Specialty Pharmaceuticals: Trends, Value and Impact

Greater Detroit Area Health Council
Coffee & Controversy
June 5th, 2013

Presented by:
Atheer Kaddis, Senior Vice President,
Business Development and Sales
<table>
<thead>
<tr>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty Pharmacy Trends</td>
<td>Atheer Kaddis</td>
</tr>
<tr>
<td>Value of Specialty Pharmaceuticals</td>
<td>Marcy Donato</td>
</tr>
<tr>
<td>Managing Specialty Pharmaceuticals – Health Plan Perspective</td>
<td>Steven Marciniak</td>
</tr>
<tr>
<td>Managing Specialty Pharmaceuticals – Payor Perspective</td>
<td>Joan Ebner</td>
</tr>
<tr>
<td>Open Discussion/Q&amp;A</td>
<td>All</td>
</tr>
</tbody>
</table>
State of the Industry
Specialty Market Dynamics

- Fastest growing segment in pharmacy today and the foreseeable future
- $100B+ in 2013
- 50% of top 100 drugs and 8 of the top 10 will be specialty pharmaceuticals by 2016
- Over 600 drugs in the specialty pharmaceutical pipeline (phase II and phase III)
- Close to 50% of drugs in the pipeline are oral drugs
- Majority of drugs are for treatment of cancer
- Active channel management moving products from retail due to low persistency
- Medical benefit to pharmacy benefit/specialty pharmacy transition

- [www.phrma.org](http://www.phrma.org)
Specialty Market Dynamics

Drivers

• Less than 1% of prescriptions filled in 2012 were for specialty medications, yet they accounted for 25% of total prescription drug expenditures. By 2019 or 2020, specialty drugs are expected to represent 50% of plan sponsors’ overall drug spend. The top three therapy classes – inflammatory conditions, multiple sclerosis and cancer – are expected to account for more than 50% of that overall spend.

• At least 60% of the new drugs expected to gain approval from the Food and Drug Administration (FDA) in 2013 alone will be specialty drugs.

• The primary driver of specialty drug spend will be a continuing increase in drug costs. Costs will rise as newer, more-sophisticated therapies with price tags worth tens and hundreds of thousands of dollars are brought to market.

• The introduction of biosimilars in key therapy classes with high-cost, highly utilized drugs has the potential to alter the trajectory of specialty drug spend.

Characteristics of Specialty Pharmaceuticals

- **High Cost**
  - Prescription cost > $600/month

- **Difficult Medication Delivery**
  - Strict temperature control
  - Restricted distribution
  - Restricted location for administration

- **Complex Treatment**
  - Personalized dosing or administration
  - Clinical management or close monitoring

The "Patent Cliff"

Patent Expiration of 10 Top Selling Drugs Each Year

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aricept</td>
<td>3,991</td>
<td>12,535</td>
<td>9,801</td>
<td>4,660</td>
</tr>
<tr>
<td>Cozaar</td>
<td>3,561</td>
<td>7,794</td>
<td>6,575</td>
<td>2,728</td>
</tr>
<tr>
<td>Effoxor XR</td>
<td>3,182</td>
<td>4,916</td>
<td>6,013</td>
<td>1,959</td>
</tr>
<tr>
<td>Taxotere</td>
<td>3,034</td>
<td>2,648</td>
<td>5,126</td>
<td>1,469</td>
</tr>
<tr>
<td>Protonix</td>
<td>2,052</td>
<td>1,737</td>
<td>4,660</td>
<td>853</td>
</tr>
<tr>
<td>Flomax</td>
<td>1,970</td>
<td>1,326</td>
<td>3,263</td>
<td>705</td>
</tr>
<tr>
<td>Arimidex</td>
<td>1,921</td>
<td>1,292</td>
<td>3,088</td>
<td>357</td>
</tr>
<tr>
<td>Gemzar</td>
<td>1,353</td>
<td>1,160</td>
<td>2,532</td>
<td>166</td>
</tr>
<tr>
<td>NovoSeven</td>
<td>1,320</td>
<td>1,020</td>
<td>1,892</td>
<td>80</td>
</tr>
<tr>
<td>Coreg^</td>
<td>253</td>
<td>548</td>
<td>724</td>
<td>26</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$22,647</strong></td>
<td><strong>$34,976</strong></td>
<td><strong>$43,674</strong></td>
<td><strong>$13,003</strong></td>
</tr>
</tbody>
</table>

*Year of first available generic
^US Sales only

Source: Ken Kaitin, Tufts University, SCB's Pharma. R&D Productivity Conference, May 5, 2011
20 of the 37 New Molecular Entities approved in 2012 were specialty drugs.

Source: www.fda.gov
The Pipeline

Number of Drugs in Development

- Cancer
- Infectious Disease
- Autoimmune
- AIDS/HIV
- Cardiovascular
- Neurologic
- Diabetes
- Gastrointestinal
- Respiratory
- Other
- Blood
- Genetic
- Skin
- Eye
- Growth
- Transplant

www.phrma.org
Drug Trend: Traditional vs. Specialty

“Specialty Drug Trend Across the Pharmacy and Medical Benefit” – Artemetrx a PSG Company January 2013
What to Expect Over The Next 12 Months

Oncology

Current Therapy
Primarily infused chemotherapy, however, there is a significant shift to new oral therapies
Significant increases in cost of therapy with some treatments exceeding $100,000 per patient per year

Pipeline
Introduction of additional oral therapies with new mechanisms of action
Disease with continued focus include prostate cancer, leukemia, and multiple myeloma
Development of novel vaccine-based and gene-based therapies

Bottom Line
Expect cost trends to continue to be in 15%-25% range in near future
Payors will continue to be challenged with utilization management strategies due to novel therapies entering the market
What to Expect Over The Next 12 Months

**Immunology/Infectious Disease**

**Current Therapy**

Significant new introductions of therapies for multiple sclerosis, hepatitis C, and immune globulins over past 12 months

**Pipeline**

Orals expected for multiple sclerosis and psoriasis

Advances in treatment of hepatitis C with more oral therapies

Continued shift from intravenous immune globulin to subcutaneous immune globulin

New therapies for cystic fibrosis, including focus on pneumonia

**Bottom Line**

These categories will significantly impact cost trends due to new drugs and price increases on existing drugs

Shift to subcutaneous immune globulin will now impact pharmacy benefit
Are Biosimilars The Solution?

Federal Trade Commission Report 2009:

• Competition Between Biologic Drugs and Biosimilars is more likely to resemble brand-brand competition than brand-generic competition
• The costs of FDA approval and manufacturing costs will limit the number of Biosimilar entrants
• Because of the costs, it is expected that large manufacturers with substantial resources will bring Biosimilars to market and only two or three Biosimilars will compete with a specific reference product
• The lack of automatic substitution will delay the uptake of Biosimilar products
• There will be concerns about safety and efficacy of a Biosimilar compared to a reference product
• Biosimilars are expected to enter the market at no more than 10-30 percent lower cost than their respective reference products
• Existing patent protection and market based pricing strategies are sufficient to promote competition between Biosimilars and reference products

Thank You!