The U.S. Pharmaceutical Market: Trends, Issues, and Outlook
PharMEDium Lunch and Learn Series

The U.S. Pharmaceutical Market:
Trends, Issues, and Outlook
November 9, 2018

Featured Speaker: Doug Long, MBA
Vice President, Industry Relations
IQVIA

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Resources

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  - Handouts
  - Activity information
  - Upcoming live webinar dates
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Learning Objectives

- Discuss where the US Pharmaceutical market growth has been and near-term forecast for growth
- Review the performance of the various sectors of the dispensing side of the US pharmaceutical market
- Discuss the performance of brand, generic, and specialty products
- Identify which factors will affect future growth of the US pharmaceutical market

Key recent happenings in the US!

**Market Performance**
- Dollar growth has improved slightly to +5.3% (YTD JUN 18)
- Unadjusted TRx growth YTD JUN 18 is flat (-0.4%) while Adjusted 90-Day TRX growth is up 2.5%
- 90 day scripts continue to grow
- Major 17-18 Flu Season
- Generic $ sales decreases

**Mergers / Alliances**
- Walgreens & Rite Aid
- Walgreens & Freds
- CVS & Aetna
- CVS & Stater Brothers
- Cigna & Express Scripts
- Walmart & Anthem (OTC)
- Amazon: Whole Foods, PillPack, Xealth, MedPlus
- Amazon, Berkshire Hathaway and JP Morgan

**Reimbursement**
- DIR fees and audits
- Patient’s behavior during their deductible period
- Co-pay cards
- Accumulator programs

**Generic Launches**
- Record number of ANDA approvals and faster approvals, but fewer products launched
- Cialis
- Advair Diskus?

**Regulation**
- Opioids recognized as a national crisis
- FDA Priority list of no or limited generic entries and complex generics

**Price / Politics**
- Much more public/media scrutiny on drug prices
- Potential administrative actions
- Gross-to-net and rebates
- Generic deflation
- Less brand price inflation
- Repeal and replace?
Agenda

1. Medicine Spending and Growth Dynamics
2. Medicine Usage Trends
4. Opioids
5. Adherence
6. Profile of New Medicines and Pipeline
7. Outlook to 2022

Medicine Spending and Growth Dynamics

• Spending grew 0.6% net of off-invoice discounts and rebates, as invoice-level growth slowed to 1.4%
• Discounts, rebates and other price concessions on brands reduced absolute invoice spending by an estimated 28% to $324.4 billion
• Spending continues to shift from traditional to specialty medicines, which now account for $407 of the $876 per person per year spent on medicines.
• Growth fell to $0.7 billion as new and protected brands grew $4.9 billion less than 2016 and generics declined by $5.5 billion
• Protected brand net prices increased by 1.9% on average in 2017, continuing below invoice price growth and now lower than inflation
• Generics declined by $5.5 billion as competition drove shifts in volume to lower cost alternatives and price declines
• Spending on new brands has shifted dramatically to specialty medicines which drove $9.8 billion of the $12.0 billion net growth
• Biologics growth continues, while biosimilars now compete in medicines with $11.5 billion in spending
The U.S. Pharmaceutical Market: Trends, Issues, and Outlook
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U.S. medicines growth slowed to 0.6% in 2017 on a net basis

Total Spending on Medicines

Protected brand net prices increased by 1.9% on average in 2017, below invoice price growth and now lower than inflation

Protected Brand Invoice and Net Price Growth
Gross-to-net reductions for brand-name drugs were $153B in 2017

What falls between gross and net?

Source: Drug Channels Institute analysis of IQVIA Institute data. 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.

Source: Nephron Research, IQVIA, October 2018
Real net per capita spending declined by 2.2% in 2017 with spending on traditional medicines declining by 7.3%.

### Real Net Per Capita Medicine Spending and Growth by Type

- **Traditional**: $876
- **Specialty**: $407

### U.S. Pharma Spending

- **New Brand Spending (excluding Hepatitis C)**: $12.1B
- **Total Increase**: $12.6B in the past 12 months

### Source

IQVIA, National Sales Perspectives, Mar 2018

Note: HCV is carverd out and separate from all other groupings; moving annual total (MAT) represents the latest 12 months.
Spending on Brands Launched in the Last 24 Months Grew by $15.1B for Total Sales of $25.2B in 2017

Genvoya, Descovy, and Odefsey drive growth in HIV therapy in 2017

Total US market dollar sales growth is rebounding following the Hepatitis C boom in 2014/2015

Source: IQVIA, National Sales Perspectives, Jan 2018

Source: IQVIA, National Sales Perspectives, July 2018
Hepatitis C dollar growth peaked in 2015 and has been exhibiting negative dollar growth since 2016 (-28.1% year to date)

Narcotic analgesics have been exhibiting negative dollar growth since 2015 (-0.1%) and remains at -19.5% year to date
Increasingly comfortable that Gx deflation is ‘normalizing’ in the mid-single digits

Nephron Gx Price Auditor finds total deflation improved to -5.0% in July 2018, from -7.5% in June 2018 and -13.0% in July 2017

Source: Nephron Research, Glass Box Analytics, IQVIA, August 2018

In MAT JUN 2018, specialty spend is growing at 10.6% while traditional is declining at 0.9%

Specialty growth is outpacing traditional growth and now has 44.5% share of total non-discounted spend in the most recent 12 months

In MAT JUN 2018, specialty spend is growing at 10.6% while traditional is declining at 0.9%

Specialty growth is outpacing traditional growth and now has 44.5% share of total non-discounted spend in the most recent 12 months

Specialty growth is outpacing traditional growth and now has 44.5% share of total non-discounted spend in the most recent 12 months

Source: IQVIA, National Sales Perspectives, July 2018
Oncology, Autoimmune, and HIV lead specialty therapy areas absolute value growth

**Absolute Value Growth for Top Specialty Therapy Areas**

**Absolute Value Growth (US$ B)**

<table>
<thead>
<tr>
<th>Therapy Areas</th>
<th>MAT JUN 2018-MAT JUN 2017</th>
<th>MAT JUN 2018-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONCOCLOGY</td>
<td>$6.7</td>
<td>$26.0</td>
</tr>
<tr>
<td>AUTOIMMUNE</td>
<td>$7.7</td>
<td>$31.9</td>
</tr>
<tr>
<td>HIV</td>
<td>$2.0</td>
<td>$9.5</td>
</tr>
<tr>
<td>MULTIPLE SCLEROSIS</td>
<td>$0.7</td>
<td>$7.1</td>
</tr>
<tr>
<td>HEPATITIS C</td>
<td>-$3.4</td>
<td>$7.2</td>
</tr>
<tr>
<td>HEMATOPOIETIC GROWTH FACTOR</td>
<td>$0.0</td>
<td>$0.4</td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>$0.7</td>
<td>$2.4</td>
</tr>
<tr>
<td>ERYTHROPOIETINS</td>
<td>-$0.1</td>
<td>$1.6</td>
</tr>
<tr>
<td>POLYVAL. IMMUNOGLOBULINS &amp; WBM</td>
<td>-0.8</td>
<td>$0.5</td>
</tr>
<tr>
<td>IMMUNOSUPpressive FOR ORGAN TRANSPLANTS</td>
<td>$0.1</td>
<td>$1.8</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>$0.6</td>
<td>$0.6</td>
</tr>
<tr>
<td>GROWTH HORMONES</td>
<td>$0.1</td>
<td>$14.0</td>
</tr>
<tr>
<td>ALL OTHER</td>
<td>$4.0</td>
<td></td>
</tr>
</tbody>
</table>

**Source:** IQVIA, National Sales Perspectives, August 2018

Note: Top Therapy areas listed in MAT JUN 2018 non-discounted spend

Diabetes, respiratory and anticoagulants lead traditional therapy areas absolute value growth while pain, mental health, and antihypertensives contribute most to value decline

**Absolute Value Growth for Top 15 Traditional Therapy Areas**

**Absolute Value Growth (US$ B)**

<table>
<thead>
<tr>
<th>Therapy Areas</th>
<th>MAT JUN 2018-MAT JUN 2017</th>
<th>MAT JUN 2018-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIABETES</td>
<td>$6.0</td>
<td>$31.9</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>$5.1</td>
<td>$8.3</td>
</tr>
<tr>
<td>ANTICOAGULANTS</td>
<td>$2.4</td>
<td>$5.2</td>
</tr>
<tr>
<td>PAIN</td>
<td>$2.3</td>
<td>-$3.1</td>
</tr>
<tr>
<td>NERVOUS SYSTEM DISORDERS</td>
<td>-$0.9</td>
<td>-$7.5</td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>$0.3</td>
<td>$3.1</td>
</tr>
<tr>
<td>VACCINES</td>
<td>-$1.1</td>
<td>-$0.8</td>
</tr>
<tr>
<td>ADHD</td>
<td>$0.3</td>
<td>$3.4</td>
</tr>
<tr>
<td>DERMATOLOGICS</td>
<td>-$1.1</td>
<td>-$5.6</td>
</tr>
<tr>
<td>GI PRODUCTS</td>
<td>$0.2</td>
<td>$1.2</td>
</tr>
<tr>
<td>ANTIHYPERSENSITIVES</td>
<td>$0.2</td>
<td>$1.1</td>
</tr>
<tr>
<td>OTHER CNS</td>
<td>$0.2</td>
<td>$1.6</td>
</tr>
<tr>
<td>OTHER CARDIOVASCULARS</td>
<td>-$0.6</td>
<td></td>
</tr>
<tr>
<td>ANTIBACTERIALS</td>
<td>-$0.9</td>
<td></td>
</tr>
<tr>
<td>OPHTHALMOLOGY</td>
<td>$0.2</td>
<td></td>
</tr>
</tbody>
</table>

**Source:** IQVIA, National Sales Perspectives, August 2018

Note: Top Therapy areas listed in MAT JUN 2018 non-discounted spend
Medicine Usage Trends

- Adjusted dispensed prescriptions exceeded 5.8 billion in 2017, significantly different than unadjusted due to rising 90-day scripts.
- Generics accounted for 90% of prescriptions and were dispensed 97% of the time it was possible to do so.
- Prescription growth has been driven mainly by the aging population despite slowing per capita use in those over 65 years old.
- Hypertension, Mental Health and Diabetes accounted for 55% of prescription growth over five years while pain medicines declined.
- Hypertension affects nearly one third of the US population and new guidelines are set to raise that to nearly half.
- Mental Health treatment patterns have changed very little in the past ten years but per capita usage increase by 28% since 2008.
- Prescription opioid volumes peaked in 2011 at 240 billion milligrams of morphine and have declined by 29% to 171 billion.
- The decline in the number of retail opioid prescriptions accelerated to 10.2% during 2017, while high doses declined by 16.1%.
- Opioid new therapy starts fell to 2.9 million per month at the end of 2017 while medically assisted treatment starts increased sharply.
- Type II Diabetes treatment initiation has shifted to metformin and pushed novel therapies to later lines of treatment.

Although unadjusted dispensed Rx growth appears to be flat, adjusted Rx growth is up 2.5% year to date.
Hypertension, Mental Health and Diabetes accounted for 55% of prescription growth over five years while pain medicines declined

Adjusted Dispensed Prescriptions for Selected Therapy Areas (in Millions)

In the moving annual total August 2018 period, adjusted Rx growth from the top 10 therapy areas is up 2.6% vs the decline in unadjusted Rx at -1.1%

<table>
<thead>
<tr>
<th>THERAPY AREA</th>
<th>MAT AUG 2018 RX MNs</th>
<th>MARKET SHARE</th>
<th>ABSOLUTE GROWTH MNs</th>
<th>GROWTH</th>
<th>UNADJUSTED</th>
<th>MAT AUG 2018 RX MNs</th>
<th>MARKET SHARE</th>
<th>ABSOLUTE GROWTH MNs</th>
<th>GROWTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTIHYPERTENSIVES</td>
<td>1,144</td>
<td>19.6%</td>
<td>40.6</td>
<td>3.7%</td>
<td>687</td>
<td>15.7%</td>
<td>-8.1</td>
<td>-1.2%</td>
<td></td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>524</td>
<td>9.0%</td>
<td>26.9</td>
<td>5.4%</td>
<td>403</td>
<td>9.2%</td>
<td>7.1</td>
<td>1.8%</td>
<td></td>
</tr>
<tr>
<td>PAIN</td>
<td>450</td>
<td>7.7%</td>
<td>-20.2</td>
<td>-4.3%</td>
<td>424</td>
<td>9.7%</td>
<td>-23.4</td>
<td>-5.2%</td>
<td></td>
</tr>
<tr>
<td>LIPID REGULATORS</td>
<td>448</td>
<td>7.7%</td>
<td>21.1</td>
<td>4.9%</td>
<td>251</td>
<td>5.7%</td>
<td>-3.5</td>
<td>-1.4%</td>
<td></td>
</tr>
<tr>
<td>DIABETES</td>
<td>335</td>
<td>5.8%</td>
<td>14.3</td>
<td>4.5%</td>
<td>222</td>
<td>5.1%</td>
<td>0.3</td>
<td>-0.1%</td>
<td></td>
</tr>
<tr>
<td>ANTIBACTERIALS</td>
<td>262</td>
<td>4.5%</td>
<td>-7.2</td>
<td>-2.7%</td>
<td>259</td>
<td>5.9%</td>
<td>-7.5</td>
<td>-2.8%</td>
<td></td>
</tr>
<tr>
<td>NERVOUS SYSTEM DISORDERS</td>
<td>244</td>
<td>4.2%</td>
<td>7.9</td>
<td>3.4%</td>
<td>202</td>
<td>4.6%</td>
<td>2.5</td>
<td>1.2%</td>
<td></td>
</tr>
<tr>
<td>ANTI-ULCERANTS</td>
<td>241</td>
<td>4.1%</td>
<td>6.2</td>
<td>2.6%</td>
<td>167</td>
<td>3.8%</td>
<td>-2.8</td>
<td>-1.7%</td>
<td></td>
</tr>
<tr>
<td>THYROID</td>
<td>219</td>
<td>3.8%</td>
<td>6.0</td>
<td>2.8%</td>
<td>132</td>
<td>3.0%</td>
<td>-1.6</td>
<td>-1.2%</td>
<td></td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>216</td>
<td>3.7%</td>
<td>9.6</td>
<td>4.6%</td>
<td>186</td>
<td>4.2%</td>
<td>4.9</td>
<td>2.7%</td>
<td></td>
</tr>
<tr>
<td><strong>TOP 10</strong></td>
<td><strong>4,084</strong></td>
<td><strong>70.1%</strong></td>
<td><strong>105.2</strong></td>
<td><strong>2.6%</strong></td>
<td><strong>2,934</strong></td>
<td><strong>67.1%</strong></td>
<td><strong>-32.7</strong></td>
<td><strong>-1.1%</strong></td>
<td></td>
</tr>
</tbody>
</table>

Source: IQVIA, RxInsights, October 2018
Note: Rank is based on the total MAT Aug 2018 adjusted script volume
Medicare D is the biggest contributor to growth for method of payment

[Graph showing Retail Adjusted Rx Volumes (in Millions) with a +3.4% growth from Q2 2017 to Q2 2018]

Source: IQVIA Xponent, Rolling Quarter Ending June 2018

Cash and Medicaid scripts exhibit a slight increase in Q1; no discernable pattern for Medicare D Third Party scripts exhibit a slight bump at the end of Q4/early Q1;

[Graphs showing 3 Mth. Average Rx ($M) for Third Party Combined Retail, Cash Combined Retail, Medicare Part D Combined Retail, and Medicaid Combined Retail]

Source: IQVIA, Payertrak, June 2018
The current trend through June 2018 is an increase in Discount Cards (all forms)

Methods of payment are shifting over time

Unbranded and branded generics account for 21.4% of spending year to date

86.2% of prescriptions are dispensed as unbranded generics

Unbranded and branded generics account for 21.4% of spending year to date
ANDA approvals have continued to accelerate since 2014; at the same time, withdrawals are increasing

Monthly ANDA withdrawals spiked in fiscal 2018 as companies realized that “me-too” type products, which make up a portion of the FDA backlog, are unlikely to be financially viable.

From January 2016 through March 2018, only 34% (524 of 1551) of ANDA final approvals were launched; 66% (1027 of 1551) were not launched.

The percentage of launched approvals is getting lower:
- In 2016, nearly half, 48% (298 of 624) of approvals, were launched and 52% (326 of 624) were not launched
- In 2017, only 27% (216 of 810) of approvals were launched and 73% (594 of 810) were not launched
- In the 1st quarter of 2018, only 8.5% (10 of 117) of approvals were launched
US is facing price deflation, decreased dollar growth, and concentrated buying power in generics market

- Generic dollar sales have declined for 25 consecutive months (through Jun. 18)
- 15 of top 20 generic companies had negative dollar growth over the last 12 months
  - Zydus, Amneal, Alvogen, Aurobindo, and Lannett Company all exhibited positive dollar growth in the last 12 months
- Three generic purchasers have 90% share of generic purchases
- The top 4 generic companies have 35% dollar share and 32% of TRx share
- It would only take 22 generic companies to comprise 75+% dollar share and 20 generic companies to comprise 75% Rx share

Consolidated buying power

Source: IQVIA, National Sales Perspectives and National Prescription Audit, August 2018

Patent expirations suggest continued generic opportunities in US


- Small Molecules
- Biologics
- Total Brand Losses due to LOE

Source: IQVIA Institute, Jan 2018
4 of the 12 FDA approved biosimilars have launched

<table>
<thead>
<tr>
<th>Approval Count</th>
<th>FDA Approval Date</th>
<th>Biosimilar</th>
<th>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>
<td>2015</td>
</tr>
<tr>
<td>2</td>
<td>April 2016</td>
<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>
<td>August 2016</td>
<td>Erelzi</td>
<td>Sandoz Novartis</td>
<td>Enbrel</td>
<td>Amgen</td>
<td>etanercept</td>
<td>2018</td>
</tr>
<tr>
<td>4</td>
<td>September 2016</td>
<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>Remuflexis</td>
<td>Merck &amp; Co</td>
<td>Remicade</td>
<td>Janssen (J&amp;J)</td>
<td>infliximab</td>
<td>2017</td>
</tr>
<tr>
<td>6</td>
<td>August 2017</td>
<td>Cytezno</td>
<td>Boehringer Ingelheim</td>
<td>Humira</td>
<td>Abbvie</td>
<td>adalimumab</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>September 2017</td>
<td>Mvasi</td>
<td>Amgen</td>
<td>Avastin</td>
<td>Genentech</td>
<td>bevacizumab</td>
<td>2019</td>
</tr>
<tr>
<td>8</td>
<td>December 2017</td>
<td>Ogivri</td>
<td>Mylan</td>
<td>Herceptin</td>
<td>Genentech</td>
<td>trastuzumab</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>December 2017</td>
<td>Ixifi</td>
<td>Pfizer</td>
<td>Remicade</td>
<td>Janssen (J&amp;J)</td>
<td>infliximab</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>May 2018</td>
<td>Retacrit</td>
<td>Hospira (Pfizer)</td>
<td>Epogen</td>
<td>Amgen</td>
<td>epoetin alfa</td>
<td>2018</td>
</tr>
<tr>
<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>
</tr>
<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></td>
</tr>
</tbody>
</table>

Source: FDA and GDR List of Licensed Biological Products, accessed on August 8, 2018

Market Access & Patient Out-of-Pocket Costs

• Market Access teams are currently facing 6 key issues: 1) tighter, more consolidated payer management, 2) higher patient out-of-pocket payments, 3) amplified public pressure and demand for price transparency, 4) more stringent medical benefit management, 5) increase in value based models, and 6) evolving payer landscape

• Brand prices at pharmacies, before the application of coupons, have increased by 58% since 2013, while costs for retail prescription drugs of all types have declined by 17%, as a combination of greater generic use and the use of coupons have lowered patient costs

• Patients exposure to brand costs increased by from an average $231 to an average $364, but final out-of-pocket costs were unchanged at around $30 for the past five years

• Patient out-of-pocket costs for brands and generics in total have decreased by $1.54 since 2013

• Almost 31% of prescriptions were dispensed at zero patient out-of-pocket cost while 2.5% cost more than $50

• 97.5% of prescription cost less than $50 in 2017 but for the 2.5% of prescriptions where costs were above $50, those patients paid nearly 41% of all patient out-of-pocket costs

• Patients paid $500 or more out-of-pocket when filling 3.4 million prescriptions in 2017, amounting to $5.2 billion in total

• Coupon usage has reached 18% of all branded prescriptions filled under commercial plans and 42% of specialty prescriptions

• With rising exposure to costs, the rate of prescription abandonment has increased only marginally over time
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

  ![Graph showing the number of CVS / ESI drug exclusions from 2012 to 2018](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 $US Billions)

$0 $250 $500 $750


$338 $350 $366 $383 $401 $424 $446 $469 $492 $517 $542

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

14%

CAGR: Compound Annual Growth Rate

Source: CMS National Health Expenditure Accounts Data; IQVIA Formulary Impact Analyzer (FIA); *Excludes buy-and-bill and hospital products

Changing benefit-designs and high cost-sharing impacts patient behavior & therapy consumption

- In 2013, 46% of patient out-of-pocket spend was attributed to coinsurance and deductible claims → increased to 55% in 2017

- Below demonstrates the relationship between a patient’s propensity to fill a medication and the medication’s cost for new commercially insured patient abandonment


Cost sensitivity observed for over $125

Source: IQVIA, Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption, April 2018

Note: Sample limited to new patient approvals across Top Brands which span over 25 traditional and specialty therapeutic areas
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)*

*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
On average, manufacturers receive 56% of list price for protected brand-name drugs

<table>
<thead>
<tr>
<th>Company</th>
<th>List Price Increase</th>
<th>Net Price Increase</th>
<th>Gross-to-Net Difference</th>
<th>Average Discount from List Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eli Lilly and Co</td>
<td>9.7%</td>
<td>6.0%</td>
<td>-3.7%</td>
<td>-51%</td>
</tr>
<tr>
<td>Janssen</td>
<td>8.1%</td>
<td>-4.6%</td>
<td>-12.7%</td>
<td>-42%</td>
</tr>
<tr>
<td>Merck &amp; Co</td>
<td>6.6%</td>
<td>-1.9%</td>
<td>-8.5%</td>
<td>-45%</td>
</tr>
</tbody>
</table>

Source: Drug Channels Institute analysis of company reports
Published on Drug Channels [www.DrugChannels.net] on April 5, 2018.

Multiple factors contribute to gross-to-net disparities for pharma manufacturers:
1. PBM Consolidation – ~75% of all scripts are processed by 3 PBMs
2. Risk of formulary exclusion
3. Crowded therapeutic categories
4. Generics – GDR is 90%
5. Deeper mandatory discounts – ACA Medicaid and Medicare D Coverage Gap Rebates

The average discount for Lilly, Janssen and Merck ranged from 42% to 51%

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

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

Development of Vertically Integrated Payer Models

Increased vertical integration between PBMs and Managed Care Organizations (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**

*Increased vertical integration between PBMs and MCOs leads to increased ability to manage both pharmacy and medical costs*

Source: Drug Channels, Cigna-Express Scripts: Vertical Integration and PBMs’ Medical-Pharmacy Future, March 2018

Amazon’s healthcare focus has increased this year

**January 2018**
Amazon-JPM-Berkshire Hathaway announcement

**February 2018**
Launch of Basic Care (OTC)

**June 2018**
Acquired PillPack

**July 2018**
1. Reported talks with Xealth / hospitals for a pre-fill of OTC medical supplies for patients upon discharge
2. Job posting to lead outreach for medical-products manufacturers and service providers
3. Reported acquisition talks for MedPlus

**September 2018**
B2B sales now at $10B run rate vs. $1B run rate in 2016

Source: Morgan Stanley Research, September 2018
5. Value frameworks are expanding influence, and use of value-based payment models and innovative agreements has increased

### Increase in Value Based Models

<table>
<thead>
<tr>
<th>Development of Value Frameworks</th>
<th>Recent Examples of Value-Based Payment Models</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ESMO</strong></td>
<td><strong>Entresto</strong></td>
</tr>
<tr>
<td>Magnitude of Clinical Benefit Scale</td>
<td>\textsuperscript{TM}</td>
</tr>
<tr>
<td>Drug Abacus, June 2015</td>
<td>Entresto (Sacubitril/Valsartan) Tablets</td>
</tr>
<tr>
<td>ASCO Value Framework, June 2015</td>
<td>Entresto 200mg 40mg/100mg</td>
</tr>
<tr>
<td>ICER Value Framework, Sept. 2015</td>
<td>Novartis negotiated pay-for-performance agreements with Aetna and Cigna</td>
</tr>
<tr>
<td>Value Framework</td>
<td>\hspace{2em}Cigna: Payments depend on patient hospitalization rates</td>
</tr>
<tr>
<td>Value Framework</td>
<td>\hspace{2em}Aetna: Payments linked to delivering real-world results similar to those seen in clinical trials</td>
</tr>
<tr>
<td>Evidence Blocks, Oct. 2015</td>
<td>\hspace{2em}Amgen negotiated outcomes-based agreements with Harvard Pilgrim</td>
</tr>
<tr>
<td>Value Framework, Nov. 2015</td>
<td>\hspace{2em}Amgen will pay a refund for all eligible patients who had a heart attack or stroke while on Repatha</td>
</tr>
</tbody>
</table>

Overall, in the coming years, the concept of value will become part of the fabric of US healthcare.

### Examples of the shift to value-based care

- **Accountable care organizations**: coordinated group of providers that provide high-quality care to Medicare patients and operate on a shared savings model
- **Hospital readmission reduction program** – links payments to patient readmissions within 30 days post discharge
- **Performance-based retail pharmacy networks** – tying reimbursement levels to quality metrics, such as adherence
- **DIR fees** that tie pharmacy reimbursement to a set of performance metrics
- **Incremental discounts** from drug manufacturers if drugs don’t meet or exceed certain efficacy targets
- **Population health solutions** and data/analytics tools to help providers manage costs and improve health outcomes

Source: Obtained from J.P. Morgan North American Equity Research, March 2018
Number of U.S. publicly announced outcomes-based contracts and expected increase to 2022

Chart Notes: Publicly disclosed outcomes-based contracts between manufacturers and payers
Source: IQVIA Consulting Group, Dec 2017

6. Finally, the provider landscape is constantly evolving, with continued growth in the number of IDNs and ACOs

Evolving Provider Landscape

- 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
Opioids

- Prescription opioid usage was about 22 pills or 134 morphine milligram equivalents (MMEs) per adult American in 1992 and rose to a peak of 72 pills or 1,011 MMEs in 2011. Usage has since declined to 52 pills or 676 MMEs per adult.
- High doses of prescription opioids, defined by the CDC as greater than or equal to 90 MMEs per day, declined by 16.1% during 2017, and 33.1% since January 2016.
  - The CDC has highlighted elevated risks of dependence and overdose when patients receive more than 90 MMEs per day.
- Opioid regulatory changes included:
  - Extension of prescription drug monitoring programs (PDMPs) to 49 states.
  - Changes to the FDA label.
  - Risk Evaluation and Mitigation Strategies [REMS].
  - Changing hydrocodone from scheduling III to schedule II (national in 2014).
- Seven new state laws have been passed in the past two years for a total of 24 states with restrictions on opioid prescribing: limits to number of days, MMEs or MMEs per day for new patients.

Opioid Overdoses are a Key Driver of Overdose Deaths in the US

More than 40% of all U.S. opioid overdose deaths in 2016 involved a prescription opioid.

The U.S. Pharmaceutical Market: Trends, Issues, and Outlook
PharMEDium Lunch and Learn Series

Prescription opioids have declined while overdoses increased

Comparing per capita usage in MMEs to Reported Overdose Deaths

The decline in the number of retail opioid prescriptions accelerated to 10.2% during 2017, while high doses declined by 16.1%

Monthly Retail Opioid Prescriptions and Prescriptions Dispensed at ≥ 90 MMEs per Day

Source: IQVIA National Prescription Audit, Xponent, IQVIA Institute, Mar 2018
Opioid new therapy starts fell to 2.9 million per month at the end of 2017, while medically assisted treatment starts increased sharply

**Rolling 3-Month Average of New Therapy Starts Thousands**

<table>
<thead>
<tr>
<th>Month</th>
<th>Opioids Total</th>
<th>Medically Assisted Treatment (MAT)</th>
<th>Abuse-Deterrent Forms (ADF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec 2015</td>
<td>3,381</td>
<td>44</td>
<td>7</td>
</tr>
<tr>
<td>Apr 2016</td>
<td>3,262</td>
<td>82</td>
<td>4</td>
</tr>
<tr>
<td>Aug 2016</td>
<td>3,057</td>
<td>72</td>
<td>4</td>
</tr>
</tbody>
</table>

**Source:** IQVIA National Prescription Audit, Mar 2018

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**How script opioids are obtained**

*National Survey on Drug Use and Health, 2016*

- **Given by, Bought from, or Took from a Friend or Relative, 53.0%**
  - 40.4% received from Friend or Relative for free
  - 8.9% bought from Friend or Relative
  - 3.7% took from Friend or Relative without asking
- **Got through Prescription(s) or Stole from a Health Care Provider, 37.5%**
  - 35.4% received from one Doctor
  - 1.4% received from More Than One Doctor
  - 0.7% stole from Doctor’s Office, Clinic, Hospital or Pharmacy
- **Some Other Way, 3.4%**
- **Bought from Drug Dealer or Other Stranger, 6.0%**
Impact of Substantial Costs of Prescription Opioid Abuse on Payers*1

- Opioid abusers had significantly higher annual healthcare resource utilization than nonabusers
- Leading to $15,753† in per-patient incremental annual healthcare costs

“\text{The results demonstrate the substantial costs of prescription opioid abuse borne by payers}”

Annual Healthcare Costs for Opioid Abusers: More than Twice as High as Costs for Nonabusers

<table>
<thead>
<tr>
<th></th>
<th>Opioid Abuser</th>
<th>Non Abuser</th>
</tr>
</thead>
<tbody>
<tr>
<td>$30,527</td>
<td>$14,784†</td>
<td></td>
</tr>
</tbody>
</table>

*A retrospective claims database study of commercially insured patients diagnosed with prescription opioid abuse (including dependence, abuse, and overdose/poisoning) between 2012 and 2015.


Adherence

- 90-day prescription is one way to increase adherence rates
  - Adherence rates across all patients in STAR therapy markets are ~20 points higher for patients getting a 90-day prescription in comparison to patients not receiving a 90-day prescription
- While 90-day fills are an effective way to increase adherence, geography still plays a large part in understanding adherence dynamics
- When patients are on an antidepressant, if they are adherent to their antidepressant, patients are ~65% or more likely to be adherent to their STAR therapy
  - For example, diabetes patients on antidepressants that are adherent to antidepressants have an average all-pay-type diabetes adherence rate of ~79%
  - When diabetes patients are non-adherent to antidepressants, they have an average all-pay-type diabetes adherence rate of ~48%.
90-day RxS are an effective way to increase adherence rates

Adherence rates in each market are more than 20 points higher for patients getting 90-day RxS

Adherence Rates by 90-day Utilization

- PDC ≥ 80%
- PDC < 80%

- No 90-day
- Maj 90-day
- No 90-day
- Any 90-day
- No 90-day
- Maj 90-day

Diabetes: 50% 82% 57% 85% 53% 82%
RAS Antagonists: 50% 82% 57% 85% 53% 82%
Statins: 50% 82% 57% 85% 53% 82%

Note: PDC represents the proportion of days covered for the year (365 days)

The Case for Risk Adjustment in Medication Adherence

“When used in accountability applications, performance measures that are influenced by factors other than the care received, particularly outcomes, need to be adjusted for relevant differences in patient case mix to avoid incorrect inferences about performance.”

Clinically Complex Patient
- Multiple Chronic Conditions
- Severe Primary Condition (e.g., Severe heart failure, metastatic cancer, end-stage renal disease)
- Concurrent mental and physical health problems
- Disease affects multiple organ systems
- Disease causes significant functional deficit or disability
- Condition requires treatment by multiple providers and/or specialized sites of care

Sociodemographically Complex Patient
- Poverty – Low income and/or no liquid assets
- Low levels of formal education, literacy or health literacy
- Limited English proficiency
- Minimal or no social support – not married, living alone, no help available for essential health related tasks
- Poor living conditions – homeless, no heat or air conditioning in home or apartment, unsanitary home environment, high risk of crime
- No community resources – social support programs, public transportation, retail outlets

“The Case for Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors TECHNICAL REPORT August 15, 2014,” National Quality Forum
Patients who are adherent to antidepressants are the most adherent to their STAR therapies

Non-Adherent Antidepressant Patients are the least adherent to their STAR Therapy Meds

Profile of New Medicines and Pipeline

- There were 42 New Active Substances (NAS) launched in the United States in 2017, up from 19 in 2016.
- Half of the launches were orphan drugs focused in, with 10 in cancer and 5 in nervous system disorders.
- Breakthrough designations were granted by the FDA to 19 NAS in 2017, 12 of orphan drugs, and 10 in cancer.
- There have been 80 new cancer medicines launched in the past 10 years, 52 in the last five years and 33 in the past three years.
- Increasingly, new cancer medicines are targeting smaller patient populations, with 40 of the 52 oncology NAS in the past five years being orphan drugs, compared to 14 of the 28 in the prior 5 years.
- The FDA granted orphan status to 476 drugs in 2017, and 77 orphan indications received marketing approval, both the most in a single year since the introduction of the Orphan Drug Act in 1983.
- The 2017 late phase pipeline includes 2,601 novel products, with a focus on cancer and nervous system disorders.
Ocrevus leads dollar performance, yet Shingrix is already a top 10 branded launch since launching in December 2017

2017 – Top 10 Performers (Sales through June 2018)

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Indication</th>
<th>Launch</th>
<th>Yr 1 Sales to date</th>
<th>Share of Non-Retail Spend</th>
<th>Share of Retail Spend</th>
<th>Share of Mail Spend</th>
<th>Specialty/Traditional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocrevus</td>
<td>Genentech</td>
<td>Multiple sclerosis</td>
<td>Apr-17</td>
<td>$1.8B</td>
<td>89.4%</td>
<td>0.8%</td>
<td>9.8%</td>
<td>Specialty</td>
</tr>
<tr>
<td>Mavyret</td>
<td>AbbVie</td>
<td>Hepatitis C</td>
<td>Aug-17</td>
<td>$1.2B</td>
<td>23.5%</td>
<td>28.3%</td>
<td>48.2%</td>
<td>Specialty</td>
</tr>
<tr>
<td>Spinraza</td>
<td>Biogen</td>
<td>Spinal muscular atrophy</td>
<td>Feb-17</td>
<td>$614M</td>
<td>99.9%</td>
<td>0.0%</td>
<td>0.1%</td>
<td>Specialty</td>
</tr>
<tr>
<td>Dupixent</td>
<td>Sanofi / Regeneron</td>
<td>Moderate-to-severe atopic dermatitis</td>
<td>Mar-17</td>
<td>$569M</td>
<td>5.8%</td>
<td>12.0%</td>
<td>82.1%</td>
<td>Specialty</td>
</tr>
<tr>
<td>Shingrix</td>
<td>GlaxoSmithKline</td>
<td>Shingles</td>
<td>Dec-17</td>
<td>$393M</td>
<td>28.0%</td>
<td>71.3%</td>
<td>0.7%</td>
<td>Traditional</td>
</tr>
<tr>
<td>Vosevi</td>
<td>Gilead</td>
<td>Hepatitis C</td>
<td>Jul-17</td>
<td>$346M</td>
<td>22.0%</td>
<td>27.6%</td>
<td>50.5%</td>
<td>Specialty</td>
</tr>
<tr>
<td>Eucrisa</td>
<td>Pfizer</td>
<td>Mild atopic dermatitis</td>
<td>Feb-17</td>
<td>$236M</td>
<td>2.6%</td>
<td>90.2%</td>
<td>7.2%</td>
<td>Traditional</td>
</tr>
<tr>
<td>Tremfya</td>
<td>Janssen</td>
<td>Plaque psoriasis</td>
<td>Jul-17</td>
<td>$196M</td>
<td>7.2%</td>
<td>12.4%</td>
<td>80.4%</td>
<td>Specialty</td>
</tr>
<tr>
<td>Imfinzi</td>
<td>AstraZeneca</td>
<td>NSCLC</td>
<td>May-17</td>
<td>$192M</td>
<td>98.7%</td>
<td>0.3%</td>
<td>1.0%</td>
<td>Specialty</td>
</tr>
<tr>
<td>Soliqua</td>
<td>Sanofi</td>
<td>Diabetes</td>
<td>Jan-17</td>
<td>$144M</td>
<td>3.2%</td>
<td>91.1%</td>
<td>5.7%</td>
<td>Traditional</td>
</tr>
</tbody>
</table>

Source: IQVIA, SMART Launch MVP, August 2018
* Likely understated owing to product reporting blocks

The 2017 late phase R&D pipeline remains robust with a focus on cancer and nervous system disorders

Oncology Therapeutics | 557 | 748 | Oncology Supportive Care and Next Generation Biotech | 3 | 138
Oncology Next-Generation Biotech | 53 | 38
Oncology Supportive Care | 30
Nervous System | 285
Anti-infectives & Antivirals | 164
Dermatology | 134
Arthritis/Pain | 128
Autoimmune & Non-oncology Immunology | 126
Cardiovascular | 126
Genitourinary | 107
GI | 102
Vaccines | 90
Other Next Generation Biotech | 89
Diabetes | 81
Respiratory | 49
All Others | 372
Phase 2 | 285
Phase 3 | 134
Pre-Reg/Registered | 164

Sources: IQVIA, ARIK R&D Insights, IQVIA Institute, Mar 2018
There are new treatments for unmet needs

Characteristics of 2017 New Active Substances

Outlook to 2022

- Net total spending growth will average 2-5% over the next five years while invoice growth will average 4-7%.
- Retail and mail-order spending will grow at 3-6% on an invoice basis and 1-4% on a net basis.
- Invoice price increases for protected brands are expected to average 6-9% per year through 2022.
- Net price growth for protected brands is forecast to be 1-4% through 2022.
- Growth will continue to be driven by innovation, and be offset by slower price growth and the increasing impact of patent expiries.
- Impact of losses of exclusivity are expected to be 40% greater in next five years including biosimilars.
- There remain significant uncertainties in the outlook, including the revenue that will be achieved by new products, the extent of biosimilar penetration and systemic cost savings from them.
Net total spending growth will average 2-5% over the next five years while invoice growth will average 4-7%.

Net price growth for protected brands is forecast to be 1-4% through 2022.

Protected Brand Invoice and Net Price Growth

Source: IQVIA, National Sales Perspectives, IQVIA Institute, Mar 2018
The U.S. Pharmaceutical Market: Trends, Issues, and Outlook
PharMEDium Lunch and Learn Series

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

US Telehealth visits are expected to grow between 4.2% to 7.5% from 2017 to 2022

Source: IQVIA National Disease and Therapeutics Index, Jan 2018; IQVIA Institute, Feb 2018
What themes should stakeholders recognize today?

<table>
<thead>
<tr>
<th>Pharmacies</th>
<th>Generic Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reimbursement</td>
<td>• Purchasing Alliances</td>
</tr>
<tr>
<td>• Controlled Substances</td>
<td>• Portfolio Optimization (“Shrink to Grow”) / Market Saturation</td>
</tr>
<tr>
<td>• Access to Specialty Drugs</td>
<td>• Brand /Niche Drugs (Complex Generics)</td>
</tr>
<tr>
<td>• Purchasing Alliances</td>
<td>• Generic Price Deflation</td>
</tr>
<tr>
<td>• Track and Trace</td>
<td>• Which Approvals to Launch?</td>
</tr>
<tr>
<td>• Amazon and the Cash Customers</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wholesalers</th>
<th>Brand/Specialty Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Contract Negotiations</td>
<td>• Price Increase Backlash</td>
</tr>
<tr>
<td>• Controlled Substances</td>
<td>• Becoming More Specialized / Oral Specialty</td>
</tr>
<tr>
<td>• Generic Price Deflation / Slow Brand Inflation</td>
<td>• Declining Hepatitis C and Pain Dollars</td>
</tr>
<tr>
<td>• Track and Trace</td>
<td>• Orphan Drugs</td>
</tr>
<tr>
<td>• Purchasing Alliances</td>
<td>• Copay Accumulators</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Payers</th>
<th>Consumers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Managing Specialty Drug Costs</td>
<td>• Rising Costs: High Out-of-Pocket Costs / Coinsurance / Accumulators</td>
</tr>
<tr>
<td>• Rising Oncology Costs</td>
<td>• Quality of Insurance Coverage</td>
</tr>
<tr>
<td>• Formularies Blocks and Exclusive Launches</td>
<td>• Specialty Tiers</td>
</tr>
</tbody>
</table>

Thank you

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Doug Long, Vice President, Industry Relations

Doug Long is Vice President of Industry Relations at IQVIA (formerly QuintilesIMS), the world’s largest pharmaceutical information company. IQVIA offers services to the pharmaceutical industry in over 100 countries around the globe. Doug has been with IQVIA since 1989.

His fundamental task is to help secure data for all existing and new databases supported by IQVIA, manage supplier, manufacturer & association relationships, and develop information for data partners. As direct consequence of his involvement in these areas, Doug has considerable experience with, and a unique perspective on the changing U.S. and global healthcare marketplace and pharmaceutical distribution.

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.