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Biosimilars and emerging challenges: Navigating pathway to approval, patent issues, and the exclusivity period

Biosimilars also known as follow-on biologics are biologic medical products, whose active drug substance are made by a living organism or derived from a living organism by means of recombinant DNA or controlled gene expression methods. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was originally sponsored and introduced on June 26, 2007 by Senator Edward Kennedy (D-MA). It was formally passed under the Patient Protection and Affordable Care Act (PPAC Act), signed into law by President Barack Obama on March 23, 2010. The BPCI Act was an amendment to the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products that are demonstrated to be highly similar (biosimilar) to a FDA approved biological product. The BPCI Act is similar, conceptually, to the Drug Price Competition and Patent Term Restoration Act of 1984 (also referred to as the "Hatch-Waxman Act") which created biological drug approval through the Federal Food, Drug, and Cosmetic Act (FFD&C Act). The BPCI Act aligns with the FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing. The FDA has released a total of four draft guidelines related to biosimilar or follow-on biologics development. Upon the release of the first three guidance documents the FDA held a public hearing on May 11, 2012. A summary of the key issues raised is available for review in the journal *New Pharma Thinkers*. A biosimilar product is "expected to produce the same clinical result in any given patient," according to the FDA. How similar is similar enough? Given the complex nature of monoclonal antibodies and soluble receptors, it's unlikely there will be a one-size-fits-all definition.

Biography

Krishna Menon has more than 25 years of experience in drug development with academia and industry. He is a Co-founder of Cellceutix and has served as President and Director since inception in June 2007. Prior to Cellceutix, he served at Eli Lilly as Group Leader, cancer *in vivo* research and clinical development. At Lilly, he played a key role in lead selection and pre-clinical development of Gemzar and Alimta, two anti-cancer drugs which have generated billions of dollars in yearly revenue. In addition, Lilly honoured him with the prestigious President's Recognition Award. Prior to Eli Lilly, he operated his own veterinary oncology and drug development consultancy practice. Earlier in his career, he held research scientist positions at Miles Laboratories and Dana Farber Cancer Research Institute, where he worked under the direction of Dr. Emil Frei, one of the world's leading oncologists and a leader in medical research. He is a trained veterinary surgeon and holds a PhD in Pharmacology from Kerala University. His PhD work focused on anti-folate therapy of various cancers.

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