Cellceutix Corporation

CTIX

100 Cummings Center, Suite 151B
Beverly, MA 01915

Within a few years, more than half of newly approved medicines will be biopharmaceuticals

.

To ensure safety and efficacy, the FDA created a daunting Biosimilar Approval Pathway

Counsel must develop new approaches to ensure a client's research, development and production of biosimilars meets these high standards.

Patents and exclusivity periods present challenges in the development and marketing of biosimilars

FDA must address these challenges by assessing the benefits and risks of patent exchange procedures, handling infringement issues, and utilizing the exclusivity period to a client's advantage.

Biosimilars should provide cost savings and greater accessibility to biopharmaceuticals. A thorough knowledge surrounding biosimilars will ensure the appropriate use of biopharmaceuticals

President, Chief Scientific Officer,

Board of Directors - Dr. Krishna Menon, VMD, MRCS,PhD

Biosimilars or follow-on biologics

Biosimilars are not generics

- **biologic medical products**
- **Active Drug Substance is made by a living organism**
- **recombinant DNA or controlled gene expression methods**
- **subsequent entry biologics (SEBs)**
- **similar biological medicinal products"**
- **Bio-interchangeables**

How it is Made

- **Active Drug Substance is made by a living organism**
- **recombinant DNA or controlled gene expression methods**
- **Recombinant therapeutic proteins are of a complex nature**
- **composed of a long chain of amino acids, modified amino acids, derivatized by sugar moieties, folded by complex mechanisms**
- **characteristics of a drug containing a recombinant therapeutic protein are to a large part determined by the process through which they are produced**
- **choice of the cell type, development of the genetically modified cell for production, production process, purification process, formulation of the therapeutic protein into a drug.**

Approval Process

- **The Biologics Price Competition and Innovation Act of 2009 (BPCI Act)**
- **Patient Protection and Affordable Care Act**
- **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).**

Data exclusivity

preserve innovation and recognize
The time allowed for data exclusivity is critical

Market implications

The legal requirements of approval pathways
costly manufacturing processes

expected to produce the same clinical result in any given patient

How similar is similar enough?

complex nature of monoclonal antibodies and soluble receptors

it's unlikely there will be a one-size-fits-all

For peptides and short proteins, possible to create bio-identical products

THANK YOU