BIOLOGICS: WHAT MAKES THEM DIFFERENT?

Small-molecule versus large-molecule medicines

With more biologic medicines becoming available to treat a broad range of health conditions, it's important to understand how these complex, "large-molecule" medicines differ from small-molecule medicines people may be more familiar with.

	WHAT ARE THEY?	HOW ARE THEY MADE?	HOW ARE THEY MANUFACTURED?
SMALL MOLECULE MEDICINES	What most people think of when they imagine a medicine – typically a tablet or capsule, taken by mouth and containing a single chemically-synthesized active ingredient, like aspirin	Small-molecule medicines are made entirely from chemically-synthesized reactions between different compounds in a lab setting [1]	By chemical processes
LARGE MOLECULE MEDICINES (BIOLOGICS)	Made by or from living cells and structurally complex; generally injected or infused in a doctor's office or hospital setting. Their active ingredients are mainly proteins such as hormones, antibodies, cytokines, and insulin	Biologics are derived from living organisms (usually by producing a recombinant protein in living cells), and their characteristics and properties are heavily influenced by the manufacturing process	Via living cells and organisms through processes that are sensitive to changes in their environment and handling[2]

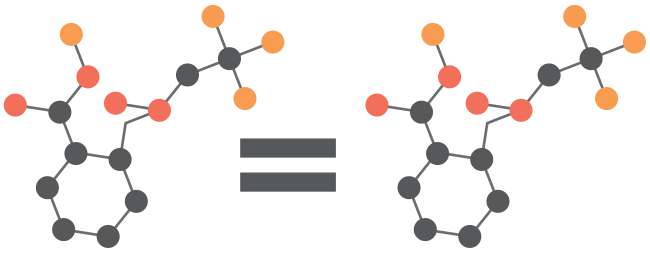
CAN THEY BE EXACTLY REPRODUCED?

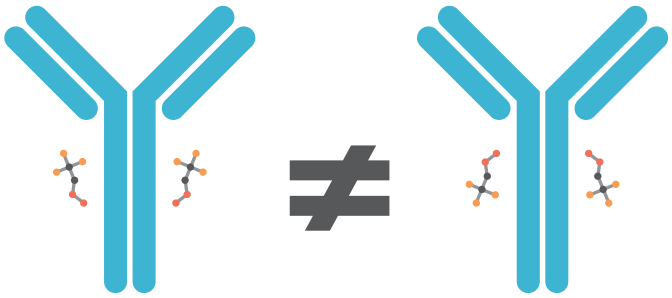
Small-molecule Medicines

Yes. Because they are produced through a chemical process, they can be copied exactly. Small-molecule medicines can be replicated as generics of an original brand-name medicines, where they share the exact same active ingredient and are therefore bioequivalent[1]

Large-molecule Medicines (Biologics)

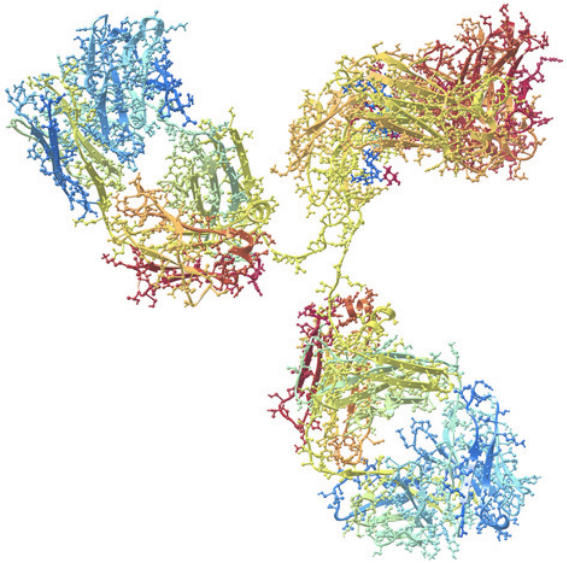
No. Because they are derived from living cells, biologics can never be exactly reproduced or copied like generics. However, a biosimilar version can be produced to be "highly similar" to the original in terms of safety, purity, and potency, and used to treat the same illness or condition as the original





SMALL- VS. LARGE-MOLECULE MEDICINES: A CLOSER LOOK

Some biologics can be 200-1,000x larger than small-molecule medicines, like aspirin.[3]



Monoclonal antibody molecular breakdown
150,000 Da*

Aspirin molecular breakdown
180 Da*

*Da: Short for "Daltons"
The standard molecular unit of measurement for any kind of matter

[1]U.S. Food and Drug Administration. "What are Biologics? Questions and Answers" http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm. Accessed March 19, 2013.
[2] H. Grabowski, "Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition," Nature Reviews Drug Discovery 7, 479-488, June 2008, available at: http://www.nature.com/nrd/journal/v7/n6/full/nrd2532.html#B51, see also A. McCook, "Manufacturing on a Grand Scale," The Scientist, February 14, 2005, available at http://www.thescientist.com
[3]American Cancer Society Cancer Action Network. Understanding Biologic Medicines from the Cancer Patient Perspective. January 2013.
Available: http://action.acscan.org/site/DocServer/ACSCAN-Biosimilars-Primer.pdf?docID=22449. Accessed: August 2013.