
4. According to at least one publication, the 2010 Obama budget assumed a 7 year exclusivity period for biosimilars.

The Legislative Path Forward: We expect an uptick in Congressional focus on biosimilars legislation during June and July as the issue is folded into the larger health care reform discussion. The exclusivity period remains the most contentious point of difference between the Eshoo and Waxman bills. Many expect that a compromise between 5 and 12/14 years will be struck to enable the legislation to move forward.