

To: ICOC Members
From: Nancy J. Koch
Date: May 8, 2009
Re: Statement of ICOC Principles Relating to Biosimilars

At its April meeting, the ICOC considered several pieces of proposed federal legislation which would create a regulatory pathway for approval of biosimilars. This discussion was based, in part, upon a large volume of materials concerning issues raised by the legislative proposals including the draft bills themselves and an analysis prepared by the Congressional Research Service. Those materials, of course, were made publicly available and remain available for your consideration.

At the conclusion of your discussion in April, the ICOC requested Staff to prepare a draft Statement of Principles relating to the biosimilars issue for consideration at the Board's June 12th telephonic meeting. Attached to this cover letter is the requested draft Statement.