Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 348 0210 fax
www.ghlf.org

50-State Network Advocate
Brief: Biosimilars

How can you help?

In March 2010, a U.S. biosimilar pathway was signed into law as part of the Affordable Care Act (ACA). In February 2012, the Food and Drug Administration (FDA) issued three draft guidance documents on biosimilar product development to assist industry in developing such products in the United States. What, if any, additional guidance FDA may issue, and when, is uncertain. [1]

Currently, state governments across the country are holding hearings to debate the framework in which biosimilar products are introduced in their state. The policy on whether one biologic product may be substituted by dispensers when a different biologic product was prescribed is governed by state law.

Innovator biologic manufacturers, biosimilar manufacturers, pharmacists, and physicians are well represented in the discussions. We must make sure the patient voice is not forgotten in this pivotal time! As a 50-State Network Advocate now is your time to shine

What are biologics?

A biologic medicine is a large molecule typically made from living cells and used in the treatment, diagnosis or prevention of disease. Biologic medicines include therapeutic proteins, DNA vaccines, monoclonal antibodies and fusion proteins. Biologic medicines are often 200 to 1,000 times the size of widely used small molecule drugs and are far more complex structurally. They are also highly sensitive, making them more difficult to characterize and produce.[2]

What are biosimilars?

Unlike generic medicines where the active ingredients are identical, biosimilars – by definition – are not likely to be identical to the originator biologic. They are similar, but not the same. Biologics made by different manufacturers differ from the original product and from each other.[3]

Why are biosimilars important?

With expanding demand for good-quality healthcare, comes the challenge of controlling healthcare costs. The safe and regulated introduction of biosimilars into the market has been forecasted to increase and improve access to much needed biologic medicines and reduce costs.[4]

---

[1] U.S. Food and Drug Administration. Guidance for Industry. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product.Draft Guidance. U.S. Food and Drug Administration. [Online] Febuary 2012. [Cited: November 20, 2012.] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf
[2] U.S. Food and Drug Administration. What are biologics: Questions and Answers. U.S. Food and Drug Administration. [Online] April 14, 2009. [Cited November 20, 2013] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.html
[3] European Medicines Agency. Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1). European Medicines Agency - Europa. [Online] May 24, 2012. [Cited: November 20, 2013.] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/05/WC500127960.pdf.
[4] Mellstedt, H., et. al. The challenge of biosimilars. Annals of Oncology 19. March 2008, pp. 411-419.

Global Healthy Living Foundation
515 North Midland Avenue
Upper Nyack, New York 10960 USA
+1 845 348 0400
+1 845 348 0210 fax
www.ghlf.org

50-State Network Advocate Talking Points:
Biosimilars

1. As patients, our core concerns are to safeguard safety and the physician-patient relationship. Physicians and their patients are in the best position to determine appropriate therapies.

2. Transparency and communication between patients and their treatment teams is paramount. The core principles that we believe should guide substitution policies for biosimilars under state law include:

    a) Substitution should occur only when the FDA has designated a biologic product as interchangeable.

    b) The prescribing physician should be able to prevent substitution.

    c) The prescribing physician should be notified of any substitution.

    d) The patient, or the patient's authorized representative, should, at a minimum, be notified of any substitution.

    e) The pharmacist and the physician should keep records of any substitution.