Specialty Pharmaceuticals and Pharmacy: Today, Tomorrow and Beyond

Adam J. Fein, Pembroke Consulting/ Drug Channels
Doug Long, QuintilesIMS
Eric Percher, Barclays
Agenda

• *The State of Specialty Pharmacy 2017* – Adam

• *Wall Street’s Perspective on Specialty Pharmacy* - Eric

• *The US Pharmaceutical Market: Trends, Issues, and Outlook* - Doug

• LIVE with Adam, Doug, and Eric!
The State of Specialty Pharmacy 2017

Adam J. Fein, Ph.D.
The Specialty Boom

PHARMACY INDUSTRY PRESCRIPTION REVENUES ($ BILLIONS)

<table>
<thead>
<tr>
<th>Year</th>
<th>Specialty Revenues</th>
<th>Traditional Revenues</th>
<th>Total Revenues</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>$299 B</td>
<td>17%</td>
<td>$299 B</td>
</tr>
<tr>
<td>2016</td>
<td>$412 B</td>
<td>28%</td>
<td>$412 B</td>
</tr>
<tr>
<td>2021</td>
<td>$572 B</td>
<td>42%</td>
<td>$572 B</td>
</tr>
</tbody>
</table>

CAGR = Compound Annual Growth Rate

Everyone Wants To Be A Specialty Pharmacy

Pharmacy Locations With Specialty Pharmacy Accreditation, by Corporate Ownership, 2015 vs. 2016

- Independent
- PBM/Health Plan
- Healthcare Provider
- Retail/LTC
- Wholesaler
- Manufacturer

2016 (n=499)
2015 (n=378)

LTC = Long-term care
1. Excludes 2,051 newly accredited retail pharmacies within the supermarket chains Albertsons, Meijer, and Price Chopper.
2. Includes private independent pharmacies, pharmacies owned by private equity firms, and independently owned franchise locations
3. Includes pharmacies owned by hospitals, health systems, physician practices, and providers’ group purchasing organizations
4. Includes pharmacy locations owned by chain drugstores, grocery chains, and national long-term care pharmacy chains

Source: The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Exhibit 44. Includes pharmacy locations accredited by URAC and ACHC.
Narrow Specialty Channels

OPEN DISTRIBUTION

LIMITED DISPENSING NETWORKS

PHARMACY BENEFIT NETWORKS
Concentration + Opportunity

SHARE OF SPECIALTY DRUG DISPENSING REVENUES, BY COMPANY, 2016

Includes prescription revenues from retail, mail, long-term care, and specialty pharmacies. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Reflects pro-forma impact of 2016 acquisitions.
The Co-evolution of Specialty Pharmacy Economics

Source: The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Chart illustrates flows for Patient-Administered, Outpatient Brand-Name Drugs. Please note that this chart is illustrative. It not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Implications

• PBM, pharmacies, wholesalers, health plans, and providers will battle for control of the specialty market and the patient journey

• Manufacturers’ specialty networks will become larger and more inclusive

• Channel control will continue migrating from manufacturers to PBM and payers

• Coevolving economics will consolidate specialty pharmacies

• Organized channels—new ownership and partnering relationships—will emerge
Wall Street’s Perspective on Specialty Pharmacy

Eric Percher
Barclays
Specialty Pharmaceuticals and Pharmacy: Today, Tomorrow and Beyond

April 24, 2017

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Wall Street’s Perspective: Value and Valuation

Source: Barclays Research, Thomson ONE
Note: Bubble size reflects company size by market cap; Rite Aid not covered; Consensus estimates from Thomson ONE

April 24, 2017
What's Top of Mind on Wall Street?
A View of the Current US Supply Chain

PBM / Payer Alignment

Integrated Models

Payor
- Aetna
- Humana
- UnitedHealth
- CVS Caremark PBM (and SP)
- CVS Pharmacy
- Cardinal Health

Independent Models

PBM
- CVS Health
- Express Scripts (Accredo SP)

Pharmacy
- Walgreens
- McKesson
- Amerisource
- Cardinal Health
- Radius Rx
- Goldco

Distributor
- Walgreens
- McKesson
- Amerisource
- Cardinal Health

Note: Lines indicate potential integration opportunities (strategic alignment and/or acquisition).

Source: Barclays Research

"Converge. Connect. Collaborate."
Hot Topic: Potential Vertical Partnership Opportunities

Pharmacy Alignment Strategy

Integrated Models
- Aetna
- Humana
- CVS Health
- CVS Pharmacy
- Cardinal Health

Independent Models
- UnitedHealthcare
- United Health Prime
- Prime Therapeutics
- Express Scripts (Accredo SP)
- Walgreens Boots Alliance
- Amerisource
- McKesson

Note: Lines indicate potential integration opportunities (strategic alignment and/or acquisition).

Source: Barclays Research
Hot Topic: Much Optionality, Few Options

Anthem Alignment Options

Integrated Models

- CVS Health
- CVS/PBM (and SP)
- Red Oak IV
- CVS/PBM
- Express Scripts (Accredo SP)

- Aetna
- United Healthcare
- Prime
- Prime
- Express Scripts (Accredo SP)

- Humana
- UnitedHealth
- Prime
- Time Warner
- Walgreens Boots Alliance

- Cardinal Health

Independent Models

- Anthem
- Express Scripts

Note: Lines indicate potential integration opportunities (strategic alignment and/or acquisition).

Source: Barclays Research
A View of Distributor Relationships

Distributor Customer Alignment

Integrated Models
- Aetna
- Humana (HUM PBM)
- UnitedHealthcare
- OptumRx (BrovaSP)
- Prime Therapeutics
- CVS/Caremark PBM (and SP)
- CVS Pharmacy
- Red Oak IV
- Cardinal Health

Independent Models
- Anthem
- Express Scripts (Accredo SP)
- CVS Health
- Amerisource
- McKesson

Note: Lines indicate potential integration opportunities (strategic alignment and/or acquisition).

Source: Barclays Research; note: Barclays is currently restricted on McKesson thus customer alignment is facts only.
Key Developments on the Horizon

As PBM, pharmacies, wholesalers, payers, and providers battle for control of specialty, new ownership and partnership models are emerging

- Horizontal consolidation is nearing an endpoint. Vertical consolidation opens opportunities to improve care and reduce systematic waste.

- United/OptumRx: It will take years to demonstrate the benefits of integrated medical/pharmacy benefit management in the real world

- CVS Health: Specialty Connect is now the most differentiated element of the integrated pharmacy/PBM model

- Walgreens/Prime: For the first time in years, Walgreens has made specialty a focus – is there space in the room for Amerisource?

- PBMs will seek to drive adoption of biosimilars under the pharmacy benefit. Distributors and Payers are developing models to impact the medical benefit.
Disclaimer

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What happened in 2016?
Snapshot of key happenings in the industry

**Market Performance**
- Dollar growth is decelerating
- TRX growth is improving
- 90 day scripts are 14% of scripts
- Below avg. Flu and Allergy Seasons
- Generic $ sales decreases

**Mergers / Alliances**
- Walgreens and Rite Aid postponed
- Ahold and Delhaize
- Target pharmacies are now CVS pharmacies
- Walmart and McKesson Alliance
- Anthem and Cigna- (Turned down)
- Aetna and Humana (Turned down)

**Generic Launches**
- Crestor
- Gleevec
- Benicar, Tamiflu
- Seroquel XR, Nuvigil, Asacol

**Regulation**
- New FDA/DEA guidelines on Controlled Substances

**Price / Politics**
- Turing, Valeant and Epipen
- 2016 Elections and public anger
- DOJ investigations

**Reimbursement**
- AMP finally arrives
- Generic Deflation
- DIR fees
- Pharmacists can prescribe in more places
Year over year market growth is decelerating from 2015 to 2016

Source: QuintilesIMS, National Sales Perspectives, Feb 2017
Specialty outpaces total market sales growth quarter over quarter with noticeable spikes during Hep C launches

Source: QuintilesIMS, National Sales Perspectives, Feb 2017
Specialty spending growth is finally slowing from the record high growth rates reached in 2014-15 with the Hep C bubble. Specialty growth would have been 3.5% higher in 2016 without HCV.

Source: QuintilesIMS, National Sales Perspectives, Dec 2016
Specialty absolute $ contribution to growth is 80% of total growth

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>Contribution to Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MARKET</strong></td>
<td>$317.8</td>
<td>$330.0</td>
<td>$378.8</td>
<td>$427.5</td>
<td>$450.1</td>
<td>3.8 14.8 12.8 5.3</td>
</tr>
<tr>
<td><strong>SPECIALTY</strong></td>
<td>$94.9</td>
<td>$104.7</td>
<td>$132.7</td>
<td>$162.3</td>
<td>$180.9</td>
<td>3.1  8.5  7.8  4.3</td>
</tr>
<tr>
<td><strong>TRADITIONAL</strong></td>
<td>$222.9</td>
<td>$225.3</td>
<td>$246.1</td>
<td>$265.1</td>
<td>$269.2</td>
<td>0.7  6.3  5.0  0.9</td>
</tr>
</tbody>
</table>

**Traditional Medicines**

**Specialty Medicines**

Specialty medicines are defined by the IMS Institute as products which treat chronic/complex or rare diseases and which meet at least four of the following six criteria: not-self-administerable, patient monitoring/counseling/REMS program, specialist-initiated, special handling requirements, unique/narrow distribution, cost in excess of $6K/year, require reimbursement assistance.

Source: QuintilesIMS, National Sales Perspectives, Feb 2017
Specialty classes Hepatitis, Autoimmune, Oncology drive non-discounted spending growth

Diabetes growth from new brands, list price growth offset by rebates

Leading Therapy Classes Non-Discounted Spending Growth by Segment ($BN) MAT Dec 2016

Source: QuintilesIMS, National Sales Perspectives, Dec 2016
## 2016 Therapeutic Area Snapshot

<table>
<thead>
<tr>
<th>Therapy Area</th>
<th>2016 (BNs)</th>
<th>Δchange (BNs)</th>
<th>Growth</th>
<th>2016 (MNs)</th>
<th>Δchange (MNs)</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>$50.7</td>
<td>$6.9</td>
<td>15.7%</td>
<td>223.2</td>
<td>12.0</td>
<td>5.7%</td>
</tr>
<tr>
<td>Oncology</td>
<td>$45.6</td>
<td>$6.5</td>
<td>16.5%</td>
<td>20.3</td>
<td>0.8</td>
<td>4.2%</td>
</tr>
<tr>
<td>Autoimmune</td>
<td>$36.7</td>
<td>$6.5</td>
<td>21.4%</td>
<td>6.9</td>
<td>0.0</td>
<td>0.7%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>$25.9</td>
<td>$2.1</td>
<td>9.0%</td>
<td>180.7</td>
<td>5.0</td>
<td>2.9%</td>
</tr>
<tr>
<td>Pain</td>
<td>$19.7</td>
<td>-$1.1</td>
<td>-5.1%</td>
<td>461.3</td>
<td>-8.3</td>
<td>-1.8%</td>
</tr>
<tr>
<td>HIV Antivirals</td>
<td>$18.7</td>
<td>$2.6</td>
<td>16.0%</td>
<td>10.9</td>
<td>0.2</td>
<td>1.7%</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>$18.6</td>
<td>$1.0</td>
<td>5.4%</td>
<td>2.4</td>
<td>-0.1</td>
<td>-3.5%</td>
</tr>
<tr>
<td>Mental Health</td>
<td>$17.2</td>
<td>-$2.5</td>
<td>-12.5%</td>
<td>394.4</td>
<td>17.9</td>
<td>4.8%</td>
</tr>
<tr>
<td>Hep C</td>
<td>$15.8</td>
<td>-$3.0</td>
<td>-16.0%</td>
<td>0.9</td>
<td>-0.1</td>
<td>-13.4%</td>
</tr>
<tr>
<td>CNS Disorders</td>
<td>$12.5</td>
<td>$1.3</td>
<td>11.8%</td>
<td>198.1</td>
<td>10.5</td>
<td>5.6%</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>$12.4</td>
<td>$2.4</td>
<td>24.3%</td>
<td>81.4</td>
<td>1.1</td>
<td>1.3%</td>
</tr>
<tr>
<td>Lipid Regulators</td>
<td>$12.1</td>
<td>-$1.3</td>
<td>-9.4%</td>
<td>263.8</td>
<td>3.7</td>
<td>1.4%</td>
</tr>
<tr>
<td>All Others</td>
<td>$164.0</td>
<td>$1.1</td>
<td>0.7%</td>
<td>2,602.0</td>
<td>36.6</td>
<td>1.4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$450.1</strong></td>
<td><strong>$22.6</strong></td>
<td><strong>5.3%</strong></td>
<td><strong>4,446.2</strong></td>
<td><strong>79.3</strong></td>
<td><strong>1.8%</strong></td>
</tr>
</tbody>
</table>

Source: QuintilesIMS, National Sales Perspectives, Dec 2016, National Prescription Audit, Dec 2016
# Top 10 Molecules by 2016 Sales (US$)

<table>
<thead>
<tr>
<th>Molecule</th>
<th>2016 (BNs)</th>
<th>Δchange (BNs)</th>
<th>Growth</th>
<th>2016 (MNs)</th>
<th>Δchange (MNs)</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMIRA</td>
<td>12.9</td>
<td>2.8</td>
<td>27.3%</td>
<td>2.57</td>
<td>0.3</td>
<td>11.0%</td>
</tr>
<tr>
<td>HARVONI</td>
<td>10.0</td>
<td>-4.3</td>
<td>-30.0%</td>
<td>0.27</td>
<td>-0.1</td>
<td>-35.8%</td>
</tr>
<tr>
<td>ENBREL</td>
<td>7.9</td>
<td>0.7</td>
<td>9.5%</td>
<td>1.55</td>
<td>-0.1</td>
<td>-5.0%</td>
</tr>
<tr>
<td>LANTUS SOLOSTAR</td>
<td>5.6</td>
<td>-0.2</td>
<td>-2.6%</td>
<td>11.78</td>
<td>0.3</td>
<td>2.6%</td>
</tr>
<tr>
<td>REMICADE</td>
<td>5.3</td>
<td>0.3</td>
<td>6.6%</td>
<td>0.09</td>
<td>0.0</td>
<td>9.9%</td>
</tr>
<tr>
<td>JANUVIA</td>
<td>4.8</td>
<td>0.6</td>
<td>14.6%</td>
<td>9.76</td>
<td>0.4</td>
<td>4.6%</td>
</tr>
<tr>
<td>ADVAIR DISKUS</td>
<td>4.6</td>
<td>-0.1</td>
<td>-1.3%</td>
<td>11.86</td>
<td>-1.3</td>
<td>-9.6%</td>
</tr>
<tr>
<td>LYRICA</td>
<td>4.4</td>
<td>0.5</td>
<td>14.4%</td>
<td>10.45</td>
<td>0.2</td>
<td>2.1%</td>
</tr>
<tr>
<td>NEULASTA</td>
<td>4.3</td>
<td>0.2</td>
<td>4.1%</td>
<td>0.04</td>
<td>0.0</td>
<td>-9.0%</td>
</tr>
<tr>
<td>CRESTOR</td>
<td>4.2</td>
<td>-2.1</td>
<td>-33.1%</td>
<td>12.03</td>
<td>-8.3</td>
<td>-40.7%</td>
</tr>
</tbody>
</table>

Source: QuintilesIMS, National Sales Perspectives, Dec 2016, National Prescription Audit, Dec 2016
## Top 11-20 Molecules by 2016 Sales (US$)

<table>
<thead>
<tr>
<th>Molecule</th>
<th>2016 (BNs)</th>
<th>Δchange (BNs)</th>
<th>Growth</th>
<th>2016 (MNs)</th>
<th>Δchange (MNs)</th>
<th>Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPAXONE</td>
<td>4.1</td>
<td>-0.3</td>
<td>-6.4%</td>
<td>0.64</td>
<td>-0.1</td>
<td>-7.9%</td>
</tr>
<tr>
<td>RITUXAN</td>
<td>3.9</td>
<td>0.2</td>
<td>6.6%</td>
<td>0.01</td>
<td>0.0</td>
<td>21.5%</td>
</tr>
<tr>
<td>TECFIDERA</td>
<td>3.7</td>
<td>0.2</td>
<td>5.7%</td>
<td>0.46</td>
<td>0.0</td>
<td>-6.4%</td>
</tr>
<tr>
<td>XARELTO</td>
<td>3.6</td>
<td>0.7</td>
<td>26.2%</td>
<td>8.44</td>
<td>1.0</td>
<td>13.9%</td>
</tr>
<tr>
<td>LANTUS</td>
<td>3.3</td>
<td>-0.5</td>
<td>-12.3%</td>
<td>7.72</td>
<td>-0.9</td>
<td>-10.2%</td>
</tr>
<tr>
<td>ELIQUIIS</td>
<td>3.1</td>
<td>1.5</td>
<td>95.5%</td>
<td>7.44</td>
<td>3.3</td>
<td>79.9%</td>
</tr>
<tr>
<td>TRUVADA</td>
<td>3.1</td>
<td>0.3</td>
<td>12.6%</td>
<td>1.97</td>
<td>0.2</td>
<td>8.6%</td>
</tr>
<tr>
<td>AVASTIN</td>
<td>3.1</td>
<td>-0.1</td>
<td>-1.8%</td>
<td>0.01</td>
<td>0.0</td>
<td>-12.8%</td>
</tr>
<tr>
<td>VYVANSE</td>
<td>3.0</td>
<td>0.4</td>
<td>15.0%</td>
<td>11.85</td>
<td>0.8</td>
<td>7.1%</td>
</tr>
<tr>
<td>SYMBICORT</td>
<td>3.0</td>
<td>0.3</td>
<td>12.2%</td>
<td>9.88</td>
<td>0.8</td>
<td>8.9%</td>
</tr>
</tbody>
</table>

Source: QuintilesIMS, National Sales Perspectives, Dec 2016, National Prescription Audit, Dec 2016
Specialty Medicines are approaching 45% of spending overall, approaching 70% of hospital but overall rise driven by the rise of retail specialty

Source: QuintilesIMS Institute, Dec 2016
Three regions make up 88% of global biologic sales and 98% of biosimilar sales*

US, Japan, Europe

Biosimilar molecule approvals to date

Source: QuintilesIMS MIDAS Q3 2016 (Europe excludes Russia and Turkey); EMA website Jan 2017; FDA website June 2016; Japan approval dates from Gabionline April 2016; *Basaglar is not a biosimilar in the USA, it is a follow-on biologic; excludes Non-original biologics
Europe has paved the way for biosimilar development

- As of the end of 2016, the EMA has approved 23 biosimilars (8 molecules)
- 2016 marks the tenth anniversary of the launch of the first biosimilar in Europe and Medicines for Europe claims:
  - Across Europe, nearly 90% of doctors now know what Biosimilar medicines are and nearly 60% have already prescribed them
  - Since the first biosimilar medicine was launched in 2006, EU-approved biosimilars have generated more than 400 million patient days of positive clinical experience
  - Between 2006 and 2014, biosimilar medicines have increased patient access by 44% overall within in the EU-5 countries*

* France, Germany, Italy, Spain, United Kingdom

References
U.S. biologic spending without biosimilars would grow at 14-17%; as low as 9-12% in greatest impact scenario

Source: QuintilesIMS Institute, Oct 2016
Key US Market Access Trends over the last decade

1. Stricter payer management
2. Increased patient OOP
3. Backlash against drug pricing
4. Increasing utilization of value-based models

SUMMARY
We are approaching the tipping point of payer price sensitivity and willingness to pay.
Today’s reality for Market Access is “*half the access at twice the cost*”

- Payers exert more market power than ever
- Formulary restrictions and blocks have become more widespread strategies for formulary control
- As a result, payers are able to extract higher rebates with each year
- Launch products are entering an environment where differentiation doesn’t guarantee access anymore
Market Access challenges and complexities now dominate the focus for commercial organizations

Prescribers used to be the primary focus for drug manufacturer’s analysis and insight
- Who are the highest volume prescribers in a TA?
- Which physicians are early adopters of new MOAs?
- Which physicians are loyal to specific brands and which switch?

As drug coverage and contracting evolved, manufacturers shifted attention to payers
- Which channels and payers are restricting access?
- How effective are their restrictions?
- How significant are the restricted books of business?

Industry trends pushed more cost sharing to patients, increasing influence on brand success
- How much of a barrier to access are deductibles, patient out of pocket, etc.?
- How does patient cost exposure influence patient compliance?
- Are patient savings programs available and effectively facilitating access?
Pharmaceutical companies must answer patient-centric questions for successful performance

- **Pricing and Contracting Strategy:**
  - What will the drug cost the patient?
  - What savings options are available?
  - What is the expected total patient cost for treatment?

- **Pull-Through and Marketing Execution:**
  - Where are benefit designs more and less favorable?
  - How do drug costs differ by geography, insurance?
  - How do phases of coverage (deductibles, coverage gap) influence patient access and behavior?

- **Performance Measurement:**
  - Where can real-world data (RWD) add commercial value and innovation?
  - What information about customers actual cost and benefit exposure should be infused into sales and marketing tactics?
Identified trends fell into two categories

**MORE OF THE SAME**

- Stricter Payer Management
- Increased Patient OOP
- Backlash Against Drug Pricing
- Increasing Utilization of Value Based Models

**GAME CHANGERS**

- Shift Away From Deep Rebate Model
- Increased Price Transparency
- Increased Management Within The Medical Benefit

What are people thinking about?

<table>
<thead>
<tr>
<th>Generic Manufacturers</th>
<th>Payers</th>
<th>Wholesalers</th>
<th>Consumers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Purchasing Alliances</td>
<td>• Exploding costs of</td>
<td>• Purchasing Alliances</td>
<td>• Rising costs</td>
</tr>
<tr>
<td>• Price increase backlash</td>
<td>Specialty Drugs</td>
<td>• Controlled Substances</td>
<td>• Specialty Tiers</td>
</tr>
<tr>
<td>• Portfolio Optimization</td>
<td>• Rising Oncology costs</td>
<td>• abuse</td>
<td>• Losing Insurance</td>
</tr>
<tr>
<td>• Brand /niche drugs</td>
<td>• Formularies blocks and</td>
<td>• Access to Specialty Drugs</td>
<td></td>
</tr>
<tr>
<td>• Proposed labeling changes</td>
<td>exclusive launches</td>
<td>• Generic Price Deflation &amp;</td>
<td></td>
</tr>
<tr>
<td>• Tax Inversion</td>
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