Specialty Pharmacy Industry Outlook: What's Next?

Adam J. Fein, Drug Channels Institute
Lisa Gill, J.P. Morgan Securities
Doug Long, IQVIA

May 1, 2019

http://drugch.nl/asembia19
Agenda

• *Pricing, Patients, and Public Policy: Implications for Specialty Pharmacy* – Adam

• *Wall Street View: Key Themes & Issues for 2019* – Lisa

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

• *Panel Time!* with Adam, Lisa, & Doug
Pricing, Patients, and Public Policy: Implications for Specialty Pharmacy

Adam J. Fein, Ph.D.
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May 1, 2019
Brand-Name Drug Pricing

Change from previous year

List price growth
- 13.5% (2013)
- 11.9% (2014)
- 9.0% (2015)
- 6.9% (2016)
- 5.7% (2017)
- 5.7% (2018)

Net price growth
- 4.7% (2013)
- 4.3% (2014)
- 2.4% (2015)
- 3.2% (2016)
- 1.9% (2017)
- 1.5% (2018)

Source: Drug Channels Institute analysis of IQVIA data. Data show invoice and net price changes for brand-name products that are more than two years old and have not yet faced generic competition. Invoice prices are the amounts paid to distributors by their pharmacy or hospital customers, including prompt payment and volume discounts. For brand-name drugs, changes in invoice and list prices are very highly correlated. Invoice price growth for 2018 is based on first three calendar quarters. Net prices equal list price minus off-invoice rebates and such other reductions as distribution fees, product returns, chargeback discounts to hospitals, price reductions from the 340B Drug Pricing Program, and other purchase discounts. See Drug Prices Are NOT Skyrocketing—They're Barely Growing at All, Drug Channels, January 2019.

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The Gross-to-Net Bubble

TOTAL VALUE OF PHARMACEUTICAL MANUFACTURERS’ GROSS-TO-NET REDUCTIONS FOR BRAND-NAME DRUGS

<table>
<thead>
<tr>
<th>Year</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$83</td>
</tr>
<tr>
<td>2014</td>
<td>$102</td>
</tr>
<tr>
<td>2015</td>
<td>$124</td>
</tr>
<tr>
<td>2016</td>
<td>$139</td>
</tr>
<tr>
<td>2017</td>
<td>$153</td>
</tr>
<tr>
<td>2018</td>
<td>$166</td>
</tr>
</tbody>
</table>

Source: Drug Channels Institute analysis of IQVIA Institute data; Drug Channels Institute estimates. Gross-to-Net Reductions include the total value of rebates, off-invoice discounts, copay assistance, price concessions, and such other reductions as distribution fees, product returns, the 340B Drug Pricing Program, and more. See The Gross-to-Net Bubble Reached a Record $166 Billion in 2018, Drug Channels, April 2019. © 2019 Pembroke Consulting, Inc., d/b/a Drug Channels Institute. All Rights Reserved.
Patients face list prices

Reverse Insurance: Sick Subsidize the Healthy

Warped incentives
Primary Options for Rebate System Reform

Point-of-Sale Rebates

Commercial

Point-of-Sale Discounts

Medicare Part D

Removal of Safe Harbor Protection for Rebates in Federal Programs, HHS, 2/6/19
(a.k.a. the Rebate Rule)

See: (1) The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Section 12.4, and
(2) The Road to 2020: Understanding the Regulatory Timeline for Part D Rebate Reform, Drug Channels, April 2019

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Scenarios For Your Consideration

PBMs Reborn

The Black Swan

See Preparing for a World Without Rebates, Drug Channels Institute webinar, April 2019
Specialty Pharmacy in a World Without Rebates

➢ Plans and PBMs directly manage specialty spending

➢ Benefit designs and formularies change

➢ More competition among specialty drugs in crowded categories

➢ Physicians and patients make cost/value tradeoffs

➢ Gross-to-net bubble pops
Top 15 Specialty Pharmacies: A Final Thought

**SHARE OF SPECIALTY DRUG DISPENSING REVENUES, BY COMPANY, 2018**

- **AmerisourceBergen**
- **McKesson**
- **Walmart**
- **Kroger**
- **Hy-vee/Amber**
- **Diplomat**
- **SenderraRx**
- **PANTHERRx**
- **BioPlus**

- **Everyone else**
- **CVS Health**
- **Cigna (ExpressScripts)**
- **OptumRx (UNH)**
- **Humana**
- **AllianceRx Walgreens Prime**
- **OptumRx (UNH)**


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Wall Street View:
Key Themes & Issues for 2019

Lisa C. Gill
JPMorgan Securities LLC
YTD 2019 Stock Price Performance

Stock Performance YTD in 2019 by Sector

Source: Bloomberg Note: Prices as of 4/15/2019.
Revisiting Key Themes for 2019

The Consumer – The Single Biggest Disrupter in Healthcare

• Patients (consumers) are getting more involved in their healthcare and making decisions on how to allocate their healthcare dollars

• The opportunity to engage the patient at their preferred point of service should be an important differentiator

• Convenience, quality and cost will be key
Key Themes Across the Sector

<table>
<thead>
<tr>
<th>Value-Based Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ongoing interest in value-based models that tie reimbursement to health outcomes</td>
</tr>
<tr>
<td>• In our view, companies that are part of the cost solution stand to benefit the most from this trend</td>
</tr>
</tbody>
</table>
Key Themes Across the Sector

**Specialty**

- Specialty remains the fastest growing area of drug spend
- Payors are looking for ways to address rising specialty costs
- Companies with a proven track record for managing specialty are likely to benefit
### Trump Blueprint

- Despite concerns over changes to the rebate model and shift to net pricing, we don’t expect a major impact to the Rx channel.

- While initially discussed eliminating middlemen, recent tone on the PBMs’ role appears more constructive.

- Expect transparency to continue to evolve for the sector.
Key Themes Across the Sector

Capital Deployment

- We expect consolidation of healthcare services to continue
- We favor companies with strong balance sheets and good cash flow
- Recent transformative deals and potential disruptive entrants could lead to more deals or JVs in the near term
Key Areas of Investor Focus

- Can Sentiment Get Any Worse for the PBM Space?
- Can Diplomat Turn Things Around?
- Are There Additional Opportunities for M&A Across the Space?
- Any Updates on the Regulatory Front?
Can Sentiment Get Any Worse for the PBM Space?

• Potential regulatory changes
• Market-driven changes
• Pharma manufacturers continue to deflect blame for rising drug prices on the Rx channel, including PBMs
• Ongoing criticism of “middlemen” from politicians and the press
• CEOs of the five largest PBMs testified before a Senate Finance Committee hearing on April 9
• While there was nothing materially incremental or surprising that came out of the hearing, we believe ongoing uncertainty around the regulatory environment remains an overhang.
Can Sentiment Get Any Worse for the PBM Space?

We continue to believe PBMs are part of the solution

▪ The ability to aggregate scale in negotiations with pharma manufacturers and dispensing pharmacies is critical

▪ Working with plan sponsors, PBMs are able to drive utilization of lower cost preferred products and/or dispensing sites

▪ PBMs offer a wide variety of clinical programs aimed at driving adherence, which can lead to lower overall healthcare costs

▪ New value-based models align economic incentives

The administration also appears to agree that PBMs will play a role

▪ The administration’s tone now seems more constructive, in our view

▪ The government has pointed to efforts to give government programs negotiation tools successfully used by the private sector
Can Diplomat Turn Things Around?

Competitive environment remains challenged, but a potential takeout

Specialty Pharmacy
- Increased competitive pressures - integrated providers more aggressive
- Company looking to target partnerships with health plans and hospitals, add innovative data and analytics capabilities and new sales resources

CastiaRx (PBM)
- Additional customer losses, subscale player
- Management remains committed to rebuilding the PBM business, investing in sales and account management to generate new sales
Can Diplomat Turn Things Around?

Specialty Infusion
- Remains a steady performer – expected to grow nicely in 2019
- We estimate specialty infusion comprises ~60% of adjusted EBITDA for FY19

Potential for takeout
- DPLO’s high touch model, therapeutic expertise and access to limited distribution drugs would be a good fit for health plans/PBMs looking for a way to better manage specialty spend
- A lack of scaled specialty assets increases relative attractiveness, in our view
Additional Opportunities for M&A Across the Space?

- We expect M&A to continue, and believe recent vertical consolidation could give rise to additional transactions, possibly a competitive response.

- We wouldn’t rule out a potential WBA-ABC deal, which has been discussed in the press.

- DPLO could represent an attractive asset for vertically integrated health insurer/PBM.
Any Updates on the Regulatory Front?

Despite tight timeline, expect push for 2020 implementation of HHS Rebate Rule:

- Key Issue: rebate rule is expected to increase Part D premiums

- Key Question: Will there be potential legal challenges that could delay implementation? Does HHS have the authority to implement the proposed rule, or is Congressional action needed?

- If the rebate safe harbor rule changes for 2020, CMS will conduct a 2-year demonstration project to modify risk corridors, limiting downside
Any Updates on the Regulatory Front?

What will be the impact of the proposed Rebate Rule:

- **PBM**
  - No material direct impact as Medicare Part D is essentially a pass through
  - Current proposal only impacts government business

- **PDP and MA Plans**
  - Shift of rebates to member must be accounted for in underwriting (premium increase)
  - Potential for underwriting risk, although demonstration program should modify risk
The US Specialty Pharmaceutical Market: Trends, Issues, and Outlook

Doug Long
Vice President, Industry Relations
doug.long@iqvia.com

May 1, 2019
Total US market dollar sales growth is at mid-single digits (6.9%) year to date

Source: IQVIA, National Sales Perspectives, March 2019
Note: Limited to Rx and OTC Insulins
U.S. Invoice Spending on Medicines and Net Manufacturer Revenue and Growth US$Bn

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute Dec 2018
U.S. Real Net Manufacturer Revenue per Capita and Growth US$

Source: IQVIA Market Prognosis Sep 2018; US Census Bureau, US Bureau of Economic Analysis (BEA), Dec 2018; IQVIA Institute, Dec 2018
Notes: Real net manufacturer revenue reflected in 2015 US$; See Methodology for estimated manufacturer net revenue
Specialty growth is outpacing traditional growth and now has ~46% share of total non-discounted spend in the most recent 12 months.

In MAT FEB 2019, specialty spend is growing at **11.7%** while traditional is relatively flat at **1.8%**.
Oncology, Autoimmune, and HIV lead specialty absolute value growth

Absolute Value Growth for Top Specialty Therapy Areas

<table>
<thead>
<tr>
<th>Specialty Area</th>
<th>∆Change from MAT FEB 2018 to MAT FEB 2019</th>
<th>Absolute Value Growth (US$ BNs)</th>
<th>∆Change from 2013 to MAT FEB 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONCOLOGICS</td>
<td></td>
<td>$9.2</td>
<td>$27.4</td>
</tr>
<tr>
<td>AUTOIMMUNE DISEASES</td>
<td></td>
<td>$8.5</td>
<td>$8.8</td>
</tr>
<tr>
<td>HIV ANTIVIRALS</td>
<td>$1.8</td>
<td>$8.5</td>
<td>$3.8</td>
</tr>
<tr>
<td>MULTIPLE SCLEROSIS</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
</tr>
<tr>
<td>VIRAL HEPATITIS</td>
<td>$3.1</td>
<td>$3.1</td>
<td>$0.7</td>
</tr>
<tr>
<td>HEMATOPOIETIC GROWTH FACTORS</td>
<td>$0.0</td>
<td>$0.0</td>
<td>$0.0</td>
</tr>
<tr>
<td>POLYVAL IMMUNOGLOBULINS IV&amp;IM</td>
<td></td>
<td>$1.3</td>
<td>$2.6</td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>$0.7</td>
<td>$0.0</td>
<td>$2.5</td>
</tr>
<tr>
<td>ERYTHROPOIETINS</td>
<td>$0.1</td>
<td>$0.1</td>
<td>$2.1</td>
</tr>
<tr>
<td>IMMUNOSUPPRESSANTS</td>
<td>$0.3</td>
<td>$0.0</td>
<td>$0.6</td>
</tr>
<tr>
<td>RESPIRATORY AGENTS</td>
<td>$0.6</td>
<td>$0.0</td>
<td>$0.8</td>
</tr>
<tr>
<td>BLOOD COAGULATION</td>
<td>$0.6</td>
<td>$0.0</td>
<td>$0.8</td>
</tr>
<tr>
<td>ALL OTHERS</td>
<td>$3.6</td>
<td>$0.0</td>
<td>$14.9</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, April 2019
Note: top therapy areas ranked on MAT FEB 2019 non-discounted spend
Diabetes, respiratory and anticoagulants lead traditional absolute value growth while pain, mental health, and ADHD contribute most to value decline.

Absolute Value Growth for Top Traditional Therapy Areas

Source: IQVIA, National Sales Perspectives, April 2019
Note: top therapy areas ranked on MAT FEB 2019 non-discounted spend
# Top 10 Specialty Therapy Areas – MAT FEB 2019

<table>
<thead>
<tr>
<th>Therapy Area</th>
<th>Specialty Rank</th>
<th>Overall Rank</th>
<th>Total Volume (in BNs)</th>
<th>% Chg vs. Yr Ago</th>
<th>Total Specialty Volume (in BNs)</th>
<th>% Chg vs Yr Ago</th>
<th>Specialty Retail &amp; Mail Volume</th>
<th>Specialty Retail &amp; Mail Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONCOLOGICS</td>
<td>1</td>
<td>2</td>
<td>$60.3</td>
<td>17.9%</td>
<td>$60.0</td>
<td>18.1%</td>
<td>$17.8</td>
<td>29.6%</td>
</tr>
<tr>
<td>AUTOIMMUNE</td>
<td>2</td>
<td>3</td>
<td>$55.8</td>
<td>18.1%</td>
<td>$55.8</td>
<td>18.1%</td>
<td>$44.1</td>
<td>79.1%</td>
</tr>
<tr>
<td>HIV ANTIVIRALS</td>
<td>3</td>
<td>5</td>
<td>$22.8</td>
<td>8.4%</td>
<td>$22.8</td>
<td>8.4%</td>
<td>$18.7</td>
<td>82.1%</td>
</tr>
<tr>
<td>MULTIPLE SCLEROSIS</td>
<td>4</td>
<td>6</td>
<td>$18.8</td>
<td>-0.3%</td>
<td>$18.6</td>
<td>-0.1%</td>
<td>$14.2</td>
<td>76.5%</td>
</tr>
<tr>
<td>VIRAL HEPATITIS</td>
<td>5</td>
<td>17</td>
<td>$7.2</td>
<td>-30.2%</td>
<td>$7.2</td>
<td>-30.2%</td>
<td>$5.8</td>
<td>80.4%</td>
</tr>
<tr>
<td>HEMATOPOIETIC GROWTH FACTORS</td>
<td>6</td>
<td>24</td>
<td>$5.1</td>
<td>-0.6%</td>
<td>$5.1</td>
<td>-0.6%</td>
<td>$0.4</td>
<td>8.2%</td>
</tr>
<tr>
<td>POLYVAL IMMUNOGLOBULINS IV&amp;IM</td>
<td>7</td>
<td>25</td>
<td>$4.5</td>
<td>42.2%</td>
<td>$4.5</td>
<td>42.2%</td>
<td>$0.4</td>
<td>9.5%</td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>8</td>
<td>8</td>
<td>$16.7</td>
<td>5.5%</td>
<td>$4.3</td>
<td>20.3%</td>
<td>$1.8</td>
<td>42.7%</td>
</tr>
<tr>
<td>ERYTHROPOIETINS</td>
<td>9</td>
<td>27</td>
<td>$3.5</td>
<td>-2.6%</td>
<td>$3.5</td>
<td>-2.6%</td>
<td>$0.2</td>
<td>6.4%</td>
</tr>
<tr>
<td>IMMUNOSUPPRESSANTS</td>
<td>10</td>
<td>31</td>
<td>$3.0</td>
<td>11.0%</td>
<td>$3.0</td>
<td>11.5%</td>
<td>$1.4</td>
<td>47.6%</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, April 2019
9 of the top 10 launches are specialty; 2 of the top 10 launched in 2018; Shingrix is over $1BN to date

Top 10 Launches in the past 24 months (sales data through Dec 2018)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Product</th>
<th>Specialty/Traditional</th>
<th>Company</th>
<th>Indication</th>
<th>Launch</th>
<th>2017-2018 $ (MNs)</th>
<th>Share of Non-Retail $</th>
<th>Share of Retail $</th>
<th>Share of Mail $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ocrevus</td>
<td>Specialty</td>
<td>Roche</td>
<td>Relapsing and Primary Progressive MS</td>
<td>Apr-2017</td>
<td>$2,999.1</td>
<td>90.3%</td>
<td>0.8%</td>
<td>8.9%</td>
</tr>
<tr>
<td>2</td>
<td>Mavyret</td>
<td>Specialty</td>
<td>Abbvie</td>
<td>Hep C</td>
<td>Aug-2017</td>
<td>$2,158.5</td>
<td>23.0%</td>
<td>28.4%</td>
<td>48.6%</td>
</tr>
<tr>
<td>3</td>
<td>Biktarvy</td>
<td>Specialty</td>
<td>Gilead</td>
<td>HIV-1</td>
<td>Feb-2018</td>
<td>$1,322.1</td>
<td>24.5%</td>
<td>60.4%</td>
<td>15.1%</td>
</tr>
<tr>
<td>4</td>
<td>Dupixent</td>
<td>Specialty</td>
<td>Sanofi Aventis</td>
<td>Moderate-to-Severe Atopic Dermatitis (eczema)</td>
<td>Mar-2017</td>
<td>$1,071.4</td>
<td>5.5%</td>
<td>11.6%</td>
<td>82.8%</td>
</tr>
<tr>
<td>5</td>
<td>Shingrix</td>
<td>Traditional</td>
<td>GlaxoSmithKline</td>
<td>Shingles</td>
<td>Dec-2017</td>
<td>$1,019.8</td>
<td>27.5%</td>
<td>71.9%</td>
<td>0.5%</td>
</tr>
<tr>
<td>6</td>
<td>Spinraza</td>
<td>Specialty</td>
<td>Biogen</td>
<td>Spinal Muscular Atrophy (SMA)</td>
<td>Feb-2017</td>
<td>$864.0</td>
<td>99.9%</td>
<td>0.0%</td>
<td>0.1%</td>
</tr>
<tr>
<td>7</td>
<td>Imfinzi</td>
<td>Specialty</td>
<td>AstraZeneca</td>
<td>Non-Small Cell Lung Cancer (NSCLC)</td>
<td>May-2017</td>
<td>$581.7</td>
<td>98.7%</td>
<td>0.3%</td>
<td>1.1%</td>
</tr>
<tr>
<td>8</td>
<td>Vosevi</td>
<td>Specialty</td>
<td>Gilead</td>
<td>Hep C</td>
<td>Jul-2017</td>
<td>$468.9</td>
<td>22.4%</td>
<td>27.0%</td>
<td>50.6%</td>
</tr>
<tr>
<td>9</td>
<td>Tremfya</td>
<td>Specialty</td>
<td>Johnson &amp; Johnson</td>
<td>Moderate-to-Severe Plaque Psoriasis</td>
<td>Jul-2017</td>
<td>$449.6</td>
<td>6.6%</td>
<td>13.0%</td>
<td>80.4%</td>
</tr>
<tr>
<td>10</td>
<td>Symdeko</td>
<td>Specialty</td>
<td>Vertex</td>
<td>Cystic Fibrosis</td>
<td>Feb-2018</td>
<td>$396.7</td>
<td>23.1%</td>
<td>1.6%</td>
<td>75.3%</td>
</tr>
</tbody>
</table>

Source: IQVIA, SMART Launch MVP, January 2019
A Record Number of Innovative Medicines were Launched in 2018 Bringing 59 New Treatment Options to Patients

New Actives Substances (NAS) Launched for the First Time in the United States in 2018

- Therapy Area:
  - Oncology: 12%
  - Infectious Disease: 8%
  - Neurology: 7%
  - Hematology: 8%
  - Endocrinology: 3%
  - Cardiovascular: 3%
  - Nephrology: 3%
  - Ophthalmology: 3%
  - Respiratory: 3%
  - Other: 12%

- Orphan Designation:
  - Orphan: 51%
  - Non-Orphan: 49%

- Type of Molecule:
  - Biologics: 73%
  - Non-Biologics: 27%

- Predictive Biomarker:
  - Predictive Biomarker: 80%
  - No Predictive Biomarker: 20%

- FDA First-in-Class:
  - FDA First-in-Class: 34%
  - Existing Mechanism: 66%

Source: IQVIA Institute, Mar 2019
Emerging Biopharma Companies Patented Almost Two-Thirds of the New Drugs in 2018, while Large Pharma Patented One-Quarter

Originator Companies and Companies Filing FDA Regulatory Submission by Company Segment

2010 NAS Launches

- EBP
- Small
- Mid
- Large

N=24

- Originator: 50%
- Filing: 33%

2018 NAS Launches

- EBP
- Small
- Mid
- Large

N=59

- Originator: 64%
- Filing: 47%

Source: IQVIA MIDAS restricted MAT Q4 2017; FDA websites; Clarivate Analytics Cortellis
The Late-Stage Development Pipeline has Expanded Steadily Over the Past Four Years with 11% Growth in Both 2017 and 2018

Number of Late-Stage Pipeline Products by Therapeutic Drug Class, 2009–2018

Source: IQVIA Pipeline Intelligence, Dec 2018; IQVIA Institute, Mar 2019
Late-Stage Pipeline Growth is Mostly Driven by Specialty and Niche Therapies Across a Range of Diseases

Late-Stage Pipeline Products and Changes from 2017 in Selected Classes

<table>
<thead>
<tr>
<th>Number of Phase II to Registered Drugs, 2018</th>
<th>Changes From 2017 to 2018, Selected Classes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology</td>
<td>ALS and Other Neuromuscular Disorders</td>
</tr>
<tr>
<td>Neurology - Behavioral</td>
<td>GI (Rare)</td>
</tr>
<tr>
<td>Infectious Diseases*</td>
<td>Non-Narcotic Pain</td>
</tr>
<tr>
<td>GI Products</td>
<td>NASH</td>
</tr>
<tr>
<td>Immunology</td>
<td>Dermatology (Biologics)</td>
</tr>
<tr>
<td>Pain</td>
<td>Dry Eye</td>
</tr>
<tr>
<td>Dermatology</td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td>Parkinson's Disease</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>Alzheimer's Disease</td>
</tr>
<tr>
<td>Vaccines</td>
<td>Viral Hepatitis</td>
</tr>
<tr>
<td>All others</td>
<td></td>
</tr>
</tbody>
</table>

849  223  188  179  165  162  161  118  110  92  644  23  17  12  9  9  8  8  7  5  -3

Source: IQVIA Pipeline Intelligence, Dec 2018; IQVIA Institute, Mar 2019
Annual and Median Costs of U.S. Brands by Type and Launch Year US$

Source: IQVIA National Sales Perspectives, Dec 2017; IQVIA Institute Dec 2018
Notes: Annual costs based on invoice prices, with overall invoice-level spending divided by estimated numbers of patients. Patient estimates are based on audited volumes assuming all patients use the drug according to the approved label. Products are included in medians based on segment assignments. Oncology includes both orphan and non-orphan products. All other products which have orphan indications are grouped together and some products have both orphan and non-orphan indications in this group. Specialty and traditional products exclude orphan or oncology products but are otherwise defined according to IQVIA definitions. Projected median costs are based on simple extrapolation of the medians in the prior ten years.
Generic dollar price deflation has not flattened out: Shortages may increase and greater scrutiny by Dept. Commerce

Source: Nephron Research, Glass Box Analytics, IQVIA; *February 2019 interim published out of cycle

Source: Nephron Research, Glass Box Analytics, IQVIA; *February 2019 interim published out of cycle
# Seven of the 18 FDA Approved Biosimilars Have Launched

<table>
<thead>
<tr>
<th>Approval Count</th>
<th>FDA Approval Date</th>
<th>Biosimilar</th>
<th>Biosimilar Manufacturer</th>
<th>Reference Product</th>
<th>Reference Manufacturer</th>
<th>Molecule</th>
<th>Launch Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>March 2015</td>
<td>Zarxio</td>
<td>Sandoz Novartis</td>
<td>Neupogen</td>
<td>Amgen</td>
<td>filgrastim</td>
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<td>2</td>
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<td>Inflectra</td>
<td>Celltrion</td>
<td>Remicade</td>
<td>Janssen (J&amp;J)</td>
<td>infliximab</td>
<td>2016</td>
</tr>
<tr>
<td>3</td>
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<td>Erelzi</td>
<td>Sandoz Novartis</td>
<td>Enbrel</td>
<td>Amgen</td>
<td>etanercept</td>
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<tr>
<td>4</td>
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<td>Amjevita</td>
<td>Amgen</td>
<td>Humira</td>
<td>Abbvie</td>
<td>adalimumab</td>
<td>2023</td>
</tr>
<tr>
<td>5</td>
<td>May 2017</td>
<td>Renflexis</td>
<td>Merck &amp; Co</td>
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<td>infliximab</td>
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<tr>
<td>6</td>
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<td>Boehringer Ingelheim</td>
<td>Humira</td>
<td>Abbvie</td>
<td>adalimumab</td>
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<tr>
<td>7</td>
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<td>Mvasi</td>
<td>Amgen</td>
<td>Avastin</td>
<td>Genentech</td>
<td>bevacizumab</td>
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<td>Mylan</td>
<td>Herceptin</td>
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<td>trastuzumab</td>
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<td>Pfizer</td>
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<td>Janssen (J&amp;J)</td>
<td>Infliximab</td>
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<td>May 2018</td>
<td>Retacrit</td>
<td>Hospira (Pfizer)</td>
<td>Epogen</td>
<td>Amgen</td>
<td>epoetin alfa</td>
<td>2018</td>
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<td>11</td>
<td>June 2018</td>
<td>Fulphila</td>
<td>Mylan</td>
<td>Neulasta</td>
<td>Amgen</td>
<td>pegfilgrastim</td>
<td>2018</td>
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<tr>
<td>12</td>
<td>July 2018</td>
<td>Nivestym</td>
<td>Hospira (Pfizer)</td>
<td>Neupogen</td>
<td>Amgen</td>
<td>filgrastim</td>
<td>2018</td>
</tr>
<tr>
<td>13</td>
<td>October 2018</td>
<td>Hyrimoz</td>
<td>Sandoz</td>
<td>Humira</td>
<td>Abbvie</td>
<td>adalimumab</td>
<td>2023</td>
</tr>
<tr>
<td>14</td>
<td>November 2018</td>
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<td>Coherus BioSciences</td>
<td>Neulasta</td>
<td>Amgen</td>
<td>pegfilgrastim</td>
<td>2019</td>
</tr>
<tr>
<td>15</td>
<td>November 2018</td>
<td>Truxima</td>
<td>Celltrion</td>
<td>Rituixan</td>
<td>Genentech</td>
<td>rituximab</td>
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<tr>
<td>16</td>
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<td>Celltrion</td>
<td>Herceptin</td>
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<td>trastuzumab</td>
<td></td>
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<tr>
<td>17</td>
<td>January 2019</td>
<td>Ontruzant</td>
<td>Samsung Bioepis (Merck)</td>
<td>Herceptin</td>
<td>Genentech</td>
<td>trastuzumab</td>
<td></td>
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<tr>
<td>18</td>
<td>March 2019</td>
<td>Trazimera</td>
<td>Pfizer</td>
<td>Herceptin</td>
<td>Genentech</td>
<td>trastuzumab</td>
<td></td>
</tr>
</tbody>
</table>

Source: FDA and CDER List of Licensed Biological Products; accessed on March 21, 2019
Biosimilar dollar share is minimal to date (MAT NOV 2018) in the US

Source: IQVIA, National Sales Perspectives, January 2019
Biologic spending could grow more dramatically without future biosimilar penetration

Source: IQVIA MIDAS, Jun 2018; Institute Dec 2018

Notes: Line on chart represents biologic spending using average growth of molecules not facing competition in 2017 continued to 2023 to represent what spending would have been without new molecules facing biosimilar competitors. Segments for biologics with and without competition are modeled using the average historic growth rates and expected entrance of biosimilars and price and volume changes associated with biosimilar entry.
Six key issues that Market Access teams are currently facing

<table>
<thead>
<tr>
<th>Key Issue</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tighter, More Consolidated Payer Management</td>
<td></td>
</tr>
<tr>
<td>Higher Patient Out-Of-Pocket Payments</td>
<td></td>
</tr>
<tr>
<td>Amplified Public Pressure and Demand for Price Transparency</td>
<td></td>
</tr>
<tr>
<td>More Stringent Medical Benefit Management</td>
<td></td>
</tr>
<tr>
<td>Increase in Value Based Models</td>
<td></td>
</tr>
<tr>
<td>Evolving Provider Landscape</td>
<td></td>
</tr>
</tbody>
</table>
1. The payer grip continues to tighten, as management across brands increases

Tighter, More Consolidated Payer Management

Managed Care Organizations (MCOs) and Pharmacy Benefit Managers (PBMs) are increasingly utilizing strict approaches to manage drugs, including formulary exclusions.

Access is now discussed in terms of “winning and losing” based on negotiations with the major PBMs and Payers.

Number of CVS/ESI Drug Exclusions

- Source: Formulary Exclusion Lists published by CVS and ESI
2. Patients are facing increasing financial pressure, as payers are transferring a higher percentage of costs to patients.

Higher Patient Out-Of-Pocket Payments

US Out-of-Pocket Health Spending (in $USD Billions)

Average Commercial Co-pay Increase (2016-2017)*

14%

Source: CMS National Health Expenditure Accounts Data; IQVIA Formulary Impact Analyzer (FIA); *Excludes buy-and-bill and hospital products.
Since 2013, the proportion of patient costs paid through deductibles and coinsurance has grown

Share of Total Patient Out-of-Pocket by Cost-Sharing Type (Commercial, All Brands)

Source: IQVIA Rx Benefit Design; IQVIA analysis
Almost 1 in 4 prescriptions are abandoned by patients during their deductible phase

Abandonment Rates for Branded Medicines

Source: Amundsen Consulting (a division of QuintilesIMS) analysis for PhRMA; IMS FIA; Rx Benefit Design, 2015
With higher cost-sharing comes greater abandonment, affecting patients with deductibles, coinsurance, and specialty co-pays.

**New Patient Abandonment by Patient Out-of-Pocket Cost Cohort (Top Brands, 2017)**

- **Deductible, Coinsurance, and Specialty Co-Pay Territory**

<table>
<thead>
<tr>
<th>Cost Sensitivity</th>
<th>Patient Out-of-Pocket Cost Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0-$9.99</td>
<td>$0-$9.99</td>
</tr>
<tr>
<td>$20-$29.99</td>
<td>$20-$29.99</td>
</tr>
<tr>
<td>$40-$49.99</td>
<td>$40-$49.99</td>
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<tr>
<td>$50-$74.99</td>
<td>$50-$74.99</td>
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<tr>
<td>$75-$124.99</td>
<td>$75-$124.99</td>
</tr>
<tr>
<td>$125-$250</td>
<td>$125-$250</td>
</tr>
<tr>
<td>$250.01+</td>
<td>$250.01+</td>
</tr>
</tbody>
</table>

Cost sensitivity observed for over $125

Note: Top Brands are defined as key products in the PayCo® tool and span more than 20 therapeutic areas. Source: IQVIA Formulary Impact Analyzer; IQVIA analysis.
3. New environment of stricter pricing scrutiny and demand for transparency

There will be an increasing push for companies to communicate a clear rationale for pricing decisions.

*AR, CA, MA, ME, NC, NY, OR; **CA, CO, LA, MD, MN, NJ, RI, TN, VA, VT, WA; ***CA, CT, IL, IN, LA, MA, MD, MT, NV, NY, OR, RI, TN, WA
4. Medical benefit drugs will no longer be protected, as payers are developing new capabilities to manage the medical benefit

**More Stringent Medical Benefit Management**

**Increased Medical Benefit Management Techniques**

- Developing medical formularies
- Increased utilization management
- Shifting medical benefit drugs to the pharmacy benefit
- Site-of-care management

**Development of Vertically Integrated Payer Models**

As specialty drugs have become increasingly costly, payers have implemented more utilization management techniques for medical benefit drugs.

Increased vertical integration between PBMs and MCOs leads to increased ability to manage both pharmacy and medical cost.
Vertically integrated Payer models are being developed to manage the increasing pharmacy and medical costs

Payer-Aligned Medical-Pharmacy Future

Insurer

PBM

Specialty Pharmacy

Cigna

aetna

UnitedHealthcare

Humana

Express Scripts

CVS Caremark

OPTUMRx

Humana Pharmacy Solutions

BlueCross BlueShield

accredo

CVS Specialty

briova

Humana Pharmacy

Source: Drug Channels Institute research. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
5. Value frameworks are expanding influence, and use of value-based payment models and innovative agreements has increased.

### Increase in Value Based Models

#### Development of Value Frameworks

<table>
<thead>
<tr>
<th>Framework</th>
<th>Launch Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mag. of Clinical Benefit Scale</td>
<td>May 2015</td>
</tr>
<tr>
<td>Drug Abacus</td>
<td>June 2015</td>
</tr>
<tr>
<td>ASCO Value Framework</td>
<td>June 2015</td>
</tr>
<tr>
<td>ICER Value Framework</td>
<td>Sept. 2015</td>
</tr>
<tr>
<td>Evidence Blocks™</td>
<td>Oct. 2015</td>
</tr>
<tr>
<td>FissticGurus</td>
<td>Nov. 2016</td>
</tr>
</tbody>
</table>

#### Recent Examples of Value-Based Payment Models

**Entresto®**

(sacubitril/valsartan) tablets

24/26 mg - 46/51 mg - 67/103 mg

- **Novartis** negotiated pay-for-performance agreements with Aetna and Cigna
  - Cigna: Payments depend on patient hospitalization rates
  - Aetna: Payments linked to delivering real-world results similar to those seen in clinical trials

**Repatha®**

(evolocumab) injection 140 mg/mL

- **Amgen** negotiated outcomes-based agreements with Harvard Pilgrim
  - Amgen will pay a refund for all eligible patients who had a heart attack or stroke while on Repatha

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Overall, in the coming years, the concept of value will become part of the fabric of US healthcare.
As more innovative products are entering the market, their high prices have come under increased scrutiny.

New and innovative products will continue to enter the market over the next 5-10 years but stakeholders are concerned over how they will be funded.

**Gene Therapies**

**Disease Modifying Therapies**

**IO Combinations**

**Cell Therapies**

---

**Immunotherapy Combos: Will Cost Put Them out of Reach?**

Kerry Dosley Young

October 18, 2018

**Managed Care**

**Gene Therapy: Must Sky-High Prices ‘Come on Down’ Before the Price Is Right?**

Managed Care July 2, 2018

**High U.S. Drug Prices Fuel Outrage, Innovation Debate: QuickTake**

By Robert Langreth | Bloomberg

May 11, 2018

**Why prescription drug prices have skyrocketed**

By Robin Feldman

November 20, 2018

**Washington Post**
Other ICER initiatives in 2019

- 2019 topics
  - Spinal muscular atrophy, including gene therapy
  - Siponimod for MS
  - Peanut allergy prophylaxis
  - Duchenne muscular dystrophy (exondys-51 and golodiresan)
  - Esketamine/ketamine for major depression
- Unsupported Price Increase (UPI) Report
- “Valuing a Cure” Project
Innovative contracts incorporate value considerations, allowing payers to de-risk high cost of new therapies

<table>
<thead>
<tr>
<th>Key Contracting Types</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional Discount Approach</td>
<td>Traditional approach where MNFs and payers negotiate pre-determined discounts for products</td>
</tr>
<tr>
<td>Financial-Based Risk Sharing</td>
<td>Financial-based risk sharing agreements link price or access conditions to non-clinical metrics/outcomes</td>
</tr>
<tr>
<td>Value-Based Risk Sharing</td>
<td>Value-based risk sharing agreements link price or access conditions to metrics related to patient clinical outcomes</td>
</tr>
<tr>
<td>Coverage with Evidence Development</td>
<td>Links access to the generation of additional evidence to address remaining uncertainty around clinical effectiveness</td>
</tr>
<tr>
<td>Financing Agreements</td>
<td>Agreement provides financing (e.g., loans, TA funds); however it does not change product price</td>
</tr>
</tbody>
</table>
Innovative contracting has emerged and grown increasingly popular among some TAs…

<table>
<thead>
<tr>
<th>Disease Area</th>
<th># of Innovative Contracts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology</td>
<td>45</td>
</tr>
<tr>
<td>CV</td>
<td>38</td>
</tr>
<tr>
<td>Autoimmune</td>
<td>29</td>
</tr>
<tr>
<td>Metabolic Disorders</td>
<td>29</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>29</td>
</tr>
<tr>
<td>CNS</td>
<td>16</td>
</tr>
<tr>
<td>Ocular</td>
<td>12</td>
</tr>
<tr>
<td>Rare Diseases</td>
<td>9</td>
</tr>
</tbody>
</table>

*IQVIA Contracting Database is based on data from both public sources and PMR/internal IQVIA expertise (no confidential information)

**Key Considerations**

- **Oncology** has a high concentration of innovative contracts due to:
  - **High cost** of treatment
  - **Increasing competition**
  - **Use across several indications**
  - **Patient population size**
  - **Tangible endpoints**
  - **Uncertain clinical outcomes**

- Innovative contracting in **infectious disease and CV** are mostly driven by novel/disruptive product launches
- **Rare diseases** see more usage of innovative contracts due to significant clinical uncertainty and high cost

Payers generally more receptive to innovative contracts in oncology

~70% of publicly available innovative contracts focus on PCSK9s since launch in 2015

Majority of contracts emerged after the launch of novel Hep C DAAs
6. Finally, the provider landscape is constantly evolving, with continued growth in the number of IDNs and ACOs.

To streamline care and costs, providers are merging to form integrated delivery networks (IDNs).

Lines are also blurring between providers and payers through the formation of vertically integrated accountable care organizations (ACOs).

IDNs/ACOs have become more influential in prescribing decisions and have demonstrated willingness to manage drug utilization at the class level.
Net total spending growth will average 2-5% over the next five years while invoice growth will average 4-7%.

Forecast

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute Dec 2018
Strong forces are driving changes in healthcare

- **Aging population** will drive more demand for mental care, homecare and assistance, social capital and self-management services.

- Rising prevalence of **chronic diseases** will drive greater demand for disease management programs (e.g. prevention, early diagnosis, IPC).

- **Adherence/Compliance** remains largest avoidable cost for healthcare systems.

- **Rising cost of care** and increasing **scrutiny around value** will need a structural re-appraisal of the payer role and new sustainable models.

- **Increasing connectivity** will drive convergence of solutions (e.g. mobile health, remote monitoring, sensor-enable pills, etc.) and **Healthcare Consumerism**.

- **Patient Centricity**: Patients are becoming more involved in healthcare decision making, choices, and becoming vocal about innovation requirements.

Notes: IPC=integrated patient care
Source: IQVIA Consulting Services; Life Sciences Trends and Growth Areas
These changes unlock new value propositions

<table>
<thead>
<tr>
<th>Integrated Care Medicine</th>
<th>Integrated care for complex chronic diseases, solutions that help to close gaps in treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision/Predictive Medicine</td>
<td>Disease detection, precise diagnosis and rational prescribing</td>
</tr>
<tr>
<td>Outcomes Based Medicine</td>
<td>Rational Prescribing and <strong>guaranteed outcomes</strong></td>
</tr>
<tr>
<td>Empowerment Medicine</td>
<td>Information-based healthcare, <strong>improve patient outcomes by providing daily solutions to HCPs and Providers</strong></td>
</tr>
<tr>
<td>Medicine Democratisation</td>
<td><strong>Any time, any place medicine</strong> (e.g. homecare, telemedicine and virtual physician visits, etc.)…Walmart, Amazon, Apple etc</td>
</tr>
</tbody>
</table>

Source: IQVIA Consulting Services; Life Sciences Trends and Growth Areas
Panel Time!

Adam Fein
DRUG CHANNELS INSTITUTE

Lisa Gill
J.P. MORGAN SECURITIES

Doug Long
IQVIA
Thank you!

Please rate this session in the 2019 Summit mobile app.
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Free industry updates from the Drug Channels blog (www.DrugChannels.net)

Daily tweets about cool and intriguing stuff

Adam J. Fein, Ph.D.
Drug Channels Institute
October 2018

https://drugch.nl/wholesale

The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers
Adam J. Fein, Ph.D.
Drug Channels Institute
March 2019

NEW

https://drugch.nl/pharmacy
Lisa C. Gill, JPMorgan Securities LLC
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  - AmerisourceBergen (ABC/$76.11/Neutral), CVS Health (CVS/$54.22/Overweight), Diplomat Pharmacy, Inc. (DPLO/$5.72/Neutral), LabCorp (LH/$159.07/Overweight), Quest Diagnostics (DGX/$90.99/Neutral), Walgreens Boots Alliance Inc (WBA/$54.24/Overweight)

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Lisa C. Gill, JPMorgan Securities LLC

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Doug is a frequent industry speaker and the recipient of many awards from trade groups. Before joining IQVIA, Doug held positions at Nielsen Market Research for 16 years in various sales and marketing capacities. A native of Illinois, Doug received a BA from DePauw University and holds an MBA in management from Fairleigh Dickinson University.
Changes in Healthcare Costs or Cost Drivers 2013–2017, Indexed (2013 Values = 100)

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2017; IQVIA Formulary Impact Analyzer (FIA), IQVIA Institute, Dec 2017
Chart notes: Indices sourced from Kaiser/HRET Employer Survey include: family coverage, premiums, workers earnings, overall inflation. Brand, generic and total final out-of-pocket costs and brand pharmacy prices are for commercially insured, Medicare Part D and cash payment types sourced from IQVIA Formulary Impact Analyzer. All charted values are indexed to set their 2013 value equal to 100
Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018