Prescription Medicines: Costs in Context

Updated August 2016
Medicines are Transforming the Treatment OF DEVASTATING DISEASES

HEPATITIS C
The leading cause of liver transplants and the reason liver cancer is on the rise – is now curable in more than 90 percent of treated patients.*

CANCER
New therapies have contributed to a 23% decline in the cancer death rate since its peak in 1991. Today, 2 out of 3 people diagnosed with cancer survive at least 5 years.**

HIGH CHOLESTEROL
America’s biopharmaceutical companies are currently developing 190 medicines to treat heart disease, stroke and other cardiovascular diseases. New PCSK9 inhibitors have revolutionized high cholesterol treatment. Between 1991 and 2011, the death rate from heart disease dropped 46%.***

*Source: U.S. Food and Drug Administration.
**Source: American Cancer Society.
***Source: Pharmaceutical Research and Manufacturers of America (PhRMA) and the Association of Black Cardiologists (ABC), "Medicines in Development for Heart Disease and Stroke," December 2015.
The Biopharmaceutical Industry’s IMPACT ON THE U.S. ECONOMY

Nearly 4.5 Million Jobs

ECONOMIC OUTPUT FROM INDUSTRY

$1.2 Trillion

Nearly $311 Billion paid in wages and benefits

Annual average compensation of $123,108 in direct jobs is more than twice the average annual salary for all other jobs.

The Biopharmaceutical Sector is the SINGLE LARGEST FUNDER OF INNOVATION IN THE UNITED STATES

Share of Total US Business R&D by Industry, 2013

- **17%** for Pharmaceuticals & Medicines
- **13%** for Software
- **5%** for Automobiles
- **4%** for Aerospace
- **3%** for Computer Systems Design
- **1%** for Scientific R&D Services

The biopharmaceutical sector accounts for the single largest share of all US business R&D, representing 17% of all domestic R&D funded by US businesses.

NOTE: The remaining 57% share of business R&D spending is conducted by other industries, including subsectors of the machinery sector, the electrical equipment sector, and the professional, scientific, and technical services sector.

Source: PhRMA analysis of National Science Foundation data.
MEDICINES PROVIDE CRITICAL SAVINGS
to the U.S. Health Care System

Estimated **10-Year savings** to Medicare from improved adherence to congestive heart failure medications, 2013-2022*

$22.4 billion

$367 billion

Costs avoided by 2050 if we develop a new medicine that delays the onset of Alzheimer’s disease by just five years**

**Source: Alzheimer’s Association.
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Medicines Help Patients
AVOID EXPENSIVE HOSPITAL SERVICES

The U.S. health care system could save $213 billion annually if medicines were used properly*

Adherence to Medicines Lowers Total Health Spending for Chronically Ill Patients**


Prescription Medicines: Costs in Context www.phrma.org/cost
Medicines Account for a Stable Share of Health Care Spending

Health Care Expenditures Attributable to Retail and Non-Retail Prescription Drugs, 2008-2024

Source: Altarum Institute, "A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail," August 2015.
POWERSFUL PURCHASERS NEGOTIATE DRUG PRICES

Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs), with the top three PBMs accounting for three quarters of the market.

PBM MARKET SHARE, BY TOTAL EQUIVALENT PRESCRIPTIONS

- Express Scripts: 29%
- CVS Health (Caremark): 25%
- OptumRx/Catamaran*: 22%
- All Other: 24%

NOTE: OptumRx and Catamaran merged in 2015. Their 2014 shares are shown combined.

Source: Drug Channels Institute.
GREATER FOCUS ON SUPPLY CHAIN

1/3 of medicine list prices rebated back to payers, government or retained by supply chain

Rebates, discounts and fees keep increasing

- 2013: $67.0B
- 2014: $84.6B
- 2015: $106.4B

- Brand Companies: 62.6%
- Market Access Rebates and Discounts: 18.5%
- Statutory Rebates and Fees: 12%
- Supply Chain Entities: 6.9%

Berkeley Research Group
Share of Commercial Plans with a PRESCRIPTION DRUG DEDUCTIBLE IS INCREASING

PERCENT OF PLANS WITH DEDUCTIBLES ON PRESCRIPTION DRUGS*

- 2012: 23%
- 2015: 46%

+100%

Cost sharing for patients is shifting from copayments to less predictable coinsurance**

*Source: IMS Health, Emergence and Impact of Pharmacy Deductibles, September 2015.

www.phrma.org/cost
PRAGMATIC SOLUTIONS

to Address Cost Concerns

MODERNIZE THE DRUG DISCOVERY AND DEVELOPMENT PROCESS

• Modernize the FDA to keep pace with scientific discovery and increase efficiency of generic approvals

PROMOTE VALUE-DRIVEN HEALTH CARE

• Address barriers to paying for value, develop patient-centered value assessment tools and support appropriate use of medicines

ENGAGE AND EMPOWER CONSUMERS

• Make quality and cost information public to aid in decisions and enforce common-sense rules that prevent discrimination against vulnerable patients

ADDRESS MARKET DISTORTIONS

• Improve risk adjustment models and reform market distorting programs like the 340B Drug Pricing program
What are Value-Based Contracts?

- **Voluntary** arrangements between manufacturers and other private entities (health plans, risk-bearing providers) in which the price or price-concession for a prescription medicine is linked to value as determined by the contracting entities.
## Continued Interest in Outcomes-Based Contracts

The table below illustrates the interest of U.S. health plans in entering into outcomes-based contracts with manufacturers across various conditions. The interest is categorized by level (Very low, Low, Moderate, High, Very high) with percentages indicating the proportion of health plans interested in such contracts.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Very low</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
<th>Very high</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis C</td>
<td>10%</td>
<td>13%</td>
<td>15%</td>
<td>40%</td>
<td>23%</td>
</tr>
<tr>
<td>Oncology</td>
<td>13%</td>
<td>18%</td>
<td>18%</td>
<td>33%</td>
<td>20%</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>18%</td>
<td>20%</td>
<td>28%</td>
<td>20%</td>
<td>15%</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>20%</td>
<td>13%</td>
<td>28%</td>
<td>28%</td>
<td>13%</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>41%</td>
<td>22%</td>
<td>24%</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>IBD</td>
<td>21%</td>
<td>28%</td>
<td>28%</td>
<td>18%</td>
<td>5%</td>
</tr>
<tr>
<td>HIV</td>
<td>25%</td>
<td>28%</td>
<td>28%</td>
<td>15%</td>
<td>5%</td>
</tr>
<tr>
<td>Growth deficiency</td>
<td>49%</td>
<td>27%</td>
<td>20%</td>
<td>5%</td>
<td>5%</td>
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A manufacturer agrees to vary the final price paid by a payer based on how well the drug improves outcomes for patients.
Specific Example 2: Indication-Based Pricing

• A manufacturer agrees to be paid differently for different uses of its medicine

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<th>Indication</th>
<th>How Effective? (metric negotiated within contract)</th>
<th>‘Example negotiated ‘value’/price</th>
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<td>Breast Cancer</td>
<td>Highly</td>
<td>$100</td>
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<td>Lung Cancer</td>
<td>Minimally</td>
<td>$20</td>
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• Actual price paid might be a blended price based on how much of the drug is expected to be used for each indication

• CVS and Express Scripts have both announced that they are implementing indication-based pricing for oncology
Recommendations to Enable Value-Based Contracts

Modernize regulations that have the effect of limiting the number and scope of value-based contracts

• **Price Reporting**
  • Price reporting rules need to be modernized to enable value-based contracting at a larger scale
Medicaid Best Price is the key example:

Hypothetical Example

- List Price (WAC)
- Negotiated Price
- Outcomes-Based Price

Best Price?
Recommendations to Enable Value-Based Contracts

Modernize regulations that have the effect of limiting the number and scope of value-based contracts

- FDA regulations and guidance governing manufacturer communications
  - Manufacturers need flexibility to communicate broadly about products with payers and population health decision makers
Manufacturer Communications

- Need greater flexibility to communicate about off-label uses
- Indication based pricing is a good example of the challenge

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Medically accepted off-label use?
Recommendations to Enable Value-Based Contracts

Modernize regulations that have the effect of limiting the number and scope of value-based contracts

• Anti-Kickback Statute
  • Value-based contracts should be clearly protected under the anti-kickback statute