BIOSIMILARS
— A Podcast Series —

The New Era of Management in Gastroenterology and Rheumatology

What Are Biosimilars?

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Learning Objective	Podcast Discussion Summary
Define Biologic Therapy	The National Cancer Institute provides a synopsis stating biologic therapies are a type of treatment that uses substances made from living organisms to treat disease. These substances may occur naturally in the body or may be made in the laboratory. Broadly speaking, biological therapies stimulate or suppress the immune system, although for GI and rheumatology purposes, we primarily aim to suppress the immune system. Common mechanisms include tumor necrosis factor inhibition, blocking various interleukins, such as IL-6, IL-17, or IL-23, and directly targeting B-cells and T-cells.
Define Biosimilar	Biologic products have been approved by demonstrating a high similarity to an FDA-approved biologic product, known as a reference product. Biosimilars are designed to have the same mechanism of action, safety, and efficacy as the reference product. It's important to note that only minor differences in clinically inactive components are allowable in biosimilar products, and they have no clinically meaningful differences in terms of safety and effectiveness from the reference product.
Define Reference Product	The reference product is an approved biologic medicine that has been previously authorized for marketing and is used as a standard for comparison with a biosimilar. The reference product is the original biologic medicine that the biosimilar is designed to replicate and is used as a benchmark for biosimilars.
Summarize the Impact of the Biologic Price Competition and Innovation Act	The Biologic Price Competition and Innovation Act is a law that was passed in 2010 as part of the Patient Protection and Affordable Care Act. The law was designed to create a regulatory pathway for the approval of biosimilars, amongst a handful of other things. Key provisions are that it not only establishes a regulatory pathway for their approval but also the Biologics Price Competition and Innovation Act defines a "biosimilar." The act also sets up a system for the exchange of information between the biosimilar applicant and the reference product sponsor. It requires the biosimilar applicant to provide the reference product sponsor with information about the biosimilar, including its manufacturing process, and to engage in a process of information exchange. The act also provides a period of market exclusivity for the reference product.

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