Navigating the Specialty Drug Cost Challenge

Steven B. Miller, M.D.
Senior Vice President and Chief Medical Officer
Express Scripts, Inc.
St. Louis, Missouri

The opinions expressed in this presentation are those of the speaker. The International Foundation disclaims responsibility for views expressed and statements made by the program speakers.
Health Care Bucket

$3.3 Trillion

Source: National Health Expenditure Accounts, Centers for Medicare & Medicaid Services
How Much Is a Trillion?

- **Nov. 2, 2016**
  - 1 million seconds
    - 12 days ago

- **1 billion seconds**
  - Reagan begins second term

- **1 trillion seconds**
  - 30,000 BC
Rx: Growing Share of HC Spend

Net spending increase (2013-2015)

- Health Care: 11%
- Prescription Drugs: 20%

Rx coverage constitutes 19% of employer-based insurance benefits.

Specialty Drives Up Drug Trend

- 0.1% traditional

17.7% specialty

> 5.2% total trend

Source: 2015 Drug Trend Report
Growing Piece of a Bigger Pie

2015
- Specialty: 30%
- Traditional: 70%

2018
- Specialty: 50%
- Traditional: 50%

Source: Express Scripts research
Unsustainable Brand Inflation

164% Increase in average price of brand medications since 2008

Source: 2015 Drug Trend Report
Drugs in Development: 7,000+

Pipeline Products by Therapeutic Area

- Cancer: 1,813
- Neurological: 475
- Infectious Disease: 159
- Immunology: 1,120
- Cardiovascular: 1,256
- Mental Health: 599
- Mental Health: 511
- Diabetes: 1,329
- HIV/AIDS: 125

Source: 2015 Profile Biopharmaceutical Research Industry, PhRMA
FDA New Drug Approvals Rising

- Traditional
- Specialty
Novel, But Unproven Drug OK’d

**The New York Times**

*F.D.A. Approves Muscular Dystrophy Drug That Patients Lobbied For*

Sarepta Prices $300K Duchenne Drug As FDA Rift Emerges Over Approval

**Bloomberg**

*Bowing to pressure, FDA approves Sarepta's Duchenne drug*
Cost at Introduction Increases

Average Cost (per month of treatment)

Share of Specialty Rx

$2,134  $4,416  $6,049  $7,463  $9,615


Source: Express Scripts research
Generic Savings Is Declining

$214 Billion

$ Billions

$35

$30

$25

$20

$15

$10

$5

$0


H12-12
Market Conditions Enable Price Spikes in Generics

- Industry consolidation
- Limited production
- Pay to delay schemes
- Captive pharmacies
- New exclusivities
Biosimilars Around the World

- EU: 2006
- South Korea: 2012
- US: Awaiting clear regulatory path to market
- Japan: 2009
- Canada: 2010
- India: 2013
- Australia: 2010
### Falling Barriers, Rising Profits Draw Competition

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>PRICE</th>
<th>MANUFACTURING COST ASSUMING 2 G/L YIELD ($/GR)*</th>
<th>COST/PRICE*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avastin</td>
<td>$687.5/100mg</td>
<td>$188</td>
<td>2.7%</td>
</tr>
<tr>
<td>Enbrel</td>
<td>$243/25mg</td>
<td>$428</td>
<td>4.4%</td>
</tr>
<tr>
<td>Remicade</td>
<td>$784/100mg</td>
<td>$188</td>
<td>2.4%</td>
</tr>
<tr>
<td>Humira</td>
<td>$1,816/40mg</td>
<td>$308</td>
<td>0.7%</td>
</tr>
<tr>
<td>Rituxan</td>
<td>$675/100mg</td>
<td>$188</td>
<td>2.8%</td>
</tr>
<tr>
<td>Herceptin</td>
<td>$3,331/440mg</td>
<td>$126</td>
<td>1.7%</td>
</tr>
<tr>
<td>Erbitux</td>
<td>$600/100mg</td>
<td>$188</td>
<td>3.1%</td>
</tr>
<tr>
<td>Soliris</td>
<td>$5,122/300mg</td>
<td>$135</td>
<td>0.8%</td>
</tr>
<tr>
<td><strong>AVERAGE</strong></td>
<td><strong>$231</strong></td>
<td><strong>$188</strong></td>
<td><strong>2.3%</strong></td>
</tr>
</tbody>
</table>

*Bernstein Research analysis, market data as of 4Q2008

Note: IP licensing is excluded from cost calculation. Calculation intends to show direct gross margin of innovators. Cost of sales and marketing and discount given by biosimilars not included.
Projected Biosimilar Savings

$250 BILLION through 2024

Projected Sales: No Biosimilars

Projected Sales: With Biosimilars

Source: Potential Savings of Biogenerics in the United States, S Miller, J Houts - Express Scripts, 2007
The First Biosimilar Arrives

Discount to Neupogen

Europe: 30%
U.S.: 15%

In Europe, lower price leads to 30% market share
Inflammatory Conditions: Significant Savings Opportunity

- Products are FDA approved
- Not available due to legal challenges by originators
- Targets 3 of the 4 top-selling drugs worldwide\(^1\)
- Already on the market in U.K.

\(^1\)Source: Lucca Dezzani, MD; Igea, April 30 2016
What can a PBM do?
Hepatitis C: Price Shock Not Felt Around The World

Breakthrough Results

- Industry-leading adherence rate
- Risk sharing with adherence guarantee
- All patients have access, not just sickest
- Cured more people with hepatitis C than at any time in history

$1B in savings for our book of business in 2015
Today: Paying a Fair Price

Price at U.S. introduction
(Net per course of treatment)

Harvoni: $94,500
Sovaldi: $84,000

Price in 2015
(Net per course of treatment)

Harvoni (U.S.): $50,400
Sovaldi (U.S.): $44,520

Harvoni (EU5): $52,280
Sovaldi (EU5): $45,100

Source: IMS Institute for Healthcare Informatics July 2016
Oncology Cost Continues to Rise

Cost drivers
- More patients
- More chronic therapy
- Expensive drugs
- Combination therapy

2015 2016 2017

44% SPEND INCREASE

Oncology Drug Spend Forecast (PMPM)
Price Surge Since Mid-1990s

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval
1965-2015

Monthly Price of Treatment (2014 $, log scale)

Year of FDA Approval

100-fold price increase

- Individual Drugs
- Median Monthly Price (per 5-year period)
Inflation Outpaces Survival Benefit

Price per life year gained versus approval date of cancer drugs

The best fit line is: Price per life year gained = $54,100 + $8,500 x Approval year.
Approval Year = 0 for 1995, 1 for 1996, etc

Source: David H. Howard, et al, National Bureau of Economic Research
One Drug, Two Very Different Results

Tarceva on Non-Small Cell Lung Cancer

- **Placebo**: median PFS: 5.2 months
- **Tarceva**: median PFS: 10.4 months

Tarceva on Pancreatic Cancer

- **Placebo**: median OS: 6.0 months
- **Tarceva**: median OS: 6.4 months

**DOUBLES SURVIVAL** (5.2 months)

**EXTENDS SURVIVAL** ONLY 12 DAYS (0.4 months)
Indication-Based Management

Based on industry thought leadership

Steve Pearson, MD, MSc, FRCP
President of Institute for Clinical and Economic Review

Peter Bach, MD
Director, Memorial Sloan Kettering’s Center for Health Policy & Outcomes

Multiple indication factors considered

Independent feedback on cost based on efficacy

Fair indication pricing
Supply Chain Management

• Appropriate pricing by cancer type
• Exclusive coverage for participating manufacturers
• Value-based contracting
• Point-of-sale discount on select medications
• Site of care management
Benefits of Specialized Care

Deep clinical knowledge

- Breast/ovarian cancer
- GI/GU cancer
- Hematologic disorders
- Pediatric cancers
- Lung cancer

- Physician outreach and clinical support
- Holistic approach to patient care
- Higher adherence
- Reduced waste
Highest Specialty Spend

Inflammatory Conditions

- Actual
- Projected


$3,036 average cost per prescription

44% of patients are nonadherent
Biosimilars and New Drugs Will Enable Competition

- Rheumatoid arthritis
- Psoriasis and psoriatic arthritis
- Ankylosing spondylitis
- Crohn’s disease and ulcerative colitis

Negotiation and indication-based pricing drive value
**Indication-Based Pricing Drives Value**

<table>
<thead>
<tr>
<th>Rheumatoid Arthritis-Like</th>
<th>Dermatological</th>
<th>GI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rheumatoid Arthritis</strong></td>
<td><strong>Psoriasis</strong></td>
<td><strong>Crohn’s Disease</strong></td>
</tr>
<tr>
<td>1.5M</td>
<td>7.5M</td>
<td>0.7M</td>
</tr>
<tr>
<td>Humira</td>
<td>Humira</td>
<td>Humira</td>
</tr>
<tr>
<td>Enbrel</td>
<td>Enbrel</td>
<td>Otezla</td>
</tr>
<tr>
<td>Xeljanz</td>
<td>Remicade</td>
<td>Enbrel</td>
</tr>
<tr>
<td>Orencia</td>
<td>Simponi</td>
<td>Cosentyx</td>
</tr>
<tr>
<td>Remicade</td>
<td>Actemra</td>
<td>Stelara</td>
</tr>
<tr>
<td>Cimzia</td>
<td>Kineret</td>
<td>Taltz</td>
</tr>
<tr>
<td>Simponi</td>
<td>RituXan</td>
<td>Remicade</td>
</tr>
<tr>
<td>Actemra</td>
<td>Simponi Aria</td>
<td>Simponi</td>
</tr>
<tr>
<td>KinereT</td>
<td></td>
<td>Remicade</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Ankylosing Spondylitis</strong></th>
<th><strong>Taltz</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5M</td>
<td></td>
</tr>
<tr>
<td>Humira</td>
<td></td>
</tr>
<tr>
<td>Cimzia</td>
<td></td>
</tr>
<tr>
<td>Enbrel</td>
<td></td>
</tr>
<tr>
<td>Simponi Remicade</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Psoriatic Arthritis</strong></th>
<th><strong>Remicade</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.6M</td>
<td></td>
</tr>
<tr>
<td>Humira</td>
<td></td>
</tr>
<tr>
<td>Otelza Remicade</td>
<td></td>
</tr>
<tr>
<td>Cimzia Remicade</td>
<td></td>
</tr>
<tr>
<td>Remicade</td>
<td></td>
</tr>
<tr>
<td>Simponi Stelara</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Juvenile Idiopathic Arthritis</strong></th>
<th><strong>Kineret</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3M</td>
<td></td>
</tr>
<tr>
<td>Humira</td>
<td></td>
</tr>
<tr>
<td>Enbrel</td>
<td></td>
</tr>
<tr>
<td>Actemra IV</td>
<td></td>
</tr>
<tr>
<td>Orencia IV Remicade</td>
<td></td>
</tr>
<tr>
<td>Remicade Kineret</td>
<td></td>
</tr>
<tr>
<td>Simponi</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>**Dermatological **</th>
<th><strong>Stelara</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7M</td>
<td></td>
</tr>
<tr>
<td>Humira</td>
<td></td>
</tr>
<tr>
<td>Cimzia Remicade</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>GI</strong></th>
<th><strong>Remicade</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7M</td>
<td>Humira</td>
</tr>
</tbody>
</table>

**IN THE PIPELINE**

<table>
<thead>
<tr>
<th>adalimumab</th>
<th>Cosentyx</th>
<th>brodalumab</th>
<th>N/A</th>
<th>adalimumab</th>
<th>inflectra Stelara IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>baricitinib</td>
<td>etanercept</td>
<td>etanercept</td>
<td>inflectra</td>
<td>sarilumab</td>
<td>IV</td>
</tr>
<tr>
<td>etanercept</td>
<td>Inflectra</td>
<td>Taltz</td>
<td></td>
<td>etanercept</td>
<td></td>
</tr>
<tr>
<td>sarilumab</td>
<td></td>
<td></td>
<td></td>
<td>sarilumab</td>
<td></td>
</tr>
</tbody>
</table>

**H12-35**
Holistic Management Approach

- Specialized care
- Right patient, right drug
- Therapy effectiveness assessments
- Value-based contracting
- Channel management
What can other stakeholders do?
Pharmaceutical Companies

- Show better judgement in pricing
- Support biosimilars
- Reduce international price disparities
- Stop patent gaming
Federal Government

- Better fund FDA
- Boost NIH research
- Reform patent system
- Adjust malpractice laws
- Bring cost into care equation
Payers

- Continue to provide coverage
- Rational benefit design
- Advocate for policy changes
- Work together for common cause
Navigating the Specialty Drug Cost Challenge

- The rising cost of prescription drugs is unsustainable
- Managing specialty spend requires a holistic approach that improves both care and value
- PBMs innovation can address the changing landscape for better outcomes
- Providing affordable, high-quality care means rebalancing innovation, policy and pharma ROI

Website Resources
https://www.ifebp.org/inforequest/ifebp/0168059.pdf
https://www.youtube.com/watch?v=7uFhrHUdaZ0
2017 Educational Programs
Health and Welfare

63rd Annual Employee Benefits Conference
October 22-25, 2017
Las Vegas, Nevada
www.ifebp.org/usannual

Certificate Series
February 27-March 4, 2017
Lake Buena Vista (Orlando), Florida
www.ifebp.org/certificateseries

July 24-29, 2017
Denver, Colorado
www.ifebp.org/certificateseries

Health Care Management Conference
May 1-3, 2017
New Orleans, Louisiana
www.ifebp.org/healthcare

Certificate of Achievement in Public Plan Policy (CAPPP®)
Part I and Part II, June 13-16, 2017
San Jose, California
Part II Only, October 21-22, 2017
Las Vegas, Nevada
www.ifebp.org/cappp

Related Reading
Visit one of the on-site Bookstore locations or see www.ifebp.org/bookstore for more books.

Self-Funding Health Benefit Plans
Item #7563
www.ifebp.org/SelfFunding