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

Planned and conducted by ASHP Advantage.
Supported by an educational donation provided by Amgen and educational grants from sanofi aventis U.S., Centocor Ortho Biotech, Inc., and Allergan.
The Future Role of Biosimilars in Health Care

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.
DISCLOSURE STATEMENTS

In accordance with the Accreditation Council for Continuing Medical Education’s Standards for Commercial Support and the Accreditation Council for Pharmacy Education’s Guidelines for Standards for Commercial Support, ASHP Advantage requires that all individuals involved in the development of activity content disclose their relevant financial relationships. A person has a relevant financial relationship if the individual or his or her spouse/partner has a financial relationship (e.g., employee, consultant, research grant recipient, speakers bureau, or stockholder) in any amount occurring in the last 12 months with a commercial interest whose products or services may be discussed in the activity content over which the individual has control. The existence of these relationships is provided for the information of participants and should not be assumed to have an adverse impact on presentations.

All faculty and planners for ASHP Advantage education activities are qualified and selected by ASHP Advantage and required to disclose any relevant financial relationships with commercial interests. ASHP Advantage identifies and resolves conflicts of interest prior to an individual’s participation in development of content for an educational activity.

The faculty and planners report the following relationships:

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

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

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.
The Future Role of Biosimilars in Health Care

Instructions for Processing Continuing Pharmacy Education (CPE)

To obtain your CPE statement of credit for this live activity, please visit the ASHP Learning Center at http://ce.ashp.org.

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.


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: 

   NEED HELP? Contact ASHP Advantage at support@ashpadvantage.com.
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Deaths</th>
<th>Death with &gt; 1 Allergic Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>55</td>
<td>3</td>
</tr>
<tr>
<td>2007</td>
<td>97</td>
<td>61</td>
</tr>
<tr>
<td>2008 (thru May)</td>
<td>149</td>
<td>88</td>
</tr>
</tbody>
</table>

http://energycommerce.house.gov
The Future Role of Biosimilars in Health Care

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

Structural Formula of Ondansetron

The empirical formula is C₂₈H₂₈N₂O•HCl•2H₂O
Molecular weight = 365.9 daltons


The Future Role of Biosimilars in Health Care

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


Structure of Human Erythropoietin

**Glycosylated protein of 166 amino acids.**

Molecular weight = 34,000 daltons


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


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 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)
- Annexes: Epoetin (July 2006), G-CSF (June 2006), Insulin (June 2006), HGH (June 2006), Heparin LMWH & Others (Draft)
- 17 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
- 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

Response From Originators
- 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

Result
- Branded EPOs are switched to biosimilars on tenders today (interchangeability)
- EU payers 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

<table>
<thead>
<tr>
<th>Company</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>AbbVie</td>
<td>2017</td>
</tr>
<tr>
<td>Amgen</td>
<td>2012</td>
</tr>
<tr>
<td>Biogen</td>
<td>2015</td>
</tr>
<tr>
<td>Genentech/Roche</td>
<td>2018</td>
</tr>
<tr>
<td>Lorrain</td>
<td>2017-2019</td>
</tr>
<tr>
<td>Novartis</td>
<td>2019-2020</td>
</tr>
<tr>
<td>Sanofi</td>
<td>2018-2019</td>
</tr>
<tr>
<td>Biogen (Biologics)</td>
<td>2018-2019</td>
</tr>
<tr>
<td>Amgen</td>
<td>2015-2016</td>
</tr>
<tr>
<td>Biogen</td>
<td>2017-2018</td>
</tr>
<tr>
<td>Pfizer</td>
<td>2019-2020</td>
</tr>
<tr>
<td>Regeneron</td>
<td>2018-2019</td>
</tr>
<tr>
<td>Sanofi</td>
<td>2017-2018</td>
</tr>
<tr>
<td>Biogen</td>
<td>2016-2017</td>
</tr>
<tr>
<td>Amgen</td>
<td>2017-2018</td>
</tr>
<tr>
<td>Biogen</td>
<td>2019-2020</td>
</tr>
</tbody>
</table>

9
The Future Role of Biosimilars in Health Care

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 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.
The Future Role of Biosimilars in Health Care

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


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

- Physicochemical Equivalence
- Biochemical Equivalence
- Pharmacologic Equivalence
- Generic Equivalence
- Therapeutic or Clinical Equivalence
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?


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?

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

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 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


The Future Role of Biosimilars in Health Care

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
### Evaluation of Educational Objectives

<table>
<thead>
<tr>
<th>After attending this knowledge-based CPE activity, I am able to</th>
<th>Strongly Disagree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Define key terms, such as biosimilars and follow-on biologics.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2. Explain how biologics compare with small molecules.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3. Describe the unique safety considerations and other issues for biologics and their implications for biosimilars.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4. Describe how recently passed law as part of health care reform will affect the approval process of biosimilars.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>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.</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

### Evaluation Content

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

### Faculty/Instructional Materials

<table>
<thead>
<tr>
<th>The teaching methods were effective</th>
<th>Strongly Disagree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. The instructional materials were effective</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Presentation Skills</th>
<th>Knowledge of Content</th>
<th>Degree of Balance, Objectivity, &amp; Scientific Rigor</th>
</tr>
</thead>
<tbody>
<tr>
<td>James M. Hoffman, Pharm.D., M.S., BCPS</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
</tr>
</tbody>
</table>

18