The Future Role of Biosimilars in Health Care

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

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ASHP ADVANTAGE

The Future Role of Biosimilars in Health Care

ACTIVITY FACULTY

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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.

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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.

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

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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.

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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.

7. Select the applicable year from the drop-down menu and locate this activity.

8. Click on **Print Statement of Credit** in the **Status** column.

Activity code: **10615**

Session code:

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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

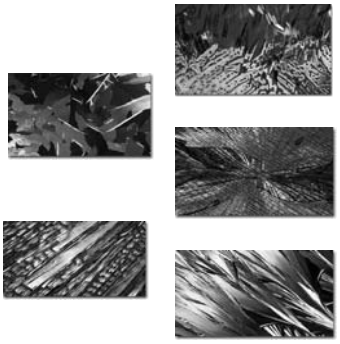
What do you know about biosimilars?

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

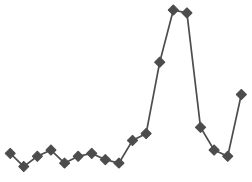
- Budweiser
- Amstel
- Heineken
- St. Pauli Girl
- Molson



Are these equivalent?

Heparin Aftermath

Heparin Reported Deaths n=398

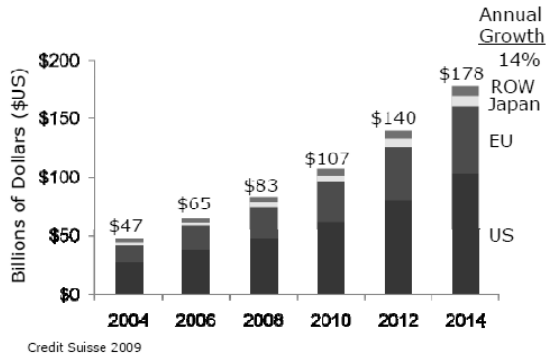


Year	Deaths	Death with > 1 Allergic Symptom
2006	55	3
2007	97	61
2008 (thru May)	149	88

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



Credit Suisse 2009

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

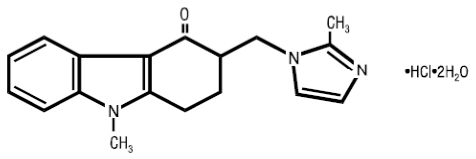
- Incontrovertible evidence that biologics (e.g., recombinant proteins, monoclonal antibodies) have resulted in incredible clinical advances and improved outcomes
- Examples
  - Insulin
  - Erythropoietin
  - Treatments for various genetic diseases

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 $C_{18}H_{19}N_3O•HCl•2H_2O$
Molecular weight = 365.9 daltons

From: Ondansetron Prescribing Information.
Available at http://us.gsk.com/products/assets/us_zofran_tablets.pdf

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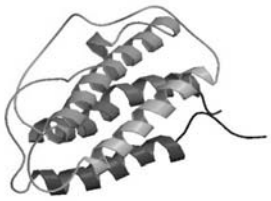
Structure of Insulin

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.

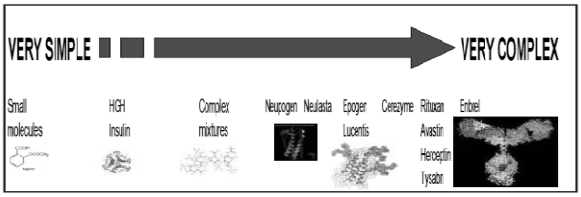
Safety of Biologics

- 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**

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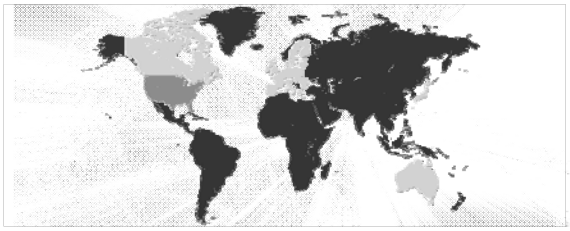
What is a biosimilar?

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 biogenerics	Feb	2008
World Health Organization	Released draft guidelines	April	2008
Japan	Established guidance for biogenerics	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

Overarching — **Guideline on Similar Biological Medicinal Products** (Oct 05)

Quality — **Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Quality Issues** (June 06)

Nonclinical & Clinical — **Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins as Active Substance: Nonclinical & Clinical Issues** (June 06)

General Applicable to all Biosimilars

Annexes — **Epoetin** July 2006 | **G-CSF** June 2006 | **Insulin** June 2006 | **HGH** June 2006 | **Heparin LMWH & Others Draft**

Specific: Product data requirements

emea

13 biosimilar marketing authorizations have been granted (as of Sept 2009)

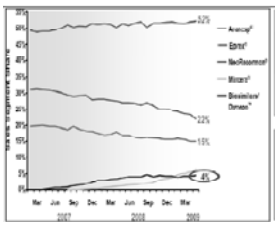
European EPO Commercial Experience

Impact on Price

- Prior to biosimilar entry, originators had already introduced price discounts
- Biosimilar EPOs are priced at ~ 20% less than the originator brands

Response From Originators

- Originators responded to limit biosimilar uptake
  - Questions on the quality, safety, and efficacy of biosimilars
  - Advising clinicians against switching EPO products
  - Questioning the adequacy of EU pharmacovigilance systems to effectively monitor biosimilars in clinical practice



Result

- Clinicians comfortable with the introduction of biosimilars
- No unexpected safety concerns identified in 24 months
- Extensive "Post Authorization Safety Studies" have been undertaken by the biosimilar manufacturers to monitor safety of their products in the market

- Branded EPOs are switched to biosmiliars on tenders today (interchangeability)
- EU payors are driving biosimilar uptake if funding mechanisms give them influence

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

Amgen (AMGN)
- Enbrel → 2012
- Neupo → 2013
- Epo → 2012-2015
- Neulasta → 2015
- Aranesp → 2024

Biogen (BIIB)
- Avonex → 2012
- Tysabri → 2012-2020

Genzyme (GENZ)
- Cerezyme → 2010-2019
- Fabrazyme →2015
- Myozyme →2018-2023

Genentech/Roche (DNA)
- Avastin → 2017-2019
- Rituxan (also BIIB) → 2014-2016
- Herceptin → 2019
- Lucentis → 2017-2019

Biologics 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 studie**s (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.**

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

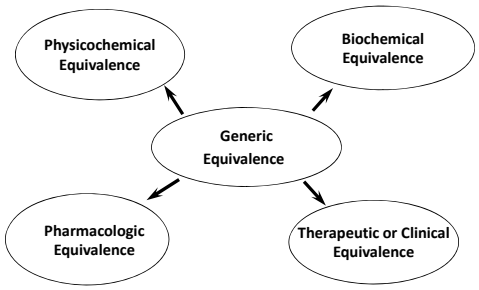
- Antibody mediated pure red-cell aplasia (PRCA) from epoetin is primary example
  - Primarily occurred with brand of epoetin not used in United States (Eprex) in patients with chronic kidney disease
- Cause of immunogenicity
  - Formulation change (removal of albumin) vs. leaching of compounds from 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

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

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

SELECTED REFERENCES

Lacana E, Amur S, Mummanneni P et al. *Clin Pharmacol Ther*. 2007; 82:466-71. Epub 2007 Aug 22.

Giezen TJ, Mantel-Teeuwisse AK, Straus SM et al. Safety-related regulatory actions for biopharmaceuticals approved in the United States and European Union. *JAMA*. 2008; 300:1887-96.

Bennett CL, Luminari S, Nissenson AR et al. Pure red-cell aplasia and epoetin therapy. *N Engl J Med*. 2004; 351:1403-9.

Committee on Energy and Commerce. The heparin disaster: Chinese counterfeits and American failures. Available at http://energycommerce.house.gov/index.php?option=com_content&view=article&id=293&catid=31&Itemid=58. Accessed 2010 Jul 8.

Whittingham JL, Havelund, S, Jonassen I. Crystal structure of a prolonged-acting insulin with albumin-binding properties. *Biochemistry.* 2007; 36:2826-31.

Cheetham JC et al. Structure of human erythropoietin and a comparison with its receptor bound conformation. *Nat.Struct.Biol*. 1998; 5:861-6.

Federal Trade Commission. Emerging health care issues: follow-on biologic drug competition. Available at http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf. Accessed 2010 Jul 8.

S E L F – A S S E S S M E N T Q U E S T I O N S

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***

ASHP Advantage appreciates your participation in this educational activity and values your feedback. Please complete this brief evaluation form to assist us in improving the quality of future educational activities.

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:
☐ Too basic ☐ Appropriate ☐ 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