

### **AARDA CO-Cosponsors Biosimilars Briefing on Capitol Hill**

Monday, July 13<sup>th</sup>, the American Autoimmune Related Disease Association (AARDA) joined with the Global Healthy Living Foundation, the Coalition of State Rheumatology Organizations, the Arthritis Foundation, and the Congressional Arthritis Caucus to present a briefing on Capitol Hill for Congressional staff titled, "Biosimilars for Arthritis Patients: Challenges and Opportunities."

The speakers' panel included Katherine Macfarlane, Global Healthy Living Foundation; Jim McKay, Sandoz Corp., Kimberly Greco, Amgen Corp.; Dr. Harry Gewanter, Pediatric Rheumatologist from Virginia Commonwealth University School of Medicine and the Alliance for Safe Biologic Medicines; and Dr. Gregory Schimizzi, Coalition of State Rheumatology Organizations. The speakers explained to the Congressional staff and others in attendance the importance of newly developed biologic drugs and biosimilars and the hope for new treatments they are bringing to autoimmune patients.

Biologic drugs are complex molecules develop from living tissue that are very complicated to replicate and difficult to compare. The characteristics of biologics and biosimilars, similar to generic versions of simpler inorganic compounds, are highly dependent upon the manufacturing process in addition to the ingredients. Biologics may be derived from many sources, including human or animal tissue, blood, plants, microorganisms, or yeast. The new generation of biologic pharmaceuticals and biosimilars now coming to market offer autoimmune disease patients the best hope yet. But patient safety remains the critical issue.

After a long arduous journey developing an appropriate pathway for approval of biosimilars, March 6<sup>th</sup> of this year, the U.S. Food and Drug Administration announced the approval of Zarxio (filgrastim-sndz), the first biosimilar product approved in the United States.<sup>1</sup> The FDA announcement stated, "A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an already-approved biological product, known as a reference product. The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. Sandoz, Inc.'s Zarxio is biosimilar to Amgen Inc.'s Neupogen (filgrastim), which was originally licensed in 1991." The FDA announcement went on to explain, "A biosimilar product can only be approved by the FDA if it has the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product, and only for the indication(s) and condition(s) of use that have been approved for the reference product. The facilities where biosimilars are manufactured must also meet the FDA's standards."

The July 13 Capitol Hill briefing panel explained to the over 110 Congressional staff and others attending that because biologics are comprised of hugely complex chemical entities that are highly dependent upon the manufacturing process in addition to the ingredients, it's much more difficult to identify medicinal similarity and to ensure the same reaction in the human body. Biosimilars can differ slightly from the reference product (originally approved biologic) in what are termed, "protein isoforms," different forms of the same protein, especially between manufacturers and manufacturing sites, but sometimes between different batches of the same ingredients by the same manufacturer explained Jim McKay from Sandoz.

Because of the difficulty ensuring the biosimilar product's acceptable comparable effectiveness to the reference product the US and other regulatory agencies around the world must maintain rigorous approval standards to ensure patient safety. Dr. Gewanter who recently attended a World Health Organization conference in Geneva, Switzerland, on worldwide biosimilar drug naming, emphasized that it's also critically important to be able to identify and track the manufacturer and the manufacturing site of biosimilars with unique nonproprietary names to avoid confusion and ensure transparency and comparability. The panelists described substitutability between biosimilars and the originator drug as when the insurance company, other payer, or pharmacy benefits manager changes the drugs on its formulary often for costs control motivations. Patient safety demands we be able to ensure substitutability and be able to track issues that may arise with unique biologics and biosimilar names and drug codes explained Dr. Schimizzi.

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<sup>i</sup> FDA News Release, March 6, 2015, FDA Approves First Biosimilar Product Zarxio, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm>