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# The Future Role of Biosimilars in Health Care

A knowledge-based CPE activity presented during the ICHP 2010 Annual Meeting

**Friday, August 27, 2010**  
**Drury Lane Theater and Conference Center**  
**Oakbrook Terrace, IL**  
**9:00 am – 10:00 am**

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# The Future Role of Biosimilars in Health Care

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## ACTIVITY FACULTY

### **James M. Hoffman, Pharm.D., M.S., BCPS, Initiative Chair**

Medication Outcomes and Safety Officer  
St. Jude Children's Research Hospital  
Memphis, Tennessee

James Hoffman is Medication Outcomes and Safety Officer in the Pharmaceutical Department at St. Jude Children's Research Hospital in Memphis, Tennessee. In his position, Hoffman leads medication use policy, medication safety, and research pharmacy services at St. Jude. Hoffman is also an assistant professor of clinical pharmacy at the University of Tennessee Health Science Center.

Dr. Hoffman received both his Bachelor of Science in Pharmacy and Doctor of Pharmacy degrees from the Philadelphia College of Pharmacy. In addition, he received a Masters of Science degree in pharmacy administration from the University of Wisconsin-Madison. He also completed a residency in pharmacy administration and a fellowship in outcomes research at the University of Wisconsin Hospital and Clinics.

Hoffman is a Board Certified Pharmacotherapy Specialist (BCPS). He is an active member of ASHP, serving on the editorial board of the *American Journal of Health-System Pharmacy (AJHP)* and on the Council on Pharmacy Practice. He has experience in analyzing various aspects of national pharmaceutical use and policy. Since 2004, Hoffman has been the lead author of an annual *AJHP* publication on prescription drug expenditures. He has made local and national presentations on several topics, including biosimilars and follow-on biologics, medication expenditure patterns, and medication safety.

# **The Future Role of Biosimilars in Health Care**

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Dr. Hoffman declares that she has no relationships pertinent to this activity.

**Catherine N. Klein, R.Ph.**

Ms. Klein declares that she has no relationships pertinent to this activity.

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## **ACTIVITY OVERVIEW**

Patents for several biologicals, which are among the most expensive therapies in hospitals and clinics, are due to expire in the next couple of years. Because of their complex structures, therapeutic biological products cannot be replicated as precisely as chemical products. Biosimilars is the term that is emerging in legislation that has been introduced in the U.S. Congress. This presentation will provide an overview of the terminology and history surrounding biologics, explain key factors that might be considered in the drug-approval process, and describe roles that pharmacists could take on once these products become available in the U.S.

## **LEARNING OBJECTIVES**

At the conclusion of this knowledge-based CPE activity, participants should be able to

- Define key terms, such as biosimilars and follow-on biologics.
- Explain how biologics compare with small molecules.
- Describe the unique safety considerations and other issues for biologics and their implications for biosimilars.
- Describe how recently passed law as part of health care reform will affect the approval process of biosimilars.
- Explain the pharmacist's leadership role for biosimilars, including educating other health care professionals and the steps required to evaluate biosimilars for inclusion on the formulary.

## **CONTINUING EDUCATION ACCREDITATION**



The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1 hour (0.1 CEU) of continuing pharmacy education credit (ACPE activity #204-000-10-439-L01P).

Attendees must complete a Continuing Pharmacy Education Request online and may print their official ASHP statements of continuing pharmacy education credit at the ASHP Learning Center (<http://ce.ashp.org>) immediately following this activity.

Complete instructions for receiving your CPE statement of credit online are on the next page.  
**Be sure to record the five-digit session code announced during this activity.**

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1. Select "Process Meeting CE" from bottom left. Log in to the ASHP Learning Center using your e-mail address and password.

**If you have not logged in to the new ASHP Learning Center (launched August 2008) and are not a member of ASHP**, you will need to create a free account by clicking on "Become a user" and following the instructions.

2. Once logged in to the site, click on "**Process Meeting CE.**"
3. If this activity title does not appear in your meeting list, enter the 5-digit activity code in the box above the list and click submit. The Activity Code for this meeting is **10615**. The **Session Code** was announced at the end of this activity. Click **register** again when prompted. When you receive the "thank you for registering" message, click **continue**. This step will bring you back to your meeting list. Click on the **start** link to the right of the activity title.
4. Enter the session code, which was announced during the activity, and select the number of hours equal to your participation in the activity. Pharmacists should only claim credit for the amount of time they participate in this activity.
5. Click **submit** to receive the attestation page.
6. Confirm your participation and click **submit**. Your transcript page will appear.
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**Activity code:**

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## **The Future Role of Biosimilars in Health Care**

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# The Future Role of Biosimilars in Health Care

## The Future Role of Biosimilars in Health Care

**James M. Hoffman, Pharm.D., M.S., BCPS,  
Initiative Chair**

Medication Outcomes and Safety Officer  
St. Jude Children's Research Hospital  
Memphis, Tennessee

## Objectives

At the conclusion of this program, participants should be able to

- Define key terms, such as biosimilars and follow-on biologics.
- Explain how biologics compare with small molecules.
- Describe the unique safety features and issues pertaining to biologics and their implications for biosimilars.

## Objectives (cont'd)

- Describe how health care reform and recently passed law are likely to affect the approval process for biosimilars.
- Explain the pharmacist's role in educating staff on biosimilars, including the steps required to evaluate them for inclusion on the formulary

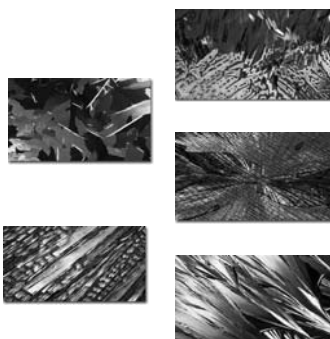
## What do you know about biosimilars?

1. This is a topic of great interest to me; I've followed it closely for many years.
2. This is a topic of great interest to me, but I'm having trouble keeping up with the latest information.
3. I'm generally aware of some of the issues surrounding biosimilars and have started paying more attention over the last couple of years.
4. Bio-what?

## First Biotechnology Process

Yeast Fermentation 4,000 BC

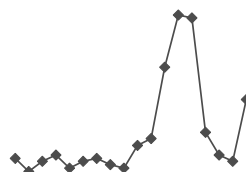
- Budweiser
- Amstel
- Heineken
- St. Pauli Girl
- Molson



Are these equivalent?

## Heparin Aftermath

Heparin Reported Deaths n=398



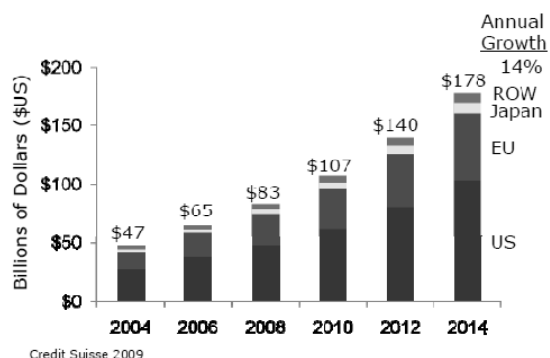
Year	Deaths	Death with > 1 Allergic Symptom
2006	55	3
2007	97	61
2008 (thru May)	149	88



<http://energycommerce.house.gov>

# The Future Role of Biosimilars in Health Care

The biologics comprise a large rapidly growing drug market that is concentrated in US and Europe



## What is a biologic?

- Technical definition from U.S. Code of Federal Regulations  
"any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man."
- Derived from living sources
  - Various cultures of bacteria or viruses
  - Human or animal sources
- Biologics do not always have a therapeutic intent
- For our purposes, think of biologics as "therapeutic proteins"

## General Classes of Biologics

- Monoclonal antibodies
- Complex sugars
- Blood derivatives
- Vaccines
- Recombinant or purified proteins, such as
  - Cytokines
  - Thrombolytic agents
  - Enzymes

## Biologics=Innovation

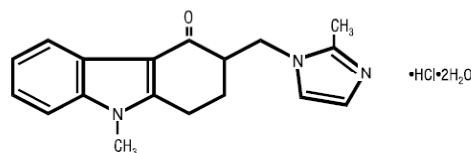
- Incontrovertible evidence that biologics (e.g., recombinant proteins, monoclonal antibodies) have resulted in incredible clinical advances and improved outcomes
- Examples
  - Insulin
  - Erythropoietin
  - Treatments for various genetic diseases

## How are therapeutic proteins different from traditional drugs?

- Selected differences
  - Molecular weight
  - Production process
  - Stability
  - Route of administration
  - Immunogenicity
  - Knowledge of mechanism of action
  - Analytic methods for pharmacokinetics

Lacana E, et al. *Clinical Pharmacology and Therapeutics* October 2007

## Structural Formula of Ondansetron



The empirical formula is  $C_{18}H_{19}N_3O \cdot HCl \cdot 2H_2O$   
Molecular weight = 365.9 daltons

From: Ondansetron Prescribing Information.  
Available at [http://us.gsk.com/products/assets/us\\_zofran\\_tablets.pdf](http://us.gsk.com/products/assets/us_zofran_tablets.pdf)

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## Structure of Insulin



**Empirical formula of Lantus is  $C_{267}H_{404}N_{72}O_{78}S_6$ .**  
**Molecular weight = 6,063 daltons**

From: <http://www.rcsb.org/pdb/explore/images.do?structureId=1XDA>  
 Based on Whittingham, J.L., Havelund, S., Jonassen, I. Crystal structure of a prolonged-acting insulin with albumin-binding properties. *Biochemistry* v36 pp. 2826-2831, 1997

## Structure of Human Erythropoietin



**Glycosylated protein of 166 amino acids.**  
**Molecular weight = 34,000 daltons**

From: <http://www.rcsb.org/pdb/explore.do?structureId=1BUY>; Cheetham JC et al. Structure of human erythropoietin and a comparison with its receptor bound conformation. *Nat.Struct.Biol.* 1998; 5:861-6.

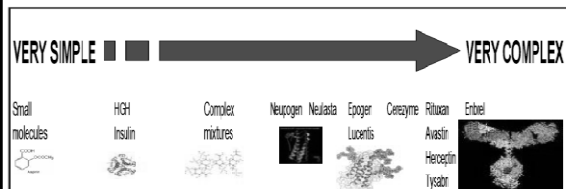
## Safety of Biologics

- Evaluation of safety related regulatory actions in U.S. and European Union (EU)
- 174 products approved between 1995 and 2007
  - 82 actions occurred on 41 of the products
  - First in class products more likely to have regulatory action
- Safety problems often related to infections and immune system disorders
- Careful monitoring encouraged, particularly for new products

Giezen TJ, et al. *JAMA*. 2008;300(16):1887-1896.

## Biosimilars Production

- Process important for biologics production
- Production process for biologics has more steps and is more complex than process for traditional drugs
- Requires significant capital investment



## Biosimilars Production and Safety

- Replication of innovator's process may be difficult or impossible
  - Innovator may hold patents for specific processes
  - Role of proprietary techniques ("trade secrets")
- Would differences in production process lead to differences in the products safety profile?
  - Cell lines
  - Yeast, bacteria, and cell cultures
  - Glycosylation



## Selected Terms Used to Describe "Generic" Biologics

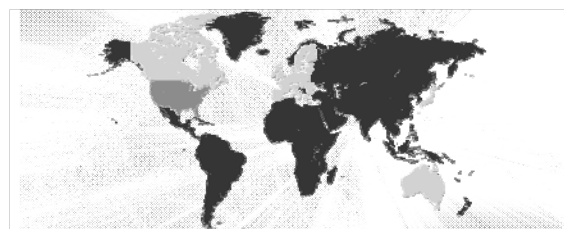
- Postpatent biologicals
- Biogenerics
- Subsequent entry protein pharmaceuticals
- Second-generation biologicals
- Follow-on biologicals
- Follow-on protein products
- **Biosimilars**

# The Future Role of Biosimilars in Health Care

## What is a biosimilar?

Various definitions, but key elements include

- Copy of a therapeutic protein
- Not made by innovator company
- Approved under an abbreviated process



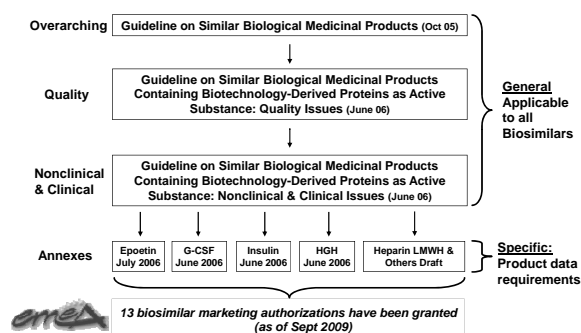
Generic biologics are advancing in the world's key regulated markets

Australia	Approved first biogeneric	2004
Europe	Established guidance for biosimilars	2005
Canada	Released draft guidance for biologics	Feb 2008
World Health Organization	Released draft guidelines	April 2008
Japan	Established guidance for biologics	March 2009
United States	No draft issued; waiting for legislation	?? ??

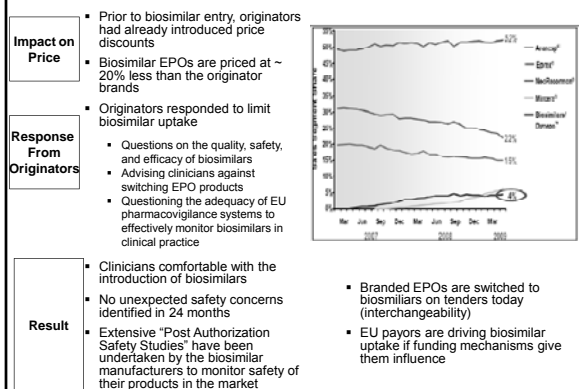
## Key Elements of Current EU System

- Includes 10–11 years of protection against follow-on products
- Basic provisions took effect in 2003
  - Govern “similar biological medicinal products” (“biosimilars”)
  - Generic applications ordinarily deemed insufficient

## Biosimilars Regulations in Europe



## European EPO Commercial Experience



## Barriers to Availability of Biosimilars

- Patents for these products expired (or are nearing expiration), but no biosimilars marketed in U.S.
- Primary barriers to the widespread commercialization of biosimilar biologics in the U.S.
  - Legal and regulatory issues
  - Production
  - Safety

<b>Amgen (AMGN)</b>	
■ Enbrel	→ 2012
■ Neupogen	→ 2013
■ Epo	→ 2012-2015
■ Neulasta	→ 2015
■ Aranesp	→ 2024
<b>Biogen (BIB)</b>	
■ Avonex	→ 2012
■ Tysabri	→ 2012-2020
<b>Genzyme (GENZ)</b>	
■ Cerezyme	→ 2010-2019
■ Fabryzyme	→ 2015
■ Myozyme	→ 2010-2013
<b>Genentech/Roche (DNA)</b>	
■ Avastin	→ 2017-2019
■ Rituxan (also BIB)	→ 2014-2016
■ Herceptin	→ 2019
■ Lucentis	→ 2017-2019

# The Future Role of Biosimilars in Health Care

## Biosimilars Regulated Under the Public Health Service (PHS) Act

- What does PHS Act currently require for a “biosimilar” version of a biologic?
- Prior to March 21, 2010
  - Required full clinical studies to demonstrate the biologics were safe, pure, and potent
  - No counterpart to the abbreviated new drug application (ANDA) or 505(b)(2) new drug application (NDA) process

## SEC. 7002: Approval Pathway for Biosimilar Biological Products

### Overview

## Biosimilarity

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- The biological product **is biosimilar** to a reference product based upon data derived from
  - **Analytical studies** that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;
  - **Animal studies** (including the **assessment of toxicity**); and
  - A **clinical study or studies** (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) **that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions** of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product.

**FDA may determine that one or more of these requirements are unnecessary**

## Required Information [1/2]

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- **Required information** shall include demonstration that
  - the biological product and reference product utilize the **same mechanism or mechanisms of action** for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, **but only to the extent the mechanism or mechanisms of action are known for the reference product**;
  - the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been **previously approved for the reference product**;

## Required Information [2/2]

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- **Required Information** shall include demonstration that
  - **the route of administration, the dosage form, and the strength** of the biological product are the same as those of the reference product; and
  - the facility in which the biological product is **manufactured**, processed, packed, or held **meets standards** designed to assure that the biological product continues to be safe, pure, and potent.

## Interchangeability

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- In determining **interchangeability**, the information submitted must be sufficient to show that the applicant
  - is biosimilar to the reference product; and
  - can be expected to produce the same clinical result as the reference product in any given patient; and
  - **for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.**

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## Review

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- One reference product per application
- By the division within the FDA that is responsible for the **review and approval of the application under which the reference product is licensed**

## Risk Evaluation and Mitigation Strategies (REMS)

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in **the same manner as such authority applies to biological products**

## Guidance Documents

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- FDA may issue general or specific guidance, after opportunity for public comment
- The issuance or non-issuance of such guidance does not preclude approval of a biosimilar
- FDA must establish a process through which the public can provide FDA with input regarding priorities for issuing guidance

## Exclusivity: First Interchangeable Biological Product

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- FDA may not approve a second interchangeable product until the earlier of
  - 1 year after commercial marketing of first interchangeable product
  - 18 months after final court decision or dismissal in patent suit under patent notice provisions
  - 42 months after approval of first interchangeable if sued for patent
  - infringement under patent notice provisions and still ongoing after 42 months
  - 18 months after approval of first interchangeable if not sued under patent notice provisions

## Exclusivity: Reference Product

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- **Twelve (12) years** data exclusivity where no biosimilar may be approved
- First 4 years where no biosimilar application may be submitted

## Class Specific Guidance

SEC. 7002: Approval Pathway for Biosimilar Biological Products

- Must include a description of the criteria that FDA will use to determine whether a biological product is highly similar to a reference product in such product class, and
- The criteria, if available, that FDA will use to determine whether a biological product is interchangeable with the reference product.
- The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license.
  - The FDA may, however, issue a subsequent guidance document to modify or reverse that prior decision.

# The Future Role of Biosimilars in Health Care

## What has your organization done to prepare for biosimilars?

1. Formal discussions and planning in organization-wide forums such as the pharmacy and therapeutics committee.
2. Informal discussions with key leaders in the institution.
3. We are still learning about the topic.

## Potential Influence of Biosimilars on Health Care

- Safety
- Interchangeability
- Cost/market

## Biosimilars - Safety

- What is true risk of immunogenicity and other types of patient harm from biosimilars?
- Can we design appropriate drug safety systems to detect adverse events with biosimilars?
- As approval pathway develops, expect extensive (and opinionated) discussion and debate of biosimilar safety.

## Biosimilars and Safety

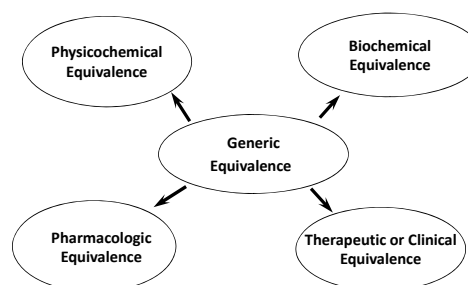
- Antibody mediated pure red-cell aplasia (PRCA) from epoetin is primary example
  - Primarily occurred with brand of epoetin not used in United States (Eprex) in patients with chronic kidney disease
- Cause of immunogenicity
  - Formulation change (removal of albumin) vs. leaching of compounds from rubber stoppers
- **Small changes in production can have important safety consequences**

Bennett CL, Luminari S, Nissenson AR et al. Pure red-cell aplasia and epoetin therapy. *N Engl J Med*. 2004; 351:1403-8.

## Equivalence of Biotech Drugs

- New products, chemically similar to the originator, could infringe upon one or more of the originator's patents
- New products may not be therapeutically equivalent to the originator (per FDA)
- The "real world" considers drugs in similar therapeutic category, with equivalent outcomes, to be "therapeutically equivalent"
  - Supported or required by many payers
  - Antibiotic classes
  - Leuprolide acetate – goserelin acetate
  - Interferon alfa-2a and alfa-2b
  - Colony-stimulating factors (granulocyte vs. granulocyte macrophage; epoetin alfa vs. darbepoetin alfa)
  - "Taxanes"

## Interchangeability and Implications for Equivalence among Branded and Biosimilar Therapies



# The Future Role of Biosimilars in Health Care

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## Interchangeability and Equivalence

- Comparing products to reference standards will be challenging and additional studies may be necessary
  - Will need different standards by drug or class
- Unlikely biosimilars will be immediately interchangeable
  - Current generic drug substitution practices in hospitals will not be appropriate for biosimilars

## Biosimilar Market

- Federal Trade Commission (FTC) Report
  - Emerging Health Care Issues: Follow-on Biologic Drug Competition – released June 2009
    - Two rounds of public comments and public discussion in November 2008
  - Overall question
    - How will competition between the innovator and the biosimilar develop?

<http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>

## Biosimilar Market

- **FTC Report conclusions**
  - Brand-to-brand competition more likely than the dynamics of brand-generic competition under Hatch-Waxman
  - Existing Incentives that support brand-to-brand competition among biologic drugs (i.e., patent protection and market-based pricing) are likely to be sufficient to support FOB competition and biologic innovation
- Fewer companies will be involved in producing biosimilars compared to current generics industry
- “Branded generic” model with substantial sales force and marketing (“quasi-brand industry”)
- Extent of competition with innovator?

## Costs of Biosimilars

- Percent savings from biosimilars will not be as significant as with generics for traditional drugs
  - Estimates range from 20-40% less than the innovator
- 25% savings is obviously still significant for expensive therapies
- Consider price calculation implications and influence on reimbursement

## Planning for the Role of Biosimilars in Health Care

- Unanswered questions for biosimilars
  - Details of approval process
  - Safety
  - Interchangeability and equivalence
  - Exact cost savings
- However, there is no doubt that
  - Despite uncertainties, products will soon be marketed in the U.S.
  - Products present opportunities and responsibilities for pharmacists

## Planning for Biosimilars in Hospitals

- Best practice will be to employ the formulary system to evaluate biosimilars for inclusion before use
- Careful and objective evaluation regarding evidence of efficacy, safety, and cost
- Safety and cost will be the most complex dimensions of analysis

# The Future Role of Biosimilars in Health Care

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## Pharmacy Practice Implications

- Biosimilars present opportunities and responsibilities for pharmacists
  - Current generic substitution practices are not appropriate for biosimilars
  - Pharmacists should lead the objective evaluation of biosimilars using the formulary system
  - Be sure your formulary system is ready for biosimilars

## What will be the primary determinant to using biosimilars in your practice setting?

1. FDA approval.
2. Comparative effectiveness studies.
3. Compendia inclusion (evidence based).
4. Payor supported.

## Conclusion

- Biologics are important therapies and are significantly different from traditional small molecules
- A framework for the introduction of biosimilars to the U.S. market is developing
- Health care legislation passed in 2010 established the legal pathway for the approval of biosimilars

## Conclusion

- Biosimilars will have important implications for health care; key considerations will include
  - Safety
  - Interchangeability and equivalence
  - Cost
- Biosimilars will require proactive planning and careful evaluation
- Use formulary system to evaluate biosimilars before use

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## **SELF-ASSESSMENT QUESTIONS**

1. Which of the following statements regarding biologics is NOT true?
  - a. Biologics are derived from living sources.
  - b. Biologics always have a therapeutic intent.
  - c. Biologics have improved clinical outcomes.
  - d. Insulin and erythropoietin are examples of biologic therapies.
2. All of the following are examples of differences between therapeutic proteins and traditional drugs EXCEPT:
  - a. Molecular weight.
  - b. Production process.
  - c. Route of administration.
  - d. Clearly identifiable mechanism of action.
3. Biosimilar products are not made by the innovator company and are approved under an abbreviated process.
  - a. True.
  - b. False.
4. In planning for the introduction of biosimilars in the hospital setting, pharmacists will need to
  - a. Create an entirely new process for evaluating products.
  - b. Assume the products are comparable in efficacy and safety.
  - c. Use the formulary system to evaluate the products before use.
  - d. Evaluate the products using typical cost-analysis methodologies.

## **Answers**

1. b
2. d
3. a
4. c

# The Future Role of Biosimilars in Health Care

## Activity Evaluation Form

August 27, 2010

James M. Hoffman, Pharm.D., M.S., BCPS

Oakbrook Terrace, IL

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1 = strongly disagree    2 = disagree    3 = neither agree nor disagree    4 = agree    5 = strongly agree

### Evaluation of Educational Objectives

After attending this knowledge-based CPE activity, I am able to	Strongly Disagree				Strongly Agree
1. Define key terms, such as biosimilars and follow-on biologics.	1	2	3	4	5
2. Explain how biologics compare with small molecules.	1	2	3	4	5
3. Describe the unique safety considerations and other issues for biologics and their implications for biosimilars.	1	2	3	4	5
4. Describe how recently passed law as part of health care reform will affect the approval process of biosimilars.	1	2	3	4	5
5. Explain the pharmacist's leadership role for biosimilars, including educating other health care professionals and the steps required to evaluate biosimilars for inclusion on the formulary.	1	2	3	4	5

### Evaluation Content

	Strongly Disagree				Strongly Agree
1. The content presented was relevant to the target audience.....	1	2	3	4	5
2. I will be able to apply the knowledge skills I learned .....	1	2	3	4	5
3. The activity fulfilled my education needs .....	1	2	3	4	5
4. The activity enhanced my ability to apply learning objectives to my practice .....	1	2	3	4	5
5. Based on my previous knowledge and experience, the content level of the activity for attending audience was: <input type="checkbox"/> Too basic <input type="checkbox"/> Appropriate <input type="checkbox"/> Too Complex					

### Faculty/Instructional Materials

	Strongly Disagree				Strongly Agree
6. The teaching methods were effective.....	1	2	3	4	5
7. The instructional materials were effective .....	1	2	3	4	5

Continue on next page →

# The Future Role of Biosimilars in Health Care

## Faculty/Instructional Materials *(continued)*

8. Please indicate the extent to which you agree or disagree with the following statement: "Faculty statements and therapeutic recommendations in this activity were based on supported evidence or professional opinion and did **NOT** evidence commercial bias."

☐ Strongly Disagree      ☐ Disagree      ☐ Agree      ☐ Strongly Agree

9. If you answered **strongly disagree or disagree** to question 8, what commercial bias did you perceive in this activity?

10. What did you find to be the most helpful aspect of this activity?

11. What was the least helpful aspect of this activity?

12. List ONE (and no more than three) changes that you intend to make in your practice as a result of this activity.

13. How confident are you that you will be able to apply these changes in your practice?

- a. Very confident
- b. Somewhat confident
- c. Not confident

14. Please indicate any barriers you perceive to implementing these changes.

- a. Cost
- b. Lack of experience
- c. Lack of resources
- d. Lack of administrative support
- e. Other, please specify: \_\_\_\_\_

15. What question(s) do you still have about this topic?

16. Based on your educational needs, list any topics you would like to see addressed in future educational activities.

17. Other comments or suggested improvements:

18. Using the following scale, in the table below rate presentation skills, content knowledge, degree of balance, objectivity, and scientific rigor of faculty:

**1 = very poor    2 = poor    3 = average    4 = above average    5 = excellent**

	Presentation Skills	Knowledge of Content	Degree of Balance, Objectivity, & Scientific Rigor
James M. Hoffman, Pharm.D., M.S., BCPS	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5