Many questions for, but not many answers from, the FDA on biosimilars implementation after last week's hearing

September 25, 2015

The US Senate Committee on Health, Education, Labor and Pensions on September 17, 2015 convened a hearing entitled Biosimilars Implementation: A Progress Report from the FDA. Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research of the FDA appeared as the witness for the agency.

The hearing began with some skepticism from Senators Bill Cassidy (R-LA) and Christopher Murphy (D-CT). In their opening statements, each raised questions about why five years after the passage of the Biologics Price Competition and Innovation Act (BPCIA) there remains significant uncertainty with respect to FDA guidance on key issues. In particular, the Senators focused on the process and standards by which the FDA will approve biologics as biosimilar, and particularly, as interchangeable.

In her testimony, Dr. Woodcock recognized the importance of biosimilars in treating life threatening illnesses and that biosimilars will create more treatment options. She noted, however, that obtaining physician and patient confidence in and acceptance of biosimilars remains an obstacle to maximizing their benefit in treatment. Toward that end, Dr. Woodcock indicated that FDA guidance would be forthcoming on considerations in demonstrating interchangeability between biosimilars and reference products, statistical approaches to evaluation of analytic similarity data to support demonstration of biosimilarity and appropriate labeling of biosimilars.

The questions from the Committee Members evidenced frustration with the pace of the FDA's progress on these issues. Dr. Woodcock acknowledged that the primary burden is on the FDA to generate and publish the guidance for the industry, developing plans for physician and patient education and establishing the standards for interchangeability and labeling. However, in response to a question from Committee Chairman Lamar Alexander (R-TN), Dr. Woodcock noted that Congress has not funded any FDA educational programs.

Senators Elizabeth Warren (D-MA) and Mark Kirk (R-IL) pointed out that the European Union and Canada have been progressing at a more rapid pace than the US. Dr. Woodcock stressed that the FDA wants to get the science right and provide guidance that is accepted in the scientific community. She also noted that the FDA has approved some of the same products as the EU and Canada, but as drugs, not biosimilars.

At the end, many unanswered questions still remain for the FDA with respect to the implementation of BPCIA. While the FDA does not yet have the answers or know when it will, the FDA is aware that Congress is impatient.

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