

4<sup>th</sup> International Conference and Exhibition on

# Biologics & Biosimilars

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## State of the biosimilar industry

The United States biosimilars market was established based upon The Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act was formally passed under the Patient Protection and Affordable Care Act (ACA), and 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) which created an abbreviated approval pathway known as the 351(k) pathway for biological products that are demonstrated to be highly similar (biosimilar) to a FDA approved biological product. Since March of 2010 there has been a flurry of activity in the US biosimilars market covering all aspects of the path to approval including a set of FDA guidance, 351(k) filings, and varying approaches to the “patent dance”. There has also been an emergence of biosimilar players from pure play biosimilar companies to large multinational pharmaceutical companies establishing divisions devoted to biosimilar development. This presentation will recap the evolution of the US Biosimilar market since the passage of the ACA and will explore the present and future global biosimilars opportunity.

## Biography

Patrick Lucy is the Chief Business Officer of Pfenex Inc. (NYSE: PFNX). He was a member of the team that founded Pfenex within The Dow Chemical Company. He has been in the biotechnology industry for over 22 years holding technical, operational and commercial roles throughout his career. He previously worked at The Dow Chemical Company, Collaborative Bio-Alliance, Lonza Biologics, Cell-tech Biologics and Repligen Corporation.

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