Defining biosimilars and their effect on healthcare: anticipated complications, possible solutions, and the need for pharmacovigilance

Organizations may not re-use material presented at this AMCP conference for commercial purposes without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. Commercial purposes include but are not limited to symposia, educational programs, and other forms of presentation, whether developed or offered by for-profit or not-for-profit entities, and that involve funding from for-profit firms or a registration fee that is other than nominal. In addition, organizations may not widely redistribute or re-use material presented at [conference] without the written consent of the presenter the person or organization holding copyright to the material (if applicable), and AMCP. This includes large quantity redistribution of the material or storage of the material on electronic systems for other than personal use.

Steve Miller, MD
November 12, 2013
Specialty Growth Continues

Now

70% Traditional
30% Specialty

In 5 Years

50% Traditional
50% Specialty
### Top 10 Worldwide Drug Sales

By 2016, Specialty Accounts for 64% of Top 10 Drugs

<table>
<thead>
<tr>
<th>2010</th>
<th>2016E</th>
</tr>
</thead>
<tbody>
<tr>
<td>$80</td>
<td>$76.5B</td>
</tr>
<tr>
<td>$60</td>
<td>$75.5B</td>
</tr>
<tr>
<td>$40</td>
<td></td>
</tr>
<tr>
<td>$20</td>
<td></td>
</tr>
<tr>
<td>$0</td>
<td></td>
</tr>
</tbody>
</table>

**2010**
- Crestor® Cholesterol
- Diovan® Hypertension
- Humira® Arthritis
- Rituxan® Oncology
- Abilify® Antipsychotic
- Enbrel® Arthritis
- Advair® Asthma
- Remicade® Arthritis
- Plavix® Arterial thrombosis
- Lipitor® Cholesterol

**2016E**
- Herceptin® Oncology
- Lantus® Diabetes
- Advair® Asthma
- Xopenex® Asthma
- Avastin® Oncology
- Crestor® Cholesterol
- Rituxan® Oncology
- Remicade® Arthritis
- Enbrel® Arthritis
- Humira® Arthritis

*Traditional* | *Specialty*
Your Know Specialty Patients

<table>
<thead>
<tr>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
</tr>
<tr>
<td>Cancer</td>
</tr>
<tr>
<td>Growth Deficiency</td>
</tr>
<tr>
<td>Hemophilia</td>
</tr>
<tr>
<td>Hepatitis</td>
</tr>
<tr>
<td>Infertility</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
</tr>
<tr>
<td>Pulmonary HTN</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
</tr>
<tr>
<td>Many others</td>
</tr>
</tbody>
</table>
Biosimilars

Source: Sarah Palin – mistydawnphoto / Shutterstock.com
FDA New Drug Approvals

- 2008
- 2009
- 2010
- 2011
- 2012
- 2013 Projected

- Traditional
- Specialty

Source: U.S. Food and Drug Administration
Biosimilars: A Path to Healthier Outcomes

Sales in 000s

$140,000,000

$120,000,000

$100,000,000

$80,000,000

$60,000,000

$40,000,000

$20,000,000

$0

Projected Sales:

No Biosimilars

Projected Sales:

With Biosimilars

$250 Billion Through 2024
Biosimilars Approved Around the World

- EU: 2006
- South Korea: 2012
- Canada: 2010
- Japan: 2009
- Australia: 2010
- India: 2013

US: Awaiting Clear Regulatory Path To Market
The Law of the Land

Potential Savings Of Biogenerics In the United States

Study Authors: Steve Miles MD, and Joash Hurts

Overview of the BPCIA (Biologics Price Competition and Innovation Act of 2009)
Enacted March 23, 2010
Déjà Vu All Over Again

“This drift in product quality attributes could be enough to be clinically meaningful, i.e. results in a change in **efficacy or safety**.”
– BIO talking points, 2012

“... FDA standards do not insure that two versions of a drug deemed equivalent will be equally **safe and effective** when used interchangeably by patients”
– President of PhRMA, 1987
Biosimilars Pathway: The Key Issues

1. Guidelines
2. Totality of Evidence
3. Clinical Program
4. Global Studies
5. Immunogenicity
6. Multiple Pathways
7. Extrapolation
8. Common Reference Product
9. Common INN (international nonproprietary name)
10. Interchangability
Originators Make “Biosimilars”

Acceptable changes in quality attributes of glycosylated biopharmaceuticals

- Brand products differ from batch to batch
  - Process improvements
  - Scale changes
  - Site transfers
  - Inherent variability

- Product labels unchanged
The Entire Marketplace Solution

- The National Council on Prescription Drug Programs
  - a multi-stakeholder forum for developing ANSI-accredited standards for electronic exchange of healthcare information

- Current (D.0) telecommunication standards include the following required fields for each claim:
  - BIN Number
  - Version/Release Number
  - Transaction Code
  - Processor Control Number
  - Transaction Count
  - Service Provider ID
  - Date of Service
  - Software Vendor/Cert ID
  - Cardholder ID
  - Group ID
  - Prescription Reference #
  - NDC
  - Prescriber ID
  - (not a complete list)
National Drug Code

- The National Drug Code is required of all manufacturers by federal law.
- The **labeler code** is 4 or 5 digits long and assigned by the FDA upon submission of a Labeler Code Request.
- The **product code** is 3 or 4 digits long and identifies a specific strength, dosage form, and formulation for a particular manufacturer.
- The **package code** is 1 or 2 digits long and identifies package forms and sizes.
Pharmacy Systems in Practice - atorvastatin

- 259,040 claims for atorvastatin
- Filled at 51,839 pharmacies
- Includes 15 different manufacturers
  - 80% of volume concentrated in four manufacturers
Pharmacy Systems in Practice - somatropin

- 419 claims for somatropin growth hormones
  - 11 unique trade names, but one INN
- Filled at 145 pharmacies
- Includes 7 different manufacturers
Pharmacy Systems in Practice – epoetin alfa

- 333 claims for epoetin alfa
- Filled at 285 pharmacies
- Includes 2 different manufacturers
Summary

- The US market place needs biosimilars
- Managed care pharmacist are crucial to bringing these products to the market
- We must work together to insure patient safety
An Opportunity for Working Together