The U.S Pharmaceutical Market:

Looking back and looking ahead!

SLA

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Most notable things about 2014

- Double Digit Dollar sales growth is back
- TRXs slow start but recovered nicely
- Generic Diovan® finally appears and Nexium® OTC is here but no Nexium® and Copaxone®
- Some Generic Concerta® generics pulled
- FTF Nexium® pulled
- Generic price inflation
- 90 day scripts approach 10% of TRXs
- Full Line to Specialty Distribution
- Controlled substances TRXs still going down
- Zohydro® approval
- DEA still on the rampage
- Track and Trace legislation passed
- HYCD products rescheduled
- Affordable Health Care Act delays but 8 million signed up? Now 9.5??
- More Limited networks and private exchanges
- Medicaid Expansion
- 340B
- Highest Healthcare Spending increases since 1980
- Generic labeling rules
- Tax Inversion
- Global Purchasing Alliances
- Solvaldi®
Most notable things about 2015

• Tavenner out
• Hamburg out
• Uhl is in
• Supreme Court King vs. Burwell
• Hep C exclusive launches and price wars
• FDA approves Biosimilar Neupogen from Sandoz
• Generic Nexium finally arrives
• Flonase OTC

• Watch for PD1s and PCSK9s

• Mergers
  • Abbvie & Pharma Cyclics,
  • Mylan & Perrigo
  • Pfizer & Hospira
  • Valeant & Dendreon
  • Valeant & Salix
  • Optum and Catamaran
Overview of Macro-changes to U.S. healthcare

The current and future state of the healthcare system

- Healthcare costs rising, drug spend on the rebound
- Specialty, niche and orphan drugs are a key driver
- Traditional therapies post-patent cliff and shifting cost burdens are driving changes across the system
- Changing structure of payment and delivery is focused on improving outcomes and lowering costs
US Market Sales and Dispensed Prescription growth

% Growth of sales and prescription of products
Total market

Source: IMS Health, National Sales Perspectives, Dec 2014
IMS Health, National Prescription Audit, Dec 2014
New brand spending has shifted to specialty

Sovaldi, Tecfidera, Olysio launched in last 24 months

Source: IMS Health, National Sales Perspectives, Sept 2014
Recent most successful launches are mostly specialist and for focused patient populations

J&J commercialised 5 of them; Sovaldi the biggest perhaps ever

Achieving >$1.0bn with a launch in the 5 year period 2008 - FY2013

- All launched into areas of high need:
- Specialty Products dominate

**Xarelto** (Bayer/J&J)  
Launch Sept 2008  
($2.124 bn, FY 2013)

**Eylea** (Bayer/Regeneron)  
Launch Dec 2011  
($1.851bn, FY 2013)

**Invega Sustenna** (J&J)  
Launch August 2009  
($1.248bn, FY 2013)

**Victoza** (Novo Nordisk)  
Launch June 2009  
($2.071bn, FY 2013)

**Zytiga** (J&J)  
Launch May 2011  
($1.698bn, FY 2013)

**Prolia/Xgeva** (Amgen/GSK)  
Launch May 2010  
($1.763bn, FY 2013)

**Gilenya** (Novartis)  
Launch Sept 2010  
($1.934bn, FY 2013)

**Stelara** (J&J)  
Launch Jan 2009  
($1.504bn, FY 2013)

**Incivek/Incivo** (Vertex/J&J)  
Launch May 2011  
($0.983bn, FY 2013)

**Sovaldi** (Gilead)  
Launch Dec 2013  
($2.27bn, Q1 2014*)

Source: Company reported information, IMS Health Dec 2013, first word and IMS analysis
Specialty drugs hold a sizeable share of new molecular entity launches

52% of NMEs in the past 5 years are specialty, up from 40% 2005-09

New Molecular Entities Launched in the US, 2002-2014

Source: FDA, IMS Institute for Healthcare Informatics, Jan 2015
Specialty now account for one third of spending up from 23% five years ago

Specialty growth coincided with the traditional “patent cliff”

Source: IMS Health, National Sales Perspectives, Dec 2014
Spending growth is being driven primarily by innovation, which is mostly specialty.

Price increases for protected brands and expiry dynamics also contribute.

**Traditional and Specialty Spending Growth Dynamics**

- New Brands
- Protected Brands Price
- Protected Brands Volume
- Generics
- LOE
- Total Growth

Source: IMS Health, National Sales Perspectives, Sep 2014
Orphan drugs are a significant driver of innovation and more can be expected in the future

- The United States (US) Orphan Drug Act (ODA) of 1983 established incentives for the development of drugs that treat rare or orphan diseases. Approximately 25-30M Americans, or 8-10% of the US population, have one.
- Total orphan drug expenditures represented 4.8-8.9% of total US drug expenditures, in 2007-2013.
- Despite the clinical value of orphan drugs, payer sensitivity to orphan drugs is increasing due to the perceived potential impact on payers’ drug budgets.

Orphan Drug Designations/Approvals 1983-2012

Approx Total # Designation requests submitted through 2012 = > 3900
Approx Total # of Designations through 2012 = > 2700
Approx Total # of approvals of orphan designated products through 2012 = >420

Chart Source: The Budget Impact of Orphan Drugs in the US: A 2007-2013 MIDAS Sales Data Analysis Victoria Divino¹ *, Mitch Dekoven, MHSA¹ *, Weiying Wang, MPH¹ *, Michael Kleinrock, MA¹ *, R. Donald Harvey, PharmD³, Rolin L. Wade, RPh, MS¹ *, and Satyin Kaura, MSci, MBA⁴ *
¹IMS Health, Fairfax, VA; ²MKTXS, Raritan, NJ; ³Winship Cancer Institute, Emory University, Atlanta, GA; ⁴Celgene, Summit, NJ

“Rare Diseases and FDA” Perspectives from the Office of Orphan Products Development (OOPD)” Presented by Katherine Needleman, MS, PhD, RAC, Director, Orphan Products Grants Program FDA/OOPD at the IRDiRC Conference, April 16 & 17, 2013 ¹
Launch success depends on a clear alignment of a product’s value to the stakeholder’s needs

Success is not limited to and doesn’t look like the top 2-3 launches

Launch Archetypes

1. High unmet need in the market with high product differentiation
   Science Sells

2. Low unmet need in the market with high product differentiation
   It’s about Shaping (market/prod)

3. High unmet need in the market with low product differentiation
   Emphasize the Difference

4. Low unmet need in the market with low product differentiation
   Who Benefits

1. Can Launch Archetypes provide insight into a product’s opportunity for success?
2. Are investment levels different for each archetype?
3. Does Managed Care treat these archetypes similarly?
Recent launch performance is improving industry-wide

First Year Sales per Launch & Percent of Launches by Archetype, 2010-2013 (Rolling 4YR)

**Science Sells** (high need, high diff)
- 2010: $86M (19%)  
- 2011: $132M (25%)  
- 2012: $141M (25%)  
- 2013*: $204M (26%)

**Its about Shaping** (low need, high diff)
- 2010: $85M (13%)  
- 2011: $78M (11%)  
- 2012: $94M (14%)  
- 2013*: $107M (16%)

**Emphasize the Difference** (high need, low diff)
- 2010: $35M (21%)  
- 2011: $34M (17%)  
- 2012: $52M (18%)  
- 2013*: $58M (18%)

**Who Benefits** (low need, low diff)
- 2010: $36M (47%)  
- 2011: $32M (47%)  
- 2012: $28M (43%)  
- 2013*: $28M (39%)

Sources: IMS Custom PLD; Thought Leadership
Changes in the healthcare environment share common interconnected themes

- **Patients:** exposure to cost / decisions / ability to get information
- **Specialty Innovation:** out of sync with patent expiries
- **Control:** involves complex multi-stakeholder decisions, constantly shifting
- **Everything is local:** Narrow networks / formularies / choice; Vast Local Variations
What are people thinking about?

- **Pharmacies**
  - Purchasing Alliances
  - Controlled Substances abuse
  - Access to Specialty Drugs
  - Generic Price Inflation
  - Track and Trace

- **Wholesalers**
  - Purchasing Alliances
  - Controlled Substances abuse
  - Access to Specialty Drugs
  - Generic Price Inflation
  - Track and Trace

- **Payers**
  - Exploding costs of Specialty Drugs
  - Generic Price Inflation
  - Formularies and exclusive launches
  - Rising Oncology costs

- **Generic Manufacturers**
  - Purchasing Alliances
  - Portfolio Optimization
  - Brand drugs
  - Proposed labeling changes
  - Tax Inversion

- **Brand/Specialty Manufacturers**
  - Price backlash
  - Becoming more specialized
  - Oral Specialty
  - Orphan Drugs
  - Tax Inversion

- **Consumers**
  - Rising costs
  - Specialty Tiers
  - Losing Insurance
## Largest absolute Dollar sales gains and losses by leading therapy classes, (2014)

<table>
<thead>
<tr>
<th>Dollars</th>
<th>AC $ Gained</th>
<th>Total Rx dispensed</th>
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<tbody>
<tr>
<td>Viral Hepatitis Products</td>
<td>10535.4</td>
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<td>Antihyperlipidemic agt</td>
<td>-549.2</td>
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<td>2158.0</td>
<td>Heparins</td>
<td>-552.5</td>
</tr>
<tr>
<td>Anticoagulants, Other</td>
<td>1445.5</td>
<td>Non-barb, oth</td>
<td>-555.1</td>
</tr>
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<td>HIV antiviral combination</td>
<td>1333.9</td>
<td>Tetracyclines</td>
<td>-581.7</td>
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<td>Antineo monoclonal antib</td>
<td>1304.3</td>
<td>Angiotensin II antagonists</td>
<td>-665.1</td>
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## Sales of leading therapy classes

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<th>US$mn</th>
<th>% Market Share</th>
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<tbody>
<tr>
<td>US Industry</td>
<td></td>
<td>373,858</td>
<td>100.0</td>
<td>13.1</td>
</tr>
<tr>
<td>1 Analogs of human insulin</td>
<td></td>
<td>18,876</td>
<td>5.0</td>
<td>35.8</td>
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<tr>
<td>2 Antiarth,biol resp mod</td>
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<td>14,805</td>
<td>4.0</td>
<td>25.3</td>
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<tr>
<td>3 Antipsychotics, oth</td>
<td></td>
<td>14,375</td>
<td>3.8</td>
<td>18.1</td>
</tr>
<tr>
<td>4 Lipid regulators</td>
<td></td>
<td>12,905</td>
<td>3.5</td>
<td>4.5</td>
</tr>
<tr>
<td>5 Viral Hepatitis Products</td>
<td></td>
<td>11,901</td>
<td>3.2</td>
<td>771.6</td>
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<tr>
<td>6 Antineo monoclonal antib</td>
<td></td>
<td>10,930</td>
<td>2.9</td>
<td>13.6</td>
</tr>
<tr>
<td>7 HIV antiviral combination</td>
<td></td>
<td>8,786</td>
<td>2.4</td>
<td>17.9</td>
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<tr>
<td>8 Proton pump inhib</td>
<td></td>
<td>8,703</td>
<td>2.3</td>
<td>-8.7</td>
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<tr>
<td>9 Analactics</td>
<td></td>
<td>8,318</td>
<td>2.2</td>
<td>-0.3</td>
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<tr>
<td>10 Steroid, inhaled bronch</td>
<td></td>
<td>8,148</td>
<td>2.2</td>
<td>8.3</td>
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<td><strong>Top 10</strong></td>
<td></td>
<td>117,747</td>
<td>31.5</td>
<td>25.1</td>
</tr>
</tbody>
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Source: IMS Health, National Sales Perspectives, Dec 2014
# Sales of 11-20 therapy classes

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<td>11 Neurological disorders</td>
<td>8,141</td>
<td>2.2</td>
<td>36.1</td>
</tr>
<tr>
<td>12 GI anti-inflam</td>
<td>8,014</td>
<td>2.1</td>
<td>13.3</td>
</tr>
<tr>
<td>13 Dpp-4 Inhib</td>
<td>6,470</td>
<td>1.7</td>
<td>23.9</td>
</tr>
<tr>
<td>14 Anti-depressants</td>
<td>6,458</td>
<td>1.7</td>
<td>-27.7</td>
</tr>
<tr>
<td>15 Angiotensin II antagonists</td>
<td>5,768</td>
<td>1.5</td>
<td>-10.3</td>
</tr>
<tr>
<td>16 Tyrosine kinase inhibitor</td>
<td>5,537</td>
<td>1.5</td>
<td>29.7</td>
</tr>
<tr>
<td>17 Codeine &amp; comb</td>
<td>5,263</td>
<td>1.4</td>
<td>7.7</td>
</tr>
<tr>
<td>18 Seizure disorders</td>
<td>5,247</td>
<td>1.4</td>
<td>13.4</td>
</tr>
<tr>
<td>19 Immunologic interferons</td>
<td>4,843</td>
<td>1.3</td>
<td>-4.4</td>
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<tr>
<td>20 Immune system adjuncts</td>
<td>4,816</td>
<td>1.3</td>
<td>4.7</td>
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<tr>
<td><strong>Top 20</strong></td>
<td><strong>178,304</strong></td>
<td><strong>47.7</strong></td>
<td><strong>17.9</strong></td>
</tr>
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### Largest absolute dollar sales gains and losses by leading products, (2014)

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<tr>
<td>Sovaldi® (Gs-)</td>
<td>7782</td>
<td>enoxaparin sod (win)</td>
<td>-183</td>
</tr>
<tr>
<td>Olysio® (Jan)</td>
<td>1957</td>
<td>Nexium® (Azn)</td>
<td>-251</td>
</tr>
<tr>
<td>Tecfidera® (Bge)</td>
<td>1675</td>
<td>Namenda® (Atv)</td>
<td>-280</td>
</tr>
<tr>
<td>Humira® (Av1)</td>
<td>1658</td>
<td>Advair Diskus® (Gsk)</td>
<td>-371</td>
</tr>
<tr>
<td>Harvoni® (Gs-)</td>
<td>1546</td>
<td>methylphenidate er (Atv)</td>
<td>-438</td>
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<tr>
<td>Lantus Solostar® (S.A)</td>
<td>1348</td>
<td>Lovaza® (Gsk)</td>
<td>-494</td>
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<tr>
<td>Abilify® (Ots)</td>
<td>1291</td>
<td>Lunesta® (S8r)</td>
<td>-513</td>
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<tr>
<td>Xarelto® (Jan)</td>
<td>1052</td>
<td>Diovan® (Nvr)</td>
<td>-734</td>
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<tr>
<td>Lantus® (S.A)</td>
<td>814</td>
<td>Lidoderm® (End)</td>
<td>-799</td>
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<tr>
<td>Enbrel® (Aai)</td>
<td>796</td>
<td>Cymbalta® (Lly)</td>
<td>-4916</td>
</tr>
</tbody>
</table>

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# Sales of leading products

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<tr>
<td>1 Sovaldi®</td>
<td>GS-</td>
<td>7,853</td>
<td>2.1</td>
<td>10910.4</td>
</tr>
<tr>
<td>2 Abilify®</td>
<td>OTS</td>
<td>7,838</td>
<td>2.1</td>
<td>19.7</td>
</tr>
<tr>
<td>3 Humira®</td>
<td>AV1</td>
<td>7,222</td>
<td>1.9</td>
<td>29.8</td>
</tr>
<tr>
<td>4 Nexium®</td>
<td>AZN</td>
<td>5,931</td>
<td>1.6</td>
<td>-4.1</td>
</tr>
<tr>
<td>5 Crestor®</td>
<td>AZN</td>
<td>5,848</td>
<td>1.6</td>
<td>8.8</td>
</tr>
<tr>
<td>6 Enbrel®</td>
<td>AAI</td>
<td>5,506</td>
<td>1.5</td>
<td>16.9</td>
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<tr>
<td>7 Advair Diskus®</td>
<td>GSK</td>
<td>4,813</td>
<td>1.3</td>
<td>-7.2</td>
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<tr>
<td>8 Remicade®</td>
<td>JAN</td>
<td>4,502</td>
<td>1.2</td>
<td>9.5</td>
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<tr>
<td>9 Lantus Solostar®</td>
<td>S.A</td>
<td>4,468</td>
<td>1.2</td>
<td>43.2</td>
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<tr>
<td>10 Copaxone®</td>
<td>TVN</td>
<td>3,881</td>
<td>1.0</td>
<td>4.6</td>
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<tr>
<td><strong>Top 10</strong></td>
<td></td>
<td>57,863</td>
<td>15.5</td>
<td>29.8</td>
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<td>Neulasta®</td>
<td>AAI</td>
<td>3,831</td>
<td>1.0</td>
<td>6.9</td>
</tr>
<tr>
<td>Rituxan®</td>
<td>GTC</td>
<td>3,473</td>
<td>0.9</td>
<td>5.0</td>
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<tr>
<td>Januvia®</td>
<td>MSD</td>
<td>3,464</td>
<td>0.9</td>
<td>20.6</td>
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<tr>
<td>Lantus®</td>
<td>S.A</td>
<td>3,402</td>
<td>0.9</td>
<td>31.5</td>
</tr>
<tr>
<td>Spiriva Handihaler®</td>
<td>B.I</td>
<td>3,329</td>
<td>0.9</td>
<td>9.7</td>
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<tr>
<td>Lyrica®</td>
<td>PFZ</td>
<td>3,087</td>
<td>0.8</td>
<td>25.8</td>
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<tr>
<td>Atripla®</td>
<td>BMG</td>
<td>2,962</td>
<td>0.8</td>
<td>2.4</td>
</tr>
<tr>
<td>Avastin®</td>
<td>GTC</td>
<td>2,888</td>
<td>0.8</td>
<td>6.7</td>
</tr>
<tr>
<td>Tecfidera®</td>
<td>BGE</td>
<td>2,580</td>
<td>0.7</td>
<td>185.0</td>
</tr>
<tr>
<td>Truvada®</td>
<td>GS-</td>
<td>2,502</td>
<td>0.7</td>
<td>10.7</td>
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What do we mean by specialty pharmaceuticals?
IMS has an industry standard definition—must have 4 or more:

Medicines that treat specific, complex chronic diseases with the following attributes:

- **Initiated only by a specialist**
  - Few prescribers/ centers
  - Low inventory important
  - Processing of pre-approval essential and competitive skill
  - Requires patient training to administer
  - Support to achieve adherence needed
  - Cold chain when needed
  - No need for supplying all pharmacies through all warehouses

- **High expense**

- **Requires reimbursement assistance**

- **Warrants intensive patient counseling**

- **Require special handling**

- **Unique distribution**
Specialty pharmaceuticals differ from common therapies in a variety of aspects

<table>
<thead>
<tr>
<th></th>
<th>Common Acute</th>
<th>Common Chronic</th>
<th>Complex Chronic</th>
<th>Rare Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Condition</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>U.S. Patient Population</strong></td>
<td>Millions</td>
<td>Affects &gt;50 million</td>
<td>Affects ~ 2 million</td>
<td>Affects ~ 20K</td>
</tr>
<tr>
<td><strong>Duration of Therapy</strong></td>
<td>About 10 days/episode</td>
<td>Ongoing (maintenance)</td>
<td>Lifelong</td>
<td>Lifelong</td>
</tr>
<tr>
<td><strong>Cost of Therapy</strong></td>
<td>~ $100/episode</td>
<td>$1,000+/year</td>
<td>$14,000+/year</td>
<td>$250,000/year</td>
</tr>
<tr>
<td><strong>Medication</strong></td>
<td>Anti-infective</td>
<td>Lipitor®</td>
<td>HUMIRA®</td>
<td>Cerezyme®</td>
</tr>
<tr>
<td><strong>Indication</strong></td>
<td>Acute bacterial infection</td>
<td>Cholesterol reduction</td>
<td>Rheumatoid arthritis</td>
<td>Gaucher’s disease</td>
</tr>
<tr>
<td><strong>Handling Requirements</strong></td>
<td>No special requirements</td>
<td>No special requirements</td>
<td>Refrigeration training</td>
<td>Refrigeration/mixing/pumps/central line training</td>
</tr>
<tr>
<td><strong>Typical Distribution Channel</strong></td>
<td>Retail</td>
<td>Retail and mail service</td>
<td>Specialty pharmacy, infusion clinics, doctor’s office, home with advanced clinical services</td>
<td>Specialty pharmacy, infusion clinics, doctor’s office, home with advanced clinical services</td>
</tr>
</tbody>
</table>
Top US Specialty events of 2014

- Hep C
- Orphan Drugs
- FDA’s first Biosimilar actions
- Tremendous pressure on Pharmaceutical budgets
Top Specialty events to watch for!

- HEP C Innovation and Pricing
- Patient as a Payer
  - Specialty tiers in exchanges
- Growing demand for value driven metrics (CE and RWE)/adoption of guidelines
- Copaxone® 3X weekly and Copaxone® generic?
- Specialty space gets more crowded with new entrants and more orals are coming
- The first Biosimilar launch
- Co Pay programs cooperation by payers
- Possible 340B changes
- Gene Therapies & Orphan drugs price discussions
# Top specialty companies – MAT Nov 2014

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Sales ($MN)</th>
<th>Share</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Gilead Sciences</td>
<td>16,416</td>
<td>14.1%</td>
<td>136.0%</td>
</tr>
<tr>
<td>2</td>
<td>Amgen</td>
<td>15,084</td>
<td>13.0%</td>
<td>10.6%</td>
</tr>
<tr>
<td>3</td>
<td>Genentech</td>
<td>13,040</td>
<td>11.2%</td>
<td>6.1%</td>
</tr>
<tr>
<td>4</td>
<td>Johnson &amp; Johnson</td>
<td>11,844</td>
<td>10.2%</td>
<td>37.7%</td>
</tr>
<tr>
<td>5</td>
<td>Abbvie</td>
<td>8,423</td>
<td>7.2%</td>
<td>22.5%</td>
</tr>
<tr>
<td>6</td>
<td>Novartis</td>
<td>6,878</td>
<td>5.9%</td>
<td>12.5%</td>
</tr>
<tr>
<td>7</td>
<td>Biogen Idec</td>
<td>6,002</td>
<td>5.2%</td>
<td>66.1%</td>
</tr>
<tr>
<td>8</td>
<td>Teva</td>
<td>5,361</td>
<td>4.6%</td>
<td>10.9%</td>
</tr>
<tr>
<td>9</td>
<td>Bristol-Myers Squibb</td>
<td>4,054</td>
<td>3.5%</td>
<td>9.4%</td>
</tr>
<tr>
<td>10</td>
<td>Lilly</td>
<td>2,810</td>
<td>2.4%</td>
<td>7.2%</td>
</tr>
</tbody>
</table>

**Top 10**

<table>
<thead>
<tr>
<th>Sales ($MN)</th>
<th>Share</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>89,911</td>
<td>77.3%</td>
<td>29.8%</td>
</tr>
</tbody>
</table>

Source: IMS Health, National Sales Perspectives, Nov 2014
## Sales of leading corps

<table>
<thead>
<tr>
<th>Leading corporations</th>
<th>MAT Dec 2014</th>
<th>US$mn</th>
<th>% Market Share</th>
<th>% Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Industry</td>
<td></td>
<td>373,858</td>
<td>100.0</td>
<td>13.1</td>
</tr>
<tr>
<td>1 Novartis (incl Sandoz)</td>
<td></td>
<td>19,486</td>
<td>5.2</td>
<td>3.0</td>
</tr>
<tr>
<td>2 Astrazeneca</td>
<td></td>
<td>19,485</td>
<td>5.2</td>
<td>7.2</td>
</tr>
<tr>
<td>3 Johnson &amp; Johnson</td>
<td></td>
<td>19,088</td>
<td>5.1</td>
<td>37.1</td>
</tr>
<tr>
<td>4 Gilead Sciences</td>
<td></td>
<td>18,387</td>
<td>4.9</td>
<td>140.9</td>
</tr>
<tr>
<td>5 Pfizer (incl Greenstone)</td>
<td></td>
<td>18,050</td>
<td>4.8</td>
<td>6.7</td>
</tr>
<tr>
<td>6 Roche (incl Genentech)</td>
<td></td>
<td>17,737</td>
<td>4.7</td>
<td>6.9</td>
</tr>
<tr>
<td>7 Merck &amp; Co</td>
<td></td>
<td>17,584</td>
<td>4.7</td>
<td>8.4</td>
</tr>
<tr>
<td>8 Teva</td>
<td></td>
<td>17,471</td>
<td>4.7</td>
<td>14.0</td>
</tr>
<tr>
<td>9 Amgen Corporation</td>
<td></td>
<td>16,398</td>
<td>4.4</td>
<td>10.9</td>
</tr>
<tr>
<td>10 Sanofi Aventis</td>
<td></td>
<td>14,602</td>
<td>3.9</td>
<td>19.9</td>
</tr>
<tr>
<td><strong>Top 10</strong></td>
<td><strong>178,289</strong></td>
<td>47.7</td>
<td>18.3</td>
<td></td>
</tr>
</tbody>
</table>

Source: IMS Health, National Sales Perspectives, Dec 2014
Leading corporations | MAT Dec 2014 | % Market Share | % Growth
--- | --- | --- | ---
11 Actavis US | 13,775 | 3.7 | -2.4
12 Abbvie Inc | 12,622 | 3.4 | 4.7
13 GlaxoSmithKline | 12,166 | 3.3 | -4.5
14 Lilly | 11,816 | 3.2 | -22.8
15 Novo Nordisk | 10,417 | 2.8 | 26.4
16 Mylan Labs, Inc. | 8,742 | 2.3 | 10.3
17 Boehringer Ingelheim | 8,256 | 2.2 | 6.9
18 Otsuka America Ph | 8,212 | 2.2 | 21.0
19 Biogen Idec Corp | 6,134 | 1.6 | 59.0
20 Shire US Corp | 5,025 | 1.3 | 18.6

Top 20 | 275,454 | 73.7 | 13.1

Source: IMS Health, National Sales Perspectives, Dec 2014
Largest absolute growth by leading corporations, Sales & TRx (MAT)

<table>
<thead>
<tr>
<th>Dollars</th>
<th>AC US$BN</th>
<th>TRx</th>
<th>AC TRx mn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilead Sciences</td>
<td>10.8</td>
<td>Novartis (incl Sandoz)</td>
<td>34.6</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>5.2</td>
<td>Endo Pharma Inc.</td>
<td>26.2</td>
</tr>
<tr>
<td>Sanofi Aventis</td>
<td>2.4</td>
<td>Legacy Pharma Pkg</td>
<td>14.5</td>
</tr>
<tr>
<td>Biogen Idec Corp</td>
<td>2.3</td>
<td>Zydus Pharma</td>
<td>14.4</td>
</tr>
<tr>
<td>Novo Nordisk</td>
<td>2.2</td>
<td>Accord Healthcare</td>
<td>13.8</td>
</tr>
<tr>
<td>Teva</td>
<td>2.1</td>
<td>Apotex Corp</td>
<td>13.5</td>
</tr>
<tr>
<td>Amgen Corporation</td>
<td>1.6</td>
<td>Lupin Pharma</td>
<td>13.5</td>
</tr>
<tr>
<td>Merck &amp; Co</td>
<td>1.4</td>
<td>Camber Pharma</td>
<td>12.4</td>
</tr>
<tr>
<td>Otsuka America Ph</td>
<td>1.4</td>
<td>Amneal Inc</td>
<td>11.6</td>
</tr>
<tr>
<td>Astrazeneca</td>
<td>1.3</td>
<td>Aurobindo Pharma</td>
<td>10.5</td>
</tr>
</tbody>
</table>

Source: IMS Health, National Sales Perspectives, Dec 2014, National Prescription Audit, Dec 2014
## Fastest growth rates by leading corporations, Sales & TRx (2014)

<table>
<thead>
<tr>
<th>Dollars</th>
<th>% Growth</th>
<th>TRx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma Cyclics, Inc</td>
<td>&gt;999</td>
<td>Bluepoint Labs</td>
</tr>
<tr>
<td>Citron Pharma, Llc</td>
<td>796</td>
<td>Citron Pharma, Llc</td>
</tr>
<tr>
<td>Horizon Pharma</td>
<td>235</td>
<td>Macleods Pharma</td>
</tr>
<tr>
<td>Gilead Sciences</td>
<td>141</td>
<td>Blu Pharma</td>
</tr>
<tr>
<td>Insys Therapeutics</td>
<td>124</td>
<td>Sancilio</td>
</tr>
<tr>
<td>Cadence Pharma</td>
<td>121</td>
<td>Virtus Pharma</td>
</tr>
<tr>
<td>Torrent Pharma</td>
<td>99</td>
<td>Unichem Pharma Usa</td>
</tr>
<tr>
<td>Rhodes Pharma</td>
<td>77</td>
<td>Solco Healthcare</td>
</tr>
<tr>
<td>Heritage Pharma</td>
<td>61</td>
<td>Accord Healthcare</td>
</tr>
<tr>
<td>Lundbeck Inc</td>
<td>60</td>
<td>Kvk-Tech</td>
</tr>
</tbody>
</table>

Source: IMS Health, National Sales Perspectives, Dec 2014, National Prescription Audit, Dec 2014
Sales and TRx share brands and generics (5yrs w/ YTD)

Source: IMS Health, National Sales Perspectives, Nov 2014, National Prescription Audit, Nov 2014, Branded generics disaggregated
Reasons for Generic Price Inflation

- **Regulatory/Quality** – with the increased scrutiny from the FDA, manufacturers need to invest more into their quality systems and when a quality / supply issue arises due to 483s, it creates the opportunity to increase prices to recoup part of their investment.

- **Customer consolidation** – with the increased purchasing power of the customers, manufacturers need to make up value on products where they can.

- **Fewer new product launches** – generic manufacturers make money by launching new products, reducing CGS, M&A activity and raising prices; with fewer launches, it puts more pressure on the “in-line” product portfolio which again is a driver to increase prices.
Top US Generic events of 2014

- Hep C
- Generic Price Inflation
- Patent Expiries
  - the ones that didn’t happen and the ones that did
- FDA’s first Biosimilar actions
- FDA raising the bar
  - Indian company inspections ramped up
  - Forced withdrawal of Concerta generic competitors
- Global purchasing alliances expanding
- More mergers
- Rx to OTC
Products facing LOE in the next 4 years are valued at $78.4Bn

Nexium, Abilify and Namenda face generic competition in 2015

U.S. Patent Expiry Exposure

Sales from year-prior to expiry for years 2009-14; sales in MAT Sep 2014 used for years 2015-18
Source: IMS Health, Dec 2014
Biologics future loss of exclusivity

Twelve compounds will present a US$ 73 billion opportunity by 2020

Global Sales (MAT 09/2013), US$ billion

<table>
<thead>
<tr>
<th>Compound</th>
<th>Global Sales (US$ billion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab (Humira)</td>
<td>9.4</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>7.8</td>
</tr>
<tr>
<td>Infliximab (Remicade)</td>
<td>7.5</td>
</tr>
<tr>
<td>Insulin Glargine (Lantus)</td>
<td>7.5</td>
</tr>
<tr>
<td>Rituximab (Mabthera)</td>
<td>6.2</td>
</tr>
<tr>
<td>Bevacizumab (Avastin)</td>
<td>5.6</td>
</tr>
<tr>
<td>Insulin Aspart (Novomix, Novorapid)</td>
<td>5.6</td>
</tr>
<tr>
<td>Interferon Beta-1A (Avonex, Rebif)</td>
<td>5.4</td>
</tr>
<tr>
<td>Trastuzumab (Herceptin)</td>
<td>5.2</td>
</tr>
<tr>
<td>Glatiramer Acetate (Copaxone)</td>
<td>4.8</td>
</tr>
<tr>
<td>Pegfilgrastim (Neulasta)</td>
<td>4.3</td>
</tr>
<tr>
<td>Ranibizumab (Lucentis)</td>
<td>4.3</td>
</tr>
</tbody>
</table>

Total ~ US$ 73 billion

Not considered existing biosimilars such as Epoetin Alfa expired in EU, but still patent protected in the US

Source: IMS MIDAS, 09/2013, IMS Patent focus
In contrast to small molecule GX, biosimilar development and marketing pose serious challenges for aspiring players.

**CLINICAL DEVELOPMENT**
Average cost is around 200M$, with a significant range of variation (from 40 to 375 M$) vs. 1 to 4M$ for a generic drug.

**REGULATORY AND MARKET ACCESS**
Uncertain regulatory framework (aside from Europe), price competition less relevant compared to generics.

**MANUFACTURING COSTS**
Difficulties in rationalizing manufacturing costs due to limited scale, at least in the short term.

**SALES AND MARKETING CAPABILITIES**
Need to adopt a branded mentality to win stakeholder trust.

**Biosimilars vs. Generics – a different game?**
A minority of patients account for the vast majority of healthcare costs.

Percent of Health Plan Members Ranked by Healthcare Spending ($)

- Top 1% (≥$48,735): 26.1%
- Top 5% (≥$15,684): 51.2%
- Top 10% (≥$8,900): 65.6%
- Top 15% (≥$5,962): 74.5%
- Top 20% (≥$4,313): 80.8%
- Top 25% (≥$3,246): 85.4%
- Top 50% (≥$937): 96.7%
- Bottom 50% (<$937): 3.3%

Source: IMS PharMetrics, Jun 2012
Cost Containment Opportunities

**Readmissions**

- **20%**
  - 1 in 5 Medicare FFS patients readmit within 30 days of discharge\(^1\)

- **21K AMI readmissions**
  - 13.4% or 21,000 AMI Medicare admissions readmit within 15 days, at a cost of $136M\(^2\)

**Coordination of Care**

- **$300B**
  - Treating 60% of high-cost chronic condition patients yields $300B in savings over 10 years\(^3\)

- **$62B**
  - 1.1% of global total health expenditure or 62B worldwide, can be avoided with timely treatment\(^4\)

**Pharmacy**

- **$500B**
  - 8% of total health expenditure = $500B globally can be avoided with optimized use of medicines\(^4\)

- **50%**
  - Prescriptions not taken as directed\(^5\) drive $260B in additional care costs\(^4\)

Sources:
4. IMS Institute, Advancing the Responsible Uses of Medicines, October 2012
The economic stakes are high for the healthcare system.

Estimated avoidable costs by lever ($Bn), 2012

- Nonadherence: $105.4
- Delayed evidence-based treatment practice: $39.5
- Antibiotic misuse: $35.1
- Medication errors: $20.0
- Suboptimal generics use: $11.9
- Mismanaged polypharmacy in the elderly: $1.3
- Total avoidable costs: $213.2

Source: Avoidable Costs in U.S. Healthcare Study by IMS Institute of HealthCare Informatics
The financial costs are caused by avoidable use of healthcare services by patients.

- $213 Bn total avoidable costs
  - 140 million hospital visits
  - 45 million outpatient visits
  - 22 million emergency room visits
  - 246 million prescriptions

Source: Avoidable Costs in U.S. Healthcare Study
Focus of study was limited to six areas

Medication access and pricing were not addressed

- Medication nonadherence
- Delayed evidence-based treatment
- Antibiotic misuse
- Medication errors
- Suboptimal generics use
- Mismanaged polypharmacy

- Improvement in health outcomes
- Decline in healthcare costs
- Increase in medicines value
It may seem like we’ve been here before ...

Tomorrow’s models will be built on alignment and cooperation

INCREASING INTEGRATION OVER TIME

Pre-1980s: FFS Model
- Hospitals
- Physicians
- Payers

1980s-90s: HMO Model
- Payers
- Hospitals
- Physicians

2000-2010: Early IDN Model
- Payers
- Hospitals
- Physicians

2011-2020: Advanced IDN Model
- Payers
- Hospitals
- Physicians
- Patients

Post 2020: Population Mgmt.
- Payers
- Hospitals
- Physicians
- Patients
Aetna plans to cover nearly 60% of US population

ACO deals in the pipeline to achieve 10% savings

ACOs today estimated to cover 15-20% of Americans

"Ascension Health (largest non-profit IDN) is in talks to acquire an unnamed insurance company that operates in 18 states...a significant escalation in the brewing shift among hospital operators toward the business of selling health plans."

Source: Modern Healthcare, 05/22/14

Source: IMS primary and secondary research
Health networks focus first on managing chronic disease and their targeted therapy areas continue to expand.

**Key focus today**
- Diabetes
- Stroke
- Cardiovascular disease
- Hip replacement
- Congestive heart failure

**Coming up**
- Depression
- Alzheimer’s
- Parkinson’s
- COPD
- Pain
- Arthritis
- Bariatric
- Oncology

PCPs and specialists driven to coordinate treatment decisions through a team approach (pharmacists, NPs, social workers etc)

Practice emerging of paying physicians bonus (even 20%) on patient outcomes

Source: IMS primary and secondary research
IDNs are organized corporatized care providers that drive care protocols and treatment choices locally.

**IDNs reduce Januvia volume today by 8%**

**IDNs reduced launch brand volume for Tradjenta by 10%**

**IDNs reduced launch brand volume for Pradaxa by 12%**
High Deductibles have a proven negative effect on patient adherence

Average Continuing Adherence by Co-Pay and HDHP Grouping
(Continuing Patients, DPP4s, 2013)

Source: IMS Formulary Impact Analyzer (January 2011-December 2014); IMS Health Analysis
Patients now use the internet to seek healthcare information before they talk to their doctor

Typical patient on-line journey

Source: IMS Health European Thought Leadership
The need is urgent for actionable use of evidence-based approaches to drive better outcomes

### Potential RWE partnerships / examples

- **Evidence of Value & Outcomes**
  - **Customer need:** As IDNs/payers take on risk, they are looking to improve patient outcomes and move to value-based model
  - **Opportunity:** Since customers are still in the initial phase of employing **specialty (oncology) metrics**, it poses an opportunity to collaborate on creating patients outcome data

- **Align metrics on payment/outcomes incentives**
  - **Customer need:** Evolving payment models incentivize IDN/payer to align on novel metrics (e.g. quality, outcomes)
  - **Opportunity:** There is an opportunity to identify progressive customers in the evolving phase and help them implement payment metrics to leverage the relation for **specialty metrics in the future**

- **Identify & partner on high risk populations**
  - **Customer need:** With increased integrated clinical and financial risk, customers will look to identify high risk populations via predictive modeling, to create solutions/protocols
  - **Opportunity:** Collaborate on initiatives to identify high risk patient population, to ensure access to protocols in the future esp. for **markets like HCV, Heart Failure, COPD, and many hard to treat mental health conditions**

Source: IMS Consulting Group
It may seem like we’ve been here before ...

Tomorrow’s models will be built on alignment and cooperation.

INCREASING INTEGRATION OVER TIME

- **Pre-1980s**
  - FFS Model
  - Hospitals
  - Physicians
  - Payers

- **1980s-90s**
  - HMO Model
  - Prescribing
  - Reimbursement
  - Marketing
  - Sales
  - Contracting

- **2000-2010**
  - Early IDN Model
  - Reimbursement
  - Prescribing
  - Marketing
  - Acct. Mgmt.

- **2011-2020**
  - Advanced IDN Model
  - B2B Outcomes
  - Contracting
  - Marketing

- **Post 2020**
  - Population Mgmt.
  - “Europe with Outcomes”
  - HEOR/RWE

**Pharma Approach**

- Objectives: Prescribing, Reimbursement, Marketing, Sales

- Methods: Contracting, Marketing, Acct. Mgmt.
Thoughts for 2015 and beyond

US market evolution at a turning point.

• Increasing numbers of specialty drugs will drive spending upwards and put greater pressure on demonstration of value
• When stakeholders work together they can achieve improved outcomes at lower costs, but is pharma a target in this effort?
• Exposure to costs and access to information is changing everything for payer/providers, for patients and for doctors
• Change is complicated and progress is uneven across the country ... adapting to change means “Everything is Local”
Medicine spending often portrayed as driving up healthcare costs, especially so with 2014 spending growth of 13%.

Medicine spending below Healthcare spending growth for 5 of the last 10 years and 3 of the next five.

Source: CMS National Health Expenditures Sep 2014; IMS Health, National Sales Perspectives, Dec 2014; U.S. Census Bureau July 2014; Economic Intelligence Unit Sep 2014; IMS Market Prognosis Sep 2014
Growth will moderate over the forecast period

Near-term is driven by less expiry impact, innovation and pricing

<table>
<thead>
<tr>
<th>Year</th>
<th>Protected Brand Volume</th>
<th>New Brands</th>
<th>Generics</th>
<th>LOE</th>
<th>Total Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>2011</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: IMS Health, Market Prognosis, Oct 2014
The Big 5 to watch for

• The HEP C market and other innovation

• Generic Price Inflation

• First Biosimilar Launch

• Supply Chain

• Regulation and Reimbursement Issues
April 2015

Medicines Use and Spending Shifts

A Review of the Use of Medicines in the U.S. in 2014

HEALTHCARE COSTS AND SPENDING ON MEDICINES

Spending on medicines increased 13.1% in 2014, the highest level since 2001 when spending growth reached 17.0%

**Medicine Spending & Growth 1995-2014**

- Real per capita spending was $995 in 2014 and has nearly tripled since 1995 when it was $339, both measured in 2005 dollars.
- Higher spending growth between 1997 and 2003 reflected the period when the largest number of blockbuster drugs launched and were increasingly used by millions of Americans.
- Lower levels of growth in spending between 2002 and 2013 were due to lower volume growth, increased use of generics, loss of patent protection for major branded products and reduced spending on new drugs.
- The sharp increase in spending in 2014 was driven by new brands, lower impact from patent expirations and increases in the list prices of branded medicines.

*Source: IMS Health National Sales Perspectives, Dec 2016; U.S. Census Bureau; U.S. Bureau of Economic Analysis.*

Chart notes:
- Measures total value of pharmaceutical spending, including generics, branded products, biologics, small molecules, retail and over-the-counter medicines, value-added at trade price — the price paid to wholesalers or manufacturers by retail and non-retail pharmacies and excluding rebates, discounts and rebates that lower net prices received by manufacturers. Real per capita adjustments based on data from U.S. Census Bureau and U.S. Bureau of Economic Analysis.
HEALTHCARE COSTS AND SPENDING ON MEDICINES

• 2014 Total Drug Spending $373.9Bn, up 13.1%
• Growth driven by innovation, less expiry impact and pricing dynamics
• Pricing growth offset by discounts and rebates
• Specialty medicines reach one-third of medicine spending
• Innovation in hepatitis C, cancer, multiple sclerosis and diabetes drove spending growth
TRANSFORMATIONS IN DISEASE TREATMENT

- 42 New Active Substances launched in 2014 up from 36 in 2013
- Hepatitis C, multiple sclerosis and oncology see major advances
- The drug R&D pipeline has shifted to specialty medicines over the past decade
- 10 Breakthrough Therapies launched, and FDA incentives have helped spur a surge in infectious disease drug development
- 18 orphan drugs launched in 2014 up from 17 in 2013, the two highest years ever
- The first biosimilars were filed in 2014 and approvals began in 2015
CHANGES IN THE DEMAND AND PAYMENT FOR MEDICINE

- Insurance coverage expansion is having a measurable impact as millions have new insurance coverage.
- Office visits and hospital utilization declined while prescription demand increased driven by Medicaid expansion.
- Hospital networks are increasingly concentrated but networks prefer different treatments.
- Changing patient share of costs through insurance design and coupons impacts behavior, care and outcomes.