Alliance for Health Reform Biosimilars Briefing

Geoff Eich, Executive Director External Affairs, Amgen Biosimilars

Union Station's Columbus Club on Capitol Hill
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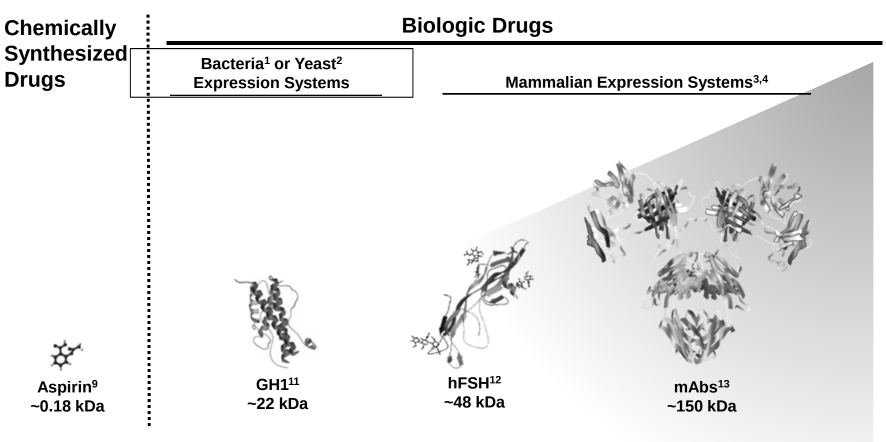
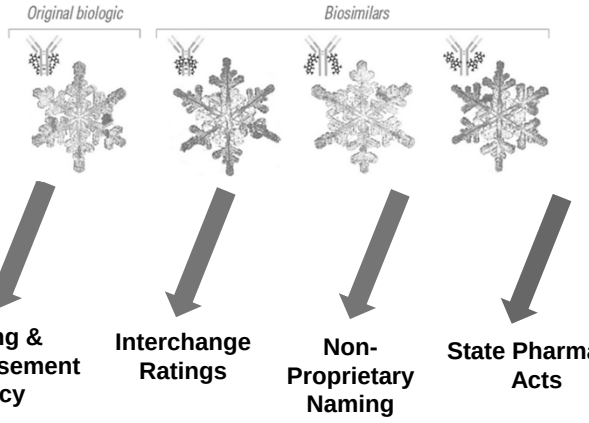
#biosimilarbasics starts with a focus on *biological* medicines



Images are not shown to relative scale.

1. Baneyx F. *Curr Opin Biotechnol.* 1999;10:411-421. 2. EMA. http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000318.jsp. Accessed February 18, 2015. 3. Rosser MP, et al. *Protein Express Pur.* 2005;40:237-243. 4. Lackner A, et al. *Anal Biochem.* 2008;380:146-148. 5. Schneider C, et al. *Nat Biotechnol.* 2008;26:985-990. 6. Berkowitz S, et al. *Nat Rev Drug Discov.* 2012;11:527-540. 7. Johnson J. Congressional Research Service. 2010. https://primaryimmune.org/advocacy_center/pdfs/health_care_reform/Biosimilars_Congressional_Research_Service_Report.pdf. Accessed April 7, 2015. 8. EMA. *Guideline on Non-clinical and Clinical Development of Similar Biological Medicinal Products Containing Recombinant Human Insulin and Insulin Analogues.* 2012. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/12/WC500136392.pdf. Accessed April 7, 2015. 9. Aspirin (acetylsalicylic acid) prescribing information, Bayer. 10. Insulin product information, Sigma-Aldrich. 11. OMIM. http://www.omim.org/entry/139250?search=human%20growth%20hormone&highlight=hormone%20growth%20human. Accessed April 30, 2015. 12. RCSB. http://www.rcsb.org/pdb/explore/explore.do?structureId=1FL7. Accessed May 5, 2015. 13. Lipman NS, et al. *ILAR J.* 2005;46:258-268.
14. FDA. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm. Accessed February 18, 2015.

Each biosimilar is a distinct choice #whatsabiosimilar



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We expect #biosimilars to look more like branded biologics than generics

		Generics	Biosimilars	Biologics
Development	Scientific Difficulty	Low	Biosimilarity	High
	Time	Short (3-4 years)	~ 8 Years	Long (10+)
	Cost	Low (<$5M) Bioequivalence	~ $200M	High (>$800M) Full Clinical Dev
Ops	Manufacturer Process	Simple, Short	Complex	Long, Complex
Commercial	Sales and Marketing	Low	Promotion, Detail, Education	High
	Decision makers	GPOs, MCOs	Prescribers and Payers	Prescribers, Patients
	Competition	Many, Little Differentiation	Several, Partially Differentiated	Few, Well-differentiated

GPO = group purchasing organization; MCO = managed care organization

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Four keys to a successful U.S. #biosimilars program

The Goal: Physician & Patient Confidence

Physicians will need to elect to use biosimilar products and patients will need to have a positive experience. No other factors are more important to a successful program in the U.S.

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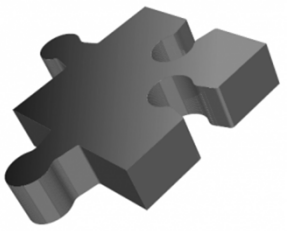
Four keys to a successful U.S. #biosimilars program



1. Appropriate Regulatory Standards

Access & cost are important; patient safety, high quality and reliable supply are paramount.

Sound scientific standards will enable biosimilars to successfully withstand scrutiny and will build trust among providers.

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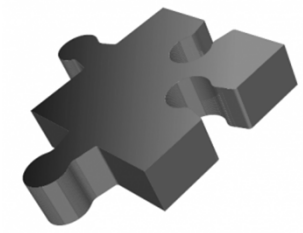

2. Transparent Disclosure of Data

Biosimilars are therapeutic alternatives, not generic drugs.

Each sponsor will approach development differently. Disclosure of this data will be essential in the selection of a biological medicine.

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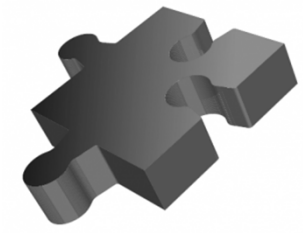

3. Accountable Manufacturers

Rules that stipulate clear product identification and accurate patient medication records hold all manufacturers accountable to the patients we serve.

These measures allow for robust competition and important patient protections. We don't have to choose just one, we can have both.

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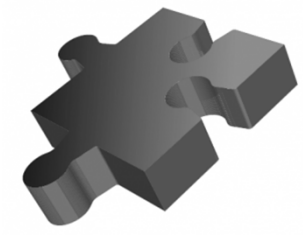
Four keys to a successful U.S. #biosimilars program



4. Healthcare Professional Education

Nearly all 3rd party analyses show that while awareness about biosimilars is increasing, many physicians, pharmacists and patients have limited understanding of the scientific principles and intended uses of these products.

Lack of familiarity or unclear definition of terms will limit the success of the U.S. biosimilars program.

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Thank you

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