discovering cures

WHAT ARE BIOLOGICS?

Biologics are treatments created from a variety of living cells including animal, yeast and plant cells. Biologic medicines are made through the science of biotechnology by engineering and controlling living processes, rather than traditional chemistry, which produces chemical pills.

Advanced biologic molecules are thousands of times larger and more complex than a typical pill molecule, and far more sensitive to changes in their environment.

Biologics are typically injected, since the human digestive tract would destroy them; also, they interact with the body in the bloodstream or on the surfaces of cells, rather than within the cells.

Many biologic medicines work by providing proteins that healthy individuals possess, but patients lack; others target specific genetic mutations.

HOW ARE BIOLOGICS DIFFERENT FROM PILLS?

There are tremendous differences between biologics and traditional pills. Pills are pure chemical substances with relatively small, simple and repeatable structures or formulas. Pills are generally easier to replicate in a generic form due to their size, structure and controlled manufacturing process. Due to the size and basic structure of traditional pills, even minor changes in the product can be easily detected.

Biologics, on the other hand, come from a unique cell line – either plant or animal – which is refined using a complex and sensitive process. Because the process is essential throughout production, replication of an identical biologic by another manufacturer is almost impossible to achieve. While advanced tools can increasingly detect differences, current science does not yet provide the ability to know which differences can affect safety and efficacy.

BIOLOGICS vs. TRADITIONAL PILLS

	Biologics	Traditional Pills
Size	Large, complex, living, growing molecules	Small, simple, chemical formulas
Structure	Biotechnology: living cells	Chemistry: chemical process
Process	Proteins, growing, living systems in varying environments	Controlled process and formula

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THE PROCESS

Different production processes tend to create different biologics, given that living cells are the source of biologic production; generally, no two different cell lines can produce an identical copy of the same biologic. As a result, unlike pills, there are no exact copies of biologics. Each stage of the production phase and/or the conditions in which these products ***live*** and ***grow*** can lead to significant differences in the final product.

The main stages of developing a biologic include:

- Identifying and replicating a genetic sequence code for a desired protein
- Inserting the modified DNA into a living cell to encode it to emit the desired protein
- Growing and replacing the production cells in a living cell culture

Changes to any step(s) in this process, or changes in the environment in which these steps take place, can have an impact on the end product. In rare cases, these differences can result in a clinical impact and have the potential to harm the patient.

HOW ARE BIOLOGICS USED?

Biologic products represent the cutting edge of medical science and research. They successfully treat patients with difficult to treat diseases including cancer, heart disease, arthritis, multiple sclerosis, HIV/AIDS, among others. Biologics are often used to treat high-risk and critically ill patients that have not been responsive to traditional medical treatments alone.

There are currently more than 200 FDA approved biologic therapies, including some of the most innovative new treatments for patients suffering from debilitating diseases and conditions, including:

- Herceptin-approved in 1998, the first personalized medicine for the treatment of a specific type of breast cancer.
- Avastin-approved in 2004 for use with other drugs as a treatment for colorectal and other types of cancers.
- Epogen-approved in 1989, for the treatment of anemia due to chemotherapy or chronic renal failure.
- Humira-approved in 2002, for the treatment of rheumatoid arthritis.
- Remicade-approved in 1998 for the treatment of auto-immune diseases such as Crohn's disease and psoriasis.
- Fabrazyme-approved in 2003 for the treatment of Fabry Disease, a serious metabolic genetic disorder.

Along with these and many other life-enhancing and lifesaving biologic products on the market, the biotech industry also has hundreds more in development.

Biologics are often designed to treat patients with significant, unmet medical needs, diseases and conditions for which traditional pills are not adequate.