Specialty Pharmacy Industry Outlook: What’s Happened & What’s Ahead

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

http://drugch.nl/asembia18
Agenda

• *The State of Specialty Pharmacy 2018* – Adam

• *Key Themes for 2018* – Lisa

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

• *Good Morning, Asembia! With Adam, Lisa, & Doug*
The State of Specialty Pharmacy 2018

Adam J. Fein, Ph.D.
Drug Channels Institute
www.DrugChannels.net
@DrugChannels

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The Specialty Pharmacy Accreditation Boom Continues

**Number of Pharmacy Locations with Specialty Pharmacy Accreditation, by Organization**

- **ACHC only**
- **CPPA only**
- **URAC only**
- **Multiple accreditations**

<table>
<thead>
<tr>
<th>Year</th>
<th>ACHC only</th>
<th>CPPA only</th>
<th>URAC only</th>
<th>Multiple accreditations</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>381</td>
<td></td>
<td></td>
<td></td>
<td>729</td>
</tr>
<tr>
<td>2016</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>499</td>
</tr>
<tr>
<td>2017</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Source: Drug Channels Institute research. Figures show number of unique accredited locations at the end of the year. For comparability, data for ACHC and CPPA exclude certain accredited pharmacy spoke locations within retail chains. Multiple category includes locations with accreditation from two or three of the accrediting organizations. Figures exclude locations with provisional, conditional, and expected accreditation. This chart appears as Exhibit 40 in The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. Available at [http://drugch.nl/pharmacy](http://drugch.nl/pharmacy)
## Hospitals and Physicians: Key Specialty Pharmacy Participants

### Percentage of Pharmacy Locations with Specialty Pharmacy Accreditation, by Corporate Ownership

<table>
<thead>
<tr>
<th>Category</th>
<th>2015 (n=381)</th>
<th>2017 (n=729)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wholesaler</strong></td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>PBM/Health Plan</strong></td>
<td>17%</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Retail/LTC Chain</strong></td>
<td>10%</td>
<td>12%</td>
</tr>
<tr>
<td><strong>Healthcare Provider</strong></td>
<td>11%</td>
<td>26%</td>
</tr>
<tr>
<td><strong>Independent</strong></td>
<td>59%</td>
<td>49%</td>
</tr>
</tbody>
</table>

LTC = Long-term care

1. Includes private independent pharmacies, pharmacies owned by private equity firms, and independently owned franchise locations.
2. Includes pharmacies owned by hospitals, health systems, physician practices, and providers’ group purchasing organizations.
3. Includes pharmacy locations owned by chain drugstores, grocery chains, and national long-term care pharmacy chains.

Source: *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 44. Figures show number of unique pharmacy locations accredited by ACHC, CPPA, and URAC at the end of the year. For comparability, data for ACHC and CPPA exclude certain accredited pharmacy spoke locations within retail chains. Figures exclude locations with provisional, conditional, and expected accreditation. Locations owned by manufacturers excluded for purposes of presentation.
Payers and PBM still dominate specialty dispensing.

**Share of Specialty Drug Dispensing Revenues, by Company, 2017**

- **PBM / health plan**: CVS Health
- **Independent**: Express Scripts
- **Retail chain**: Walgreens/Prime
- **Wholesaler**: OptumRx (UNH), Humana, Cigna

Accumulator Adjustment: A manufacturer’s patient support payments do not count toward the patient’s deductible and out-of-pocket maximum obligations

- Recognized correct definition of “health plan deductible” 62% of U.S. consumers
- Knew the meaning of the term “out-of-pocket maximum” 39% of U.S. consumers
- Had a good understanding of the term “co-insurance” 31% of U.S. consumers

See *Copay Accumulators: Costly Consequences of a New Cost-Shifting Pharmacy Benefit*, *Drug Channels*, January 2018
Utilization—Not Cost—is Driving Specialty Drug Spending

Source: Drug Channels Institute analysis of company drug trend reports. Figures represent commercially insured beneficiaries only.

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Vertical Integration: The Medical-Pharmacy Specialty Future?

See the following Drug Channels articles:
- Cigna-Express Scripts: Vertical Integration and PBMs’ Medical-Pharmacy Future
- Five Takeaways About Cigna’s Strategy for Express Scripts
- The CVS-Aetna Deal: Five Industry and Drug Channel Implications
- Why the Walgreens/Prime Deal Could Transform the PBM Industry
Outlook and Implications

• REDUX: Pharmacies, PBMAs, health plans, and providers continue to battle for control of the specialty market, the patient journey, and the public narrative.

• New accumulator adjustment benefit designs threaten to disrupt care, raise patient costs, and slow the specialty pharmacy business.

• Vertical integration will strengthen medical/pharmacy benefit management, extend payer control, and increase channel concentration.

• Politicians, regulators, and the media will scrutinize the specialty channel’s impact on “drug prices” and consumers’ out-of-pocket spending, though the system’s complexity will create deep confusion about appropriate solutions.

• Amazon may (or may not) change everything.
Key Themes for 2018

Lisa Gill
J.P. Morgan Securities
YTD 2018 Stock Performance Across the Rx Channel

The **S&P 500** is down -0.6% YTD in 2018 and the **S&P 500 Health Care Sector Index** is down +1.0% YTD. On average, the Rx channel stocks are down ~7% YTD in 2018.

- **DPLO**, the only publicly traded standalone **Specialty Pharmacy**, is down -3.5% YTD in 2018.
- **ESRX**, the only publicly traded standalone **Pharmacy Benefit Manager**, is down -4.0% YTD in 2018, despite the proposed acquisition by Cigna.
- The two large **Retail Pharmacies** (**CVS and WBA**) are down -12.3%, on average, YTD in 2018.
- The three large **Pharmaceutical Distributors** (**ABC, CAH and MCK**) are down -5.1% YTD in 2018, on average.

Source: Bloomberg; pricing as of 4/13/18.
### Thoughts on Trend Towards Integrated Models

- **The strategic rationale around vertical integration makes sense, in our view**
  - The ability to combine medical/pharmacy/lab data and apply analytics to identify opportunities
    - Target interventions to close gaps in care, drive greater adherence, better manage complex patients and reduce adverse events
  - Apply member engagement tools to drive behavior change (pharmacy is typically the most frequently used healthcare benefit)
  - Shift patient care to lower cost settings (either through owned assets or preferred relationships)

- **Benefits realized under the integrated care model accrue directly to the health plan**
  - Potential to lower medical costs by reducing overtreatment and wasteful spending, improving chronic care management and reducing failures of care delivery and readmissions
  - Treating the patient more holistically can improve overall health outcomes and allow better management of total healthcare costs
  - Ability to better underwrite risk can potentially allow the health plan to price products better and grow membership in the marketplace

- **We believe specialty has been a key factor driving the trend toward integrated models**
  - Specialty drug costs are projected to represent roughly 55% of total drug spend by 2021
  - Payors looking for ways to better manage complex chronic patients and specialty drug costs

- **“United envy”**
  - UnitedHealth Group, which runs an integrated model, trades at the highest valuation in the group
### Regulatory Environment Across the Space

Lots of discussion, although we don’t expect significant changes to current business models

<table>
<thead>
<tr>
<th>Potential new proposals to lower drug prices</th>
</tr>
</thead>
<tbody>
<tr>
<td>On 3/19, President Trump stated he would announce new proposals to bring down drug pricing in about a month, as U.S. citizens pay more than people in other countries for the same drug</td>
</tr>
<tr>
<td>On 3/7, FDA Commissioner Scott Gottlieb cited “Kabuki drug-pricing constructs” that discourage competition, drive high consumer out-of-pocket costs and obscure supply chain profits</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potential shift to Part D from Part B discussed as way to move from “buy and bill” model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior criticism that “buy and bill” model incentivizes physicians to administer higher cost drugs</td>
</tr>
<tr>
<td>Shift to pharmacy benefit could represent new opportunity for PBMs and specialty pharmacies</td>
</tr>
<tr>
<td>Pharma distributors could potentially be impacted if product leaves the specialty distribution channel or if product remains in channel under new lower margin wholesale arrangements</td>
</tr>
<tr>
<td>– ABC would potentially have largest exposure, followed by MCK and then CAH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potential for point-of-sale rebates</th>
</tr>
</thead>
<tbody>
<tr>
<td>President’s budget proposal included this, although final rule issued in early April did not include a mandate for plans to apply rebates at the point of sale in Medicare Part D</td>
</tr>
<tr>
<td>PBMs have had ability to offer point-of-sale rebates for years; option has had little client uptake</td>
</tr>
<tr>
<td>– Most clients prefer to utilize rebate dollars to lower premiums for the broader member base</td>
</tr>
<tr>
<td>United Healthcare and Aetna have discussed to offer point-of-sale rebates for fully insured commercial group plans in 2019</td>
</tr>
<tr>
<td>No impact to PBM economics</td>
</tr>
</tbody>
</table>
Update on Underlying Trends in Rx Channel

**Pharmaceutical Distribution**
- Fundamentals for the **Pharma Distributors** appear to be stabilizing. There have been no major surprises around brand and generic pricing trends, while the competitive environment remains consistent. Further, re-contracting initiatives could lead to margin improvement.

**Retail Pharmacy**
- While the **Retail Pharmacy** industry remains challenged due to reimbursement pressure and the ongoing shift to narrow and preferred networks, we believe the larger players that have invested in clinical capabilities will be share gainers as the industry shifts to performance-based networks in a value-based care world.

**Pharmacy Benefit Management (PBM)**
- We point to a favorable fundamental backdrop for the **PBM**s, with script volumes boosted by favorable demographics and the use of pharmacotherapy as a cost-effective treatment modality. Despite ongoing rhetoric in the press, we continue to believe PBM s are part of solution to rising drug costs and do not anticipate significant changes to the current PBM business model.

**Specialty Pharmacy**
- We point to a bullish view on the broader **Specialty Pharmacy** space, as growth in specialty drug spend is expected to significantly outpace traditional drug spend (driven in part by the robust biotech pipeline) and plan sponsors look for solutions to help better manage this increasing cost.
Value-Based Healthcare – Driving Future Value in Healthcare

The shift to value-based reimbursement models is coming in the pharmaceutical world – we expect more reimbursement to be tied to health outcomes.

- Pharmacotherapy is a highly cost-effective treatment modality and will become even more important in a value-based care world.
  - Disease prevention and better chronic disease management to avoid high cost episodes
  - Adherence to proper drug regimens, closing gaps in care

- As part of this, we expect a shift to performance-based pharmacy networks over time, where reimbursement will be more closely tied to quality metrics/outcomes.
  - Services around adherence and patient counseling will become important differentiators among pharmacy providers
  - Changing incentive structure within pharmacy to move away from volume-based targets to outcomes-based targets likely to occur
  - Continuity of care across various care settings could also help drive improved patient outcomes

- Over the longer term, we expect there to be winners that will become partners of choice for payors and providers.
  - Those that have invested in clinical capabilities that can drive better quality/outcomes
  - Those that can effectively engage members and influence behavior
  - Those that can provide access to lower cost sites of care
Driving Future Value in Healthcare – New Models Emerging

- **Health Transformation Alliance**
  - Formed in February 2016 with initial 20 large employers (over 40 members today representing over 6M lives and $25B in healthcare spend)
  - Goal: hold down cost of providing health benefits by changing the way they contract with providers, using collective data on spending/outcomes, and forming a purchasing cooperative
  - HTA initial PBM relationships with CVS Caremark & OptumRx (key principals include: eliminating spread pricing; moving to admin fee only model; 100% rebate pass-through)
  - HTA also has relationships with IBM Watson for data analytics and UnitedHealthcare and Cigna on the medical side
  - We haven’t seen meaningful change in the employer-sponsored healthcare market at this point

- **Amazon, Berkshire Hathaway & J.P. Morgan announce independent not-for-profit**
  - New initiative is in the early stages of a long-term effort to drive down employer healthcare costs and initially focused on the existing employees (1M+ employees across the three organizations)
  - Discussed a focus on technology solutions for simplified high-quality and transparent healthcare
  - Companies have acknowledged they “don’t come to the problem with answers” and “enter into this challenge open-eyed about the degree of difficulty” but enter with a blank slate and no preconceived notions on how to fix this enormous problem
  - Nothing to date points to disintermediating existing providers or market participants
  - This initiative reinforces our view that shift to value-based care and consumerism will represent key themes across our space going forward
Rising Specialty Costs the Biggest Concern among Plan Sponsors

- J.P. Morgan Pharmacy Benefits Survey from December 2017 confirms that plan sponsors are very concerned over specialty drugs.
- 76% of the 51 respondents indicated that specialty drugs are the biggest concern around the pharmacy benefit over the next five years.

- We expect payors to increasingly seek out solutions for controlling specialty drugs costs.
  - We have already seen greater interest in plan design options such as narrow specialty networks, step therapy, prior authorization, and exclusionary formularies.
  - Going forward, we also expect to see greater traction around evidence-based clinical guidelines, site of care management, specialty medical management, etc.

**What Is Your Biggest Concern Around the Pharmacy Benefit over the Next 5 Years?**

*n=51*

- **Specialty drugs** 76%
- **Price inflation** 22%
- **Utilization** 2%
### How Our Coverage Universe Is Positioned for Specialty

<table>
<thead>
<tr>
<th>Role</th>
<th>Dispense/Distribute Drugs</th>
<th>Manufacturer Support Services</th>
<th>Utilization Management Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Benefit Manager</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Pharmaceutical Distributor</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Specialty Pharmacy</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Retail Pharmacy</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Source: J.P. Morgan.*
How Our Coverage Universe Is Positioned for Specialty

**Pharmacy Benefit Managers (PBMs)**
- Patient-specific dispensing of drugs through internal specialty pharmacies
- Utilization management for payors (step therapy, prior authorization, formularies, etc.)
- Key differentiation is the ability to help payors manage specialty drug trend

**Pharmaceutical Distributors**
- Bulk distribution of specialty drugs to various customers, including pharmacies, hospitals, clinics, and physician offices
- Most provide additional value-added services to manufacturers of specialty drugs

**Pure-Play Specialty Pharmacies**
- Patient-specific dispensing of specialty drugs
- Most provide additional value-added services to manufacturers of specialty drugs
- Limited distribution agreements a key advantage

**Traditional Retail Pharmacies**
- Patient-specific dispensing of specialty drugs at retail locations
- Generally ill-equipped to deal with specialty drugs
- May not stock drugs, and often limited capabilities for comprehensive patient support services
Evolution of Consumerism in Healthcare

**The “Retailization” of Healthcare**
- Patients getting more involved and making decisions on how to allocate their healthcare dollars
  - Pharmacy most frequently used benefit – opportunity to better engage patients
  - A strong reputation and trusted brand will be important going forward

**Retail-Based Health Clinics**
- Opportunity to shift care to lower cost and more convenient settings
- The number of retail-based clinics has risen dramatically over the past decade
- Pharmacy chains have dominant share; health systems also participate on own or via partnership
- Opportunity to add incremental services, including higher acuity, urgent care type services

**Telehealth**
- Total addressable market in the U.S. is $17B
- Still significant runway for growth in the ambulatory care market (current penetration is <1%)
- Opportunity to expand care into other areas (e.g., chronic care management, second opinions)
- Large retail pharmacy chains have partnered with telehealth providers

**Lab Testing at Retail Pharmacy**
- Pharmacies partnering with clinical labs to offer diagnostic services through patient service centers located within the pharmacy
- Quest Diagnostics has announced collaborations with Walmart and Safeway
- LabCorp has announced a collaboration with Walgreens
Pharmaceutical Supply Chain—Amazon Threat

If Amazon did enter the pharmacy market, would likely be via a mail pharmacy offering given limited brick and mortar presence (~400 Whole Foods stores nationwide, vs. 65,000+ retail pharmacies in the U.S.)

To access larger commercial market, AMZN would need to participate in PBM pharmacy networks
- AMZN would represent one additional point of dispensing in the PBM networks
- Unlikely for a PBM to offer preferred cost sharing at AMZN vs. their own mail pharmacy

AMZN could attempt to offer low price generics model
- However, pricing likely wouldn’t be much cheaper than insured’s generic copay
- Has been tried before by Walmart with limited impact to share for other players

AMZN could offer cash alternative to patients in HDHP deductible phase
- Since not run through the pharmacy benefit, spend may not count towards deductible
- Potential safety issues around drug interactions if outside of pharmacy benefit

We don’t believe AMZN would have a solution for brand/specialty drugs
- We don’t believe AMZN will have access to competitive rebates/discounts on brands
- Branded drugs (including specialty) accounted for 74% of total drug spend in 2017

Despite convenience, mail utilization has actually been declining
- Mail represented 10.2% of adjusted Rx in 2016 vs. 15.8% in 2010 (QuintilesIMS data)
- More plan sponsors offering Retail-90; High-utilizing seniors may prefer retail over mail

J.P. Morgan
Pharmacy Benefit Management – Amazon Threat

In December 2017, we hosted a call with four HR executives that participated in our PBM Survey

- On the call, we discussed potential interest in an Amazon PBM offering, and highlight some of the interesting feedback from the participants below

  - "Would not be bowled over just because it is Amazon"
  - "Not trying to solve for a distribution issue"
  - "Don’t want to get blinded by the name of Amazon"
  - "Could present an opportunity to engage members"
  - "Would be very leery on the onset of how that would bring value to the organization"
  - "Take a wait and see approach"
  - "Would be interested in studying it, but it would be something that they would take a cautious eye to"
The US Pharmaceutical Market: Trends, Issues, and Outlook

Doug Long
IQVIA
Total Spending on Medicines in the US was $453Bn and Growth was only 1.4% in 2017
Specialty growth is outpacing traditional growth and now is 43.4% of the total non-discounted spend.

In 2017, specialty spend is growing at 9.3% while traditional is declining at 4.0%.

Source: IQVIA, National Sales Perspectives, March 2018
Real Net Per Capita Medicine Spending is growing for Specialty and declining for Traditional

Source: IQVIA, National Sales Perspectives, IQVIA Institute; U.S. Census Bureau; U.S. Bureau of Economic Analysis (BEA), Dec 2017
Chart notes: Real medicine spending reflected in 2009 US$. Specialty and Traditional medicines are defined by IQVIA, see Appendix. Includes all medicines in both pharmacy and institutional settings. Totals may not sum due to rounding.
Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018
In 2017, the majority of New Active Substances (NAS) launched in the United States were considered “Orphan”.

Source: IQVIA LifeCycle New Product Focus, IQVIA Institute, Mar 2018
Chart notes: A New Active Substance (NAS) is a new molecular or biologic entity or combination where at least one element is new; NAS launches in the United States by year of launch regardless of timing of FDA approval. New Mechanism refers to the first product with a new mechanism of action for its FDA approved indication. Existing Mechanism refers to subsequent products with existing mechanisms of action for an indication. Orphans are drugs with one or more orphan indications approved by the FDA at product launch. Products are not reclassified as orphan if they subsequently receive an approval for an orphan designated indication.
Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018
Oncology, infectious disease, and CNS are the areas with the most launches in 2017

Source: IQVIA, National Sales Perspectives
### IQVIA’s Top 2017 Performers

**Sales through Jan 2018**

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Indication</th>
<th>Launch</th>
<th>Year 1 Sales to date</th>
<th>Specialty / Traditional</th>
<th>Biologic/ Small Molecule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocrevus</td>
<td>Genentech</td>
<td>Multiple sclerosis</td>
<td>Apr-17</td>
<td>$1.1B</td>
<td>Specialty</td>
<td>Biologic</td>
</tr>
<tr>
<td>Mavyret</td>
<td>AbbVie</td>
<td>Hepatitis C</td>
<td>Aug-17</td>
<td>$480M</td>
<td>Specialty</td>
<td>Small Molecule</td>
</tr>
<tr>
<td>Dupixent</td>
<td>Sanofi/Regeneron</td>
<td>Moderate-to-severe atopic dermatitis</td>
<td>Mar-17</td>
<td>$319M</td>
<td>Specialty</td>
<td>Biologic</td>
</tr>
<tr>
<td>Spinraza</td>
<td>Biogen</td>
<td>Spinal muscular atrophy</td>
<td>Feb-17</td>
<td>$240M*</td>
<td>Specialty</td>
<td>Antisense Oligo</td>
</tr>
<tr>
<td>Vosevi</td>
<td>Gilead</td>
<td>Hepatitis C</td>
<td>Jul-17</td>
<td>$221M</td>
<td>Specialty</td>
<td>Small Molecule</td>
</tr>
<tr>
<td>Eucrisa</td>
<td>Pfizer</td>
<td>Mild atopic dermatitis</td>
<td>Feb-17</td>
<td>$133M</td>
<td>Traditional</td>
<td>Small Molecule</td>
</tr>
<tr>
<td>Radicava</td>
<td>Mitsubishi Tanabe</td>
<td>Amyotrophic lateral sclerosis</td>
<td>Aug-17</td>
<td>$86M</td>
<td>Specialty</td>
<td>Small Molecule</td>
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<tr>
<td>Kisqali</td>
<td>Novartis</td>
<td>Breast cancer</td>
<td>Mar-17</td>
<td>$79M</td>
<td>Specialty</td>
<td>Small Molecule</td>
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<tr>
<td>Tremfya</td>
<td>Janssen</td>
<td>Plaque psoriasis</td>
<td>Jul-17</td>
<td>$72M</td>
<td>Specialty</td>
<td>Biologic</td>
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<tr>
<td>Soliqua</td>
<td>Sanofi</td>
<td>Diabetes</td>
<td>Jan-17</td>
<td>$68M</td>
<td>Traditional</td>
<td>Hormone</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives

*Likely understated owing to product reporting blocks
Nephron Pharma Price Auditor: March Gx deflation is -7.5%; Bx inflation 7.2%

Source: Nephron Research, Glass Box Analytics, IQVIA
Consumer price index is above estimated brand net price growth for the first time

Source: IQVIA National Sales Perspectives, IQVIA Institute, Dec 2017
Chart notes: “Invoice” values are IQVIA reported values from wholesaler transactions measured at trade/invoice prices and exclude off-invoice discounts and rebates that reduce net revenue received by manufacturers. “Net” values denote company recognized revenue after discounts, rebates and other price concessions. Results are based on a comparative analysis of company reported net sales and IQVIA reported sales and prices at product level for branded products representing 75-93% of brand spending in the period displayed. All growth is calculated over same cohort of products in the prior year. See Methodology section for more details.
Includes all medicines in both pharmacy and institutional settings.
Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018
In 2017, Janssen’s weighted average list prices grew by 8.1%, while average net prices declined by 4.6%.

Biologics provide average rebates and discounts approximately 10% lower than small molecules on a weighted basis.

Excluding high-rebate classes, biologics provide almost 20% lower rebates.

Small Molecules:
- 16% 18% 20% 22% 23% 27% 30% 36% 37% 38%

All Biologics:
- 14% 15% 17% 16% 15% 18% 24% 29% 30% 31%

Note: *Biologics Abridged: is biologics excluding oncology, diabetes, autoimmune biologics
Source: IQVIA Institute, MIDAS, Dec 2017, annual company reports;
Specialty is continuing to show value growth in the current calendar year (+$16.8BN), while traditional value growth is declining (-$10.7BN)

Source: IQVIA, National Sales Perspectives, April 2018
Autoimmune and oncology are driving value growth in specialty; viral hepatitis value growth is declining year over year since 2015

Top Specialty Therapy Areas – Absolute Value Growth

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>AUTOIMMUNE DISEASES</td>
<td>$5.2</td>
<td>$7.3</td>
<td>$7.6</td>
<td>$7.7</td>
</tr>
<tr>
<td>ONCOLOGICS</td>
<td>$4.9</td>
<td>$6.0</td>
<td>$6.1</td>
<td>$5.2</td>
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<tr>
<td>VIRAL HEPATITIS</td>
<td>-$4.1</td>
<td>-$3.9</td>
<td>$10.3</td>
<td>$6.6</td>
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<tr>
<td>HIV ANTIVIRALS</td>
<td>$1.8</td>
<td>$2.1</td>
<td>$2.5</td>
<td>$1.9</td>
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<tr>
<td>MULTIPLE SCLEROSIS</td>
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<td>$2.5</td>
<td>$1.2</td>
<td></td>
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<tr>
<td>ALL OTHER</td>
<td>$2.7</td>
<td>$4.9</td>
<td>$4.6</td>
<td>$4.8</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, April 2018
Autoimmune products (Humira, Enbrel, and Remicade) lead specialty absolute value growth

Absolute Value Growth for Top Specialty Products

Source: IQVIA, National Sales Perspectives, April 2018
Note: top products ranked on 2017 non-discounted spend
Biosimilar uptake in the US is modest to date

Source: IQVIA National Sales Perspectives, IQVIA Institute, Dec 2017
Chart notes: Biologics are defined by IQVIA as clearly identifiable molecules of biologic origin, including but not limited to products created with recombinant DNA technology and without necessarily adhering to classifications by regulatory bodies, which are sometimes inconsistent with this approach. Biosimilars are abbreviated biologic approvals made with reference to an original biologic and demonstrating similarity to the reference product. Non-original products approved outside the official biosimilar pathway have been noted as “biosimilar”. Original biologics that have later faced competition have been shown separately in the chart based on whether or not they are facing competition in that period. Includes all medicines in both pharmacy and institutional settings.

Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018
Six key issues that Market Access teams are currently facing

- **Tighter, More Consolidated Payer Management**
- **Higher Patient Out-Of-Pocket Payments**
- **Amplified Public Pressure and Demand for Price Transparency**
- **More Stringent Medical Benefit Management**
- **Increase in Value Based Models**
- **Evolving Provider Landscape**
1. The payer grip continues to tighten, as management across brands increases

**Tighter, More Consolidated Payer Management**

**Number of CVS / ESI Drug Exclusions**

- 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.

**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)

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<tbody>
<tr>
<td>Value</td>
<td>$338</td>
<td>$350</td>
<td>$366</td>
<td>$383</td>
<td>$401</td>
<td>$424</td>
<td>$446</td>
<td>$469</td>
<td>$492</td>
<td>$517</td>
<td>$542</td>
</tr>
</tbody>
</table>

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
Deductible plans are increasingly common and deductible levels are rising

Almost 1 in 4 prescriptions are abandoned by patients during their deductible phase

*Abandonment Rates for Branded Medicines*

- No Deductible: 9%
- Brands with Deductible: 23%
- Specialty Brands with Deductible: 27%

Source: Amundsen Consulting (a division of QuintilesIMS) analysis for PhRMA; IMS FIA; Rx Benefit Design, 2015
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 Survey4 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
3. New environment of stricter pricing scrutiny and demand for transparency

Amplified Public Pressure and Demand for Price Transparency

Increased Public Scrutiny on Drug Pricing

Number of State Bills Introduced on Price Transparency (2015-2017)

*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**

<table>
<thead>
<tr>
<th>Increased Medical Benefit Management Techniques</th>
<th>Development of Vertically Integrated Payer Models</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developing medical formularies</td>
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<tr>
<td>Increased utilization management</td>
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<tr>
<td>Shifting medical benefit drugs to the pharmacy benefit</td>
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<tr>
<td>Site-of-care management</td>
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</tbody>
</table>

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.
5. Value frameworks are expanding influence, and use of value-based payment models and innovative agreements has increased

![Increase in Value Based Models](image)

### Development of Value Frameworks

- **Mag. of Clinical Benefit Scale**: May 2015
- **Drug Abacus**: June 2015
- **ASCO Value Framework**: June 2015
- **ICER Value Framework**: Sept. 2015
- **Evidence Blocks™**: Oct. 2015
- **Value framework**: Nov 2016

### Recent Examples of Value-Based Payment Models

- **Entresto® (sacubitril/valsartan) tablets**
  - 24/200mg, 48/310mg, 97/180mg

  - 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 140mg/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
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
Late Phase R&D Pipeline by Top Therapy Areas

Source: IQVIA, ARK R&D Insight, IQVIA Institute, Mar 2018
Chart notes: Late phase pipeline is defined as active programs (activity in past three years) in Phase 2 through Registered. Pipeline products are categorized by their most-advanced indication, and additional indications for pipeline drugs still in earlier phases or for already marketed drugs are not counted. GI = Gastrointestinal.
Report: Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022, Apr 2018
10 key turning points in 2018

Harbingers of change for the outlook to 2022

Innovation trends
- Real-world data use in clinical practice guided by FDA
- Next-generation biotherapeutics move toward mainstream
- Apps make their way into treatment guidelines
- Telehealth usage surges

Medicine spending growth drivers
- Branded medicine spending in developed markets falls
- Specialty medicines drive all spending growth in developed markets
- Slower growth in China and other pharmerging markets

New approaches to value
- U.S. real net per capita spending on medicines steadies
- Outcomes-based contracts find limited role
- New wave of biosimilar market opportunities emerges
Good Morning, Asembia!

Adam J. Fein, Drug Channels Institute

Lisa Gill, J.P. Morgan Securities

Doug Long, IQVIA

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*Percentage of investment banking clients in each rating category.

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