US Pharmaceutical Trends, Issues and Outlook for HDA

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Vice President, Industry Relations

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COVID-19: 100-Day Review and Lasting Trends in the U.S.
COVID-19 Impact

The pandemic created unprecedented change in the healthcare system.

It served as a catalyst for long overdue adoption of digital solutions.

At the same time, it impacted patient care dynamics, the outcomes of which we may not understand for years to come.

Environmental Changes
- System Adaptation
- R&D Changes
- Telehealth

Market Impact
- Stockpiling
- Healthcare Utilization
- Oncology

Industry Response
- Digital Migration
- Launch Adaptation
- Shift in Promotion

Enduring Changes
- Patient Backlog
- Commercialization Considerations
- Market Access
- Future Trends
System Adaptation: US environmental and policy changes in response to COVID-19

**Improving Access to Medicine**
- Permit early refills, expand Rx size (90 day) and remove prior authorizations
- Waive charges for at home delivery and permit use of out-of-network pharmacies
- Relax requirements for REMS and adverse event reporting
- Pharma expands patient assistance programs and increases production of high demand drugs

**Expand Telehealth**
- Reimburse telehealth at the same rate as in person
- Permit telehealth for first-time visits
- Waive cost sharing for all telehealth visits
- Expand approved technologies and audio only visits

**Expand System Capacity**
- Permit licensed physicians in good standing to work across state borders
- Allow states to mobilize inactive physicians into the workforce
- Provide care for patients in non-hospital centers (e.g. ambulatory surgery centers, hotels, dormitories)

**Improve Access to Healthcare**
- Reopening of healthcare exchanges in many states
- Approvals of Medicaid waivers to improve access and care
- Cover the cost of all COVID-19 testing and treatments
- New programs are established to provide deep discounts on drugs to recently uninsured patients

Sources: Kaiser Health Network - Telemedicine Surges, Fueled By Coronavirus Fears And Shift In Payment Rules, CMS updates, CVS updates, CVS and Walgreens revamp, Walmart updates, Kroger updates, RiteAid updates

Impact of the first 100 days of COVID-19
**R&D: Clinical trial continuity accelerated deployment of innovative strategies, many of which are likely to remain in place**

<table>
<thead>
<tr>
<th>Pre-COVID</th>
<th>Post-COVID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex, inflexible protocols</td>
<td>Protocol Simplification</td>
</tr>
<tr>
<td></td>
<td>Protocols that reduce patient burden and have built-in option to incorporate remote study approaches; leverage common protocols on basket studies</td>
</tr>
<tr>
<td>Primarily on-site operations</td>
<td>Remote Site Monitoring/Source Data Verification &amp; Remote Visits</td>
</tr>
<tr>
<td></td>
<td>Shift towards remote Site Selection and Initiation Visits with remote site support and increased hybrid of onsite/remote (at home) patient visits</td>
</tr>
<tr>
<td>Traditional randomized trials</td>
<td>Novel Trial Design / Hybrid Studies</td>
</tr>
<tr>
<td></td>
<td>Master/Platform protocols, real world comparator arms, merging of real world modalities and early phase engagement and planning</td>
</tr>
<tr>
<td>Site-based study procedures</td>
<td>Digitization of Study Procedures</td>
</tr>
<tr>
<td></td>
<td>Further evolution of digital patient options for clinical trial data collection such as ePRO, vitals, spirometry, ocular exam, ECGs, glucose monitoring, oximetry, etc.</td>
</tr>
<tr>
<td>Limited patient communication</td>
<td>Digital Patient Engagement</td>
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<tr>
<td></td>
<td>Increased use of digital communications to keep patients informed and engaged while reducing burden and increasing retention</td>
</tr>
</tbody>
</table>

Impact of the first 100 days of COVID-19
Telehealth: Providers and patients quickly adapted by adopting telehealth at unprecedented levels

<table>
<thead>
<tr>
<th>Learnings From COVID-19</th>
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<tbody>
<tr>
<td>Significant variability by prescriber specialty</td>
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<tr>
<td>Therapeutic area matters</td>
</tr>
<tr>
<td>Lower productivity of new-to-brand</td>
</tr>
<tr>
<td>Patient demographics influence uptake</td>
</tr>
<tr>
<td>Technology remains a barrier</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Considerations for Future Uptake</th>
</tr>
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<tbody>
<tr>
<td>Reimbursement Dynamics</td>
</tr>
<tr>
<td>EMR Integration</td>
</tr>
<tr>
<td>Ease of Billing</td>
</tr>
<tr>
<td>Access to Patient Tools &amp; Financial Assistance</td>
</tr>
<tr>
<td>Technology – Platform, Bandwidth, Accessibility</td>
</tr>
<tr>
<td>Therapeutic Area and Disease State</td>
</tr>
<tr>
<td>Therapy Mode of Administration</td>
</tr>
<tr>
<td>Socioeconomic and Demographic</td>
</tr>
<tr>
<td>Need for Diagnostic and/or Procedure</td>
</tr>
</tbody>
</table>
**Stockpiling: Faced with stay-at-home orders, patients stockpiled medications in anticipation of extended restrictions**

<table>
<thead>
<tr>
<th>Stockpiling Period Indicators</th>
<th>Market Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Sharp increases in retail prescriptions</td>
<td><strong>-2.0%</strong> Increase in share of retail prescriptions 3 months or greater</td>
</tr>
<tr>
<td><strong>2</strong> Rising continuing Rx vs. declining NBRx</td>
<td><strong>-13%</strong> Decrease in yearly NBRx through mid-year</td>
</tr>
<tr>
<td><strong>3</strong> Increasing rejects for early fills &amp; quantity limits</td>
<td><strong>+5%</strong> YTD TRx after starting the year +2.0% through 2/28/20</td>
</tr>
<tr>
<td><strong>4</strong> Patients shifts from retail to mail order</td>
<td><strong>+5%</strong> Increase in share of retail prescriptions 3 months or greater</td>
</tr>
<tr>
<td><strong>5</strong> Rise in extended days supply for retail Rx</td>
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<tr>
<td><strong>6</strong> Improvement in patient adherence rates</td>
<td></td>
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</tbody>
</table>

Impact of the first 100 days of COVID-19  

Sources: IQVIA NPA, NPA New to Brand, 2019-2020
Utilization: Ordinary healthcare trends have all been shocked by COVID and none have fully normalized

Patient Interactions
- Office and institutional visits immediately declined and were filled in part by telehealth (TH) interactions
- TH usage remains a diagnosing alternative in the right circumstance
- While TH growth has been significant, there remains a gap in interactions

Prescriptions
- Both mail and retail prescriptions were immediately stockpiled during the initial weeks
- Subsequently, demand has remained low as provider visits have not recovered
- YTD Rx trends are running - ~2% below 2019 levels

90 Day Retail Fills
- Retail pharmacies moved to quickly ensure patients were provided extended supplies of Rx
- Since the beginning of COVID-19 the proportion of 90 day Rx has increased ~5%

NBRx
- Reduction in office visits has led to decreases in NBRx
- Without new patient flows derived from NBRx, continuing prescriptions remain flat
- YoY NBRx are below 2019 volumes by ~13%

Impact of the first 100 days of COVID-19
Sources: IQVIA NPA, NPA New to Brand, 2019-2020, Medical Claims
Oncology: Early guidance shaped the market as patient treatments continued with practices designed to protect patients

**Early Guidance***

- **Low Risk** or cancer progression (all ages) – Delay treatment
- **Intermediate Risk** of cancer progression (>50 years of age) – Weigh options/delay treatment
- **High Risk** of cancer progression (all ages) – Treat as usual

**Changes in Oncology Healthcare Patterns**

- **Diagnostic tests dropped** (e.g. mammograms) to 90% at their lowest
- **Referrals fell** for many tumors (i.e. down 20% for breast cancer)
- **New diagnoses declined** although not as dramatically as other TAs
- **Oral drugs increased demand** (13% over baseline at the peak)
- **Telehealth adoption low** with hem/onc; treatments and diagnoses less amenable to virtual visits
- **Safety concerns caused**
  - Minor shift away from immuno-modulatory agents (-5% for PD-1/PD-L1 class)
  - Sustained declines for in-person detailing but with a corresponding increase in digital engagement

Sources: https://annals.org/aim/fullarticle/2764022/war-two-fronts-cancer-care-time-covid-19; *IQVIA extrapolation based on guidance considerations from Annals of Internal Medicine, IQVIA Oncology medical and pharmacy claims, IQVIA Weekly Sales Perspective (WSP), IQVIA BrandImpact HCP Network (n≈3500 unique HCPs)
Digital: COVID-19 has disrupted traditional healthcare and accelerated new digital options

- **Telehealth**: Allows remote patient-clinician contact and care
- **Remote Detailing**: Enables life sciences teams to interact with healthcare professionals remotely
- **Digital Therapeutics**: Deliver therapeutic interventions through the use of software
- **Remote Patient Monitoring**: Allows physicians to monitor patient conditions outside traditional healthcare settings
- **Remote Clinical Site Monitoring**: Allows site monitoring activities to be done remotely which were previously conducted in person

Impact of the first 100 days of COVID-19
Promotion: In-person engagement and scientific meetings were disrupted and have leveraged digital channels to re-engage

Remote detailing
- 500% increase in remote detailing
- Of the technology platforms, Zoom was the most popular even though it lacked compliance
- 25% of pharma still not satisfied with remote detailing quality
- While effective, a gap remains in the form of coupon, sampling, and patient education

Virtual meetings
- 2/3 of conferences have either been postponed or made virtual
- Considerations for digital engagement
  - Leverage social media to entertain during breaks and support virtual poster sessions through
  - Incorporate interactive content to allow HCPs to engage directly with data

Redeployment
- In-person fell 90% by April and have risen slowly in June to 30% of baseline
- Return-to-field dependent on state-by-state and local policy variability
- Safety concerns are dictating the return as field forces are considered potential vectors of infection
- HCP preference needs to be considered to confirm return-to-field
- Tailor content and channels to digital media

Sources: IQVIA BrandImpact HCP Network (n~3600 unique HCPs), Source: IQVIA Post COVID-19 Field Force Restart Readiness Survey (n=26 Pharma Execs), Source: IQVIA Return to Field Survey, June 2020 (n=168 field-based resources), Larvol, Status of Scientific Conferences 2020, (n=1112 conferences)
Launch: While approvals have not slowed, the pandemic has changed the launch environment

- **Trikafta**:  
  - Benefits of launch outweighed risks to target patients
- **Tepezza**:  
  - Approved for rare debilitating eye disease  
  - Pre-launch efforts drove awareness  
  - Facilitated access to home infusion

- **Zeposia**:  
  - Requires recent lab workups for complete blood count, ECG, and liver function  
  - Upward titration needed to reach maintenance dosage
- **Palforzia**:  
  - Patient initiation requires 2 consecutive days in the office and then every two weeks thereafter

- **Nurtec**:  
  - Oral in a crowded injectable class  
  - Collaborated with telehealth network
- **Nexletol**:  
  - Extensive market education required to change treatment protocol  
  - Strong virtual engagement effort

Sources:  
- Aimmune earnings call, Tepezza corporate update, Nexletol corporate update, Nexletol company update 2
Many unemployed workers and their dependents may become eligible. In non-expansion states, patients may become uninsured.

Historically gains in employment have not reversed shifts to Medicaid.

Downward pressures due to changes in payer mix, increased use of patient assistance programs and expanded 340b utilization.

Loss of commercial enrollees and COVID-related costs could lead to premium increases in 2021. Payers may recoup losses via rebating.

Commercialization: Current market dynamics introduce new complexities to product uptake and success

Impact of the first 100 days of COVID-19

- Easy to engage patient population
  - Simple
  - Complex: Challenges to engage (e.g., elderly, pediatric)

- Target population is easily reachable (urban/suburban)
  - Simple
  - Complex: Target population is difficult to reach (rural)

- Therapeutic area has high Dx/Tx via telehealth
  - Simple
  - Complex: Therapeutic area has low Dx/Tx via telehealth

- No diagnostic or labs required
  - Simple
  - Complex: Diagnostic or labs required

- No/Low OOP, no PA/SE
  - Simple
  - Complex: Complex Reimbursement

- No safety monitoring
  - Simple
  - Complex: Safety monitoring needed

- Oral
  - Simple
  - Complex: Infused

- No need for disease education
  - Simple
  - Complex: Need for disease education

Impact of the first 100 days of COVID-19
Patient Backlog: The disruption in the patient journey caused by missed or delayed interactions will impact patient outcomes

- **Patient Interactions**
  - Patient journeys are reinforced by ongoing interaction with providers
  - Patient visits declined 70% from ordinary levels disrupting timely diagnoses & regular health monitoring

- **Lab Services**
  - Decline in labs due to fewer provider engagements
  - Leads to delayed or missed treatment protocols
  - Impacts prescribing as different medications protocols may vary by condition severity as determined by the lab work

- **Elective Surgeries**
  - Halted in many states preserving resources for COVID emergency
  - Elective surgeries lower as labs/visits limit patient pipeline
  - Procedures will not fully return without labs/engagement restored

- **Treatment Backlog**
  - Decreased patient interactions leads to a backlog of untreated or undiagnosed patients
  - Patient journeys have been disrupted by not being treated or delayed treatment
  - Visits to doctors are forecast to be 1B (~20%) lower than expected

Patient interactions declined by 70%
Lab services have been ~70% lower than normal
Procedures were down ~90% below normal levels
Patient outcomes will be impacted for rest of 2020 and beyond

Impact of the first 100 days of COVID-19
Sources: IQVIA Real World Data, Medical Claims, 2019-2020, Custom Methodologies
Enduring trends: The pandemic will have many lasting effects on healthcare

New Commercial Models
Therapeutic Partnerships
Portfolio Prioritization
Pressure on Gross-to-Net
Shifts in Payer Mix
Increased Patient Assistance
Policy Changes
Remote Detailing
Virtual Meetings
Hybrid Trials
Remote Patient Monitoring
Telehealth
Alternate Sites of Care
Digital Therapeutics
Healthcare Utilization
Weekly Medical Claims: Office, Institutional, Telehealth vs. Baseline

Data for latest week date controlled against prior periods; estimates have been applied to reflect anticipated late-adjudicated claims based on historical rates

Total Telehealth Claims Through W/E 10/09 vs. Baseline Period
Weekly Diagnosis Visits Through W/E 10/09 Compared to Baseline Period

Source: IQVIA: Medical Claims Data Analysis, 2020; Baseline = Average of claims for period W/E 1/10/2020-2/28/2020,
Estimated amounts for latest weeks applied based on likely claims still to be received due to data latency or claim processing delays; See Appendix for further details

COVID-19 Market Impact - w/e Oct 9, 2020
Institutional & Office Medical Claims: Weekly and Cumulative YoY Growth

COVID-19 Market Impact - w/e Oct 9, 2020

Data for latest week date controlled against prior periods; estimates have been applied to reflect anticipated late-adjudicated claims based on historical rates


Estimated amounts for latest weeks applied based on likely claims still to be received due to data latency or claim processing delays; See Appendix for further details
Telehealth Medical Claims: Weekly YoY Growth

Year over Year Growth – Telehealth Claims Across Time Aligned Weeks


Estimated amounts for latest weeks applied based on likely claims still to be received due to data latency or claim processing delays; See Appendix for further details

Data for latest week date controlled against prior periods; estimates have been applied to reflect anticipated late-adjudicated claims based on historical rates

COVID-19 Market Impact - w/e Oct 9, 2020
## NBRx Productivity: Face to Face vs. Telehealth Activities by Specialties

### NBRx Per Patient Visit

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Allergists</td>
<td>0.99</td>
<td>0.99</td>
<td>0.79</td>
<td>-20%</td>
</tr>
<tr>
<td>Dermatologists</td>
<td>1.18</td>
<td>1.18</td>
<td>0.91</td>
<td>-23%</td>
</tr>
<tr>
<td>PCP</td>
<td>0.97</td>
<td>0.97</td>
<td>0.71</td>
<td>-27%</td>
</tr>
<tr>
<td>Pulmonologists</td>
<td>0.88</td>
<td>0.89</td>
<td>0.61</td>
<td>-31%</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>1.16</td>
<td>1.15</td>
<td>0.79</td>
<td>-32%</td>
</tr>
<tr>
<td>Ob/Gyn</td>
<td>1.14</td>
<td>1.14</td>
<td>0.78</td>
<td>-32%</td>
</tr>
<tr>
<td>Gastroenterologists</td>
<td>1.06</td>
<td>1.06</td>
<td>0.72</td>
<td>-32%</td>
</tr>
<tr>
<td>Rheumatologists</td>
<td>0.53</td>
<td>0.53</td>
<td>0.35</td>
<td>-34%</td>
</tr>
<tr>
<td>Cardiologists</td>
<td>0.64</td>
<td>0.64</td>
<td>0.41</td>
<td>-36%</td>
</tr>
<tr>
<td>Neurologists</td>
<td>0.58</td>
<td>0.58</td>
<td>0.36</td>
<td>-38%</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>0.46</td>
<td>0.46</td>
<td>0.27</td>
<td>-41%</td>
</tr>
<tr>
<td>Ophthalmologists</td>
<td>1.32</td>
<td>1.33</td>
<td>0.78</td>
<td>-41%</td>
</tr>
<tr>
<td>Endocrinologists</td>
<td>0.57</td>
<td>0.58</td>
<td>0.33</td>
<td>-43%</td>
</tr>
<tr>
<td>Urology</td>
<td>0.62</td>
<td>0.62</td>
<td>0.35</td>
<td>-43%</td>
</tr>
</tbody>
</table>

### Potential Drivers of Difference

- Patient mix skews towards existing patients replacing office visits with telehealth
- Willingness to initiate new therapy remotely
- Lack of diagnostics such as vitals and labs are impeding diagnosis of new conditions
- Prescribers are reporting spending less time on a telehealth call with patients which may reduce NBRx opportunity
- Many offices have now adapted protocols to safely see patients enabling the preference to NBRx office prescribing

Source: NPA New To Brand (NPA NTB); Medical Claims analysis; 2020; Custom analysis
Evaluation of medical claims visit with same patient/prescriber combination occurring as NBRx within 2 weeks of medical claim service date

COVID-19 Market Impact - w/e Oct 9, 2020
Cumulative COVID Period Prescription: NBRx vs. TRx Growth by Specialty

YoY Cumulative NBRx/TRx Growth by Selected Specialty
2019 vs. 2020 COVID Time Aligned Weeks


COVID-19 Market Impact - w/e Oct 9, 2020
Elective Procedures: Weekly YoY and Cumulative Growth

Year over Year Growth – Elective Procedure Across Time Aligned Weeks

Estimated amounts for latest 2 weeks applied based on likely claims still to be received due to data latency or claim processing delays; Elective procedures based on IQVIA custom analysis; Data includes claims from inpatient and outpatient sites of care; See Appendix for further details

COVID-19 Market Impact - w/e Oct 9, 2020
Where are we now?
The Non-Retail channel has been affected the most by COVID-19

### Growth (%) of Sales

<table>
<thead>
<tr>
<th>Total Market (Retail, Non-Retail and Mail)</th>
<th>Retail and Mail</th>
<th>Non-Retail</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.6% 1.9% 6.3% 5.7% 3.8% 3.7%</td>
<td>5.0% 0.3% 4.6% 5.0% 4.1% 4.6%</td>
<td>3.6% 6.0% 10.6% 7.2% 2.9% 1.6%</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>4.6%</td>
<td>5.0%</td>
<td>3.6%</td>
</tr>
<tr>
<td>1.9%</td>
<td>0.3%</td>
<td>6.0%</td>
</tr>
<tr>
<td>6.3%</td>
<td>4.6%</td>
<td>10.6%</td>
</tr>
<tr>
<td>5.7%</td>
<td>5.0%</td>
<td>7.2%</td>
</tr>
<tr>
<td>3.8%</td>
<td>4.1%</td>
<td>2.9%</td>
</tr>
<tr>
<td>3.7%</td>
<td>4.6%</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, August 2020
Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail
Hospitals and Long Term Care have been most affected by COVID-19 while Home Health Care is booming!

<table>
<thead>
<tr>
<th>Year</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>MAT AUG 2020</th>
<th>YTD AUG 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinics</td>
<td>11.9%</td>
<td>11.2%</td>
<td>13.8%</td>
<td>12.0%</td>
<td>8.3%</td>
<td>7.2%</td>
</tr>
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<table>
<thead>
<tr>
<th>Year</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>MAT AUG 2020</th>
<th>YTD AUG 2020</th>
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</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>2.4%</td>
<td>-0.6%</td>
<td>7.0%</td>
<td>1.5%</td>
<td>-6.8%</td>
<td>-9.3%</td>
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<table>
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<tr>
<th>Year</th>
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<th>2018</th>
<th>2019</th>
<th>MAT AUG 2020</th>
<th>YTD AUG 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Health Care</td>
<td>34.5%</td>
<td>11.1%</td>
<td>15.6%</td>
<td>16.5%</td>
<td>17.8%</td>
<td>-3.0%</td>
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</tr>
</thead>
<tbody>
<tr>
<td>Other Non-Retail</td>
<td>1.8%</td>
<td>1.2%</td>
<td>5.5%</td>
<td>3.5%</td>
<td>-3.6%</td>
<td>-14.6%</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, August 2020
Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail
Mail has strong dollar growth because of Specialty products

**Growth (%) of Sales**

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<tbody>
<tr>
<td>Retail</td>
<td>3.6%</td>
<td>-2.2%</td>
<td>2.0%</td>
<td>2.3%</td>
<td>1.8%</td>
<td>2.2%</td>
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<tbody>
<tr>
<td>Mail</td>
<td>7.4%</td>
<td>5.4%</td>
<td>8.7%</td>
<td>9.1%</td>
<td>7.4%</td>
<td>8.1%</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, August 2020
Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail
Branded growth has weakened but still growing and unbranded generics are recovering

Growth (% of Sales)

<table>
<thead>
<tr>
<th>Year</th>
<th>MAT AUG 2020</th>
<th>YTD AUG 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>6.0%</td>
<td>5.2%</td>
</tr>
<tr>
<td>2017</td>
<td>4.7%</td>
<td>5.3%</td>
</tr>
<tr>
<td>2018</td>
<td>9.0%</td>
<td>7.6%</td>
</tr>
<tr>
<td>2019</td>
<td>6.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>2019</td>
<td>6.4%</td>
<td>1.9%</td>
</tr>
<tr>
<td>2016</td>
<td>-3.9%</td>
<td>-4.6%</td>
</tr>
<tr>
<td>2017</td>
<td>-11.4%</td>
<td>-5.7%</td>
</tr>
<tr>
<td>2018</td>
<td>-11.4%</td>
<td>-5.7%</td>
</tr>
<tr>
<td>2019</td>
<td>MAT AUG 2020</td>
<td>YTD AUG 2020</td>
</tr>
<tr>
<td>2016</td>
<td>Unbranded Generics</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>-1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>2018</td>
<td>-5.7%</td>
<td>-0.4%</td>
</tr>
<tr>
<td>2019</td>
<td>-3.3%</td>
<td>-0.8%</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, August 2020
Note: Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail
Specialty growth is outpacing traditional product growth and now has ~49% share of total non-discounted spend in the total market.

In MAT August 2020, specialty spend grew by 8.8% while traditional decreased 0.8%.

Source: IQVIA, National Sales Perspectives, August 2020
Just three therapy areas are responsible for over 60% of positive absolute growth in the US and 40% of recent launches.

*US total market absolute growth, $Bn*

### Top-10 therapy area growth ($Bn)

<table>
<thead>
<tr>
<th>Therapy Area</th>
<th>5-year absolute growth</th>
<th>1-year absolute growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMUNOLOGY</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>ANTICOAGULANTS</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>ANTIDIABETICS</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>MS</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>PAIN</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>OTHER CV</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HIV</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>HIV</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### 2017-19 NAS launches

- **ONCOLOGICS**: 34
- **ANTIDIABETICS**: 2
- **AUTOIMMUNE**: 7
- **RESPIRATORY**: 2
- **HIV**: 3
- **ANTICOAGULANTS**: 0
- **MS**: 2
- **MENTAL HEALTH**: 0
- **PAIN**: 4
- **NERVOUS SYSTEM**: 1

---

IQVIA NSP, Rx + OTC insulins only, Jun 2020 MAT; Notes: NAS = New active substance (recent launches with commercially valuable sales)
## Immunology, Oncology, and HIV lead specialty absolute value growth

### Absolute Value Growth for Top Specialty Therapy Areas

<table>
<thead>
<tr>
<th>Therapy Area</th>
<th>Absolute Value Growth (US$ BNs)</th>
<th>∆Change from MAT JUN 2019 to MAT JUN 2020</th>
<th>∆Change from 2015 to MAT JUN 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMMUNOLOGY</td>
<td>$11.5</td>
<td></td>
<td>$44.9</td>
</tr>
<tr>
<td>ONCOLOGICS</td>
<td>$6.8</td>
<td></td>
<td>$34.2</td>
</tr>
<tr>
<td>HIV ANTIVIRALS</td>
<td>$2.2</td>
<td></td>
<td>$2.3</td>
</tr>
<tr>
<td>MULTIPLE SCLEROSIS</td>
<td>-$0.1</td>
<td></td>
<td>-$1.2</td>
</tr>
<tr>
<td>VIRAL HEPATITIS</td>
<td>-$1.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POLYVAL IMMUNOGLOBULINS IV&amp;IM</td>
<td>$0.2</td>
<td></td>
<td>$0.2</td>
</tr>
<tr>
<td>HEMATOPOIETIC GROWTH FACTORS</td>
<td>-$0.4</td>
<td></td>
<td>$0.4</td>
</tr>
<tr>
<td>MENTAL HEALTH</td>
<td>-$0.1</td>
<td></td>
<td>$0.3</td>
</tr>
<tr>
<td>ALL OTHER RESPIRATORY</td>
<td>$1.0</td>
<td></td>
<td>$1.6</td>
</tr>
<tr>
<td>RESPIRATORY AGENTS</td>
<td>$0.4</td>
<td></td>
<td>$2.2</td>
</tr>
<tr>
<td>BLOOD COAGULATION</td>
<td>$0.3</td>
<td></td>
<td>$3.3</td>
</tr>
<tr>
<td>PAIN</td>
<td>$0.9</td>
<td></td>
<td>$2.6</td>
</tr>
<tr>
<td>All Others</td>
<td>$1.8</td>
<td></td>
<td>$2.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$12.4</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Sales Perspectives, June 2020

Note: Top therapy areas ranked on MAT December 2019 non-discounted spend

*For Client's internal use only*
In 2020, anti-diabetics, anticoagulants, and respiratory led traditional absolute value growth while nervous system disorders, pain and cardiovasculars contributed most to value decline

Absolute Value Growth for Top Traditional Therapy Areas

Source: IQVIA, National Sales Perspectives, June 2020
Note: top therapy areas ranked on MAT September 2019 non-discounted spend
*For Client’s internal use only
Unadjusted Rx growth for MAT and YTD July is still negative, but adjusted growth is higher, at 3.3% for MAT July and 2.5% year to date.

**Growth (%) of Dispensed Rx**

### Unadjusted Rx

<table>
<thead>
<tr>
<th>Year</th>
<th>MAT AUG 2020</th>
<th>YTD AUG 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>2.3%</td>
<td>-1.0%</td>
</tr>
<tr>
<td>2017*</td>
<td>-0.6%</td>
<td>-0.9%</td>
</tr>
<tr>
<td>2018</td>
<td>0.1%</td>
<td>-2.2%</td>
</tr>
<tr>
<td>2019</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Adjusted Rx

<table>
<thead>
<tr>
<th>Year</th>
<th>MAT AUG 2020</th>
<th>YTD AUG 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>3.9%</td>
<td>-7.0%</td>
</tr>
<tr>
<td>2017*</td>
<td>2.7%</td>
<td>-5.0%</td>
</tr>
<tr>
<td>2018</td>
<td>3.2%</td>
<td>-3.0%</td>
</tr>
<tr>
<td>2019</td>
<td>3.3%</td>
<td>-1.0%</td>
</tr>
<tr>
<td>2020</td>
<td>2.5%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

Source: IQVIA, National Prescription Audit & RxInsight, July 2020; Retail, Mail, and LTC limited to Rx and OTC Insulins

*Note: Declines between 2016 and 2017 are due to VRAF enhancement from 2017 onwards.*
88.5% of prescriptions are dispensed as unbranded generics for 2020 (adjusted)

Unbranded and branded generics account for 19.1% of spending in 2020
On an adjusted basis current trends have been running positive, the only exceptions have been holiday weeks.

Data Source: IQVIA Xponent®
On an adjusted basis the rolling 4 week average trends are running above 2019 while the unadjusted trends fluctuate weekly.
During the most recent 4 week rolling average, Adjusted Rx’s have surpassed Pre-COVID volumes while Unadjusted Rx’s are running slightly behind.

Notes: Data is based on Adjusted Rx’s, Current Trends are defined as the weeks ending 6/12/20 through 9/25/20, the 4 Wk Avg is based on the most current 4 weeks rolling average volumes.
Acute and new scripts are now running ahead of 2019 on an adjusted rolling 4 week average

All Rx’s shown in Millions

Data Source: IQVIA Xponent®
New to Therapy patient counts dropped steeply after the stockpiling and have not recovered as quickly as they fell.

Note: All Patient Counts are displayed in Millions.
As a percent of total Adj. Rx’s, Discount Cards and Med D have been running above 2019 levels while Medicaid has just surpassed 2019 levels.
Supply Chain Dynamics & Vaccines
COVID-19 is undoubtably a major supply chain disruptor

Real implications for the supply chain affect multiple points to be discussed

**Corporate HQ**
Responsible for understanding their supply chain, and COVID-19 treatment capacity

**Patient**
Patient demand for e-scripts or home delivery

**Pharmacies**
Hospital/retail/chain/independent resilience to demand peaks and troughs. Notably impacted by location

**Wholesalers**
Safety stock, or stockpiling key medicines, PPE, vaccination, home delivery all become altered

**API**
Location of raw material, and visibility to volumes

**Finished dose**
Collation of raw materials and manufacturing (stockpiling)

**Packaging**
Often separate sites to package finished medicines

**Logistics**
Disruption to commercial airline industry, and cross-border travel

**Key:**
High to low impact

IQVIA Global Supplier & Association Relations Perspectives, June 2020
Focus towards international availability of API and logistics

There are risks that the required supply will not be problematic, now and for the future

- China manufacturing is **coming back on line**
  - Slipped by 10% to 20% during early days of outbreak

- India **lock-down and export ban affect supply**
  - 21-day lock down; essential services including pharmaceutical manufacturing are allowed to continue
  - Ban on export of 26 APIs, including paracetamol, in March; mostly lifted in April

- **Air freight shortage** limits access to medicines
  - Medicines for Europe have called for the EU to make use of grounded commercial aircraft for drug supply
  - In the US cargo capacity is less than 50% of normal. Rates that are 4-6X normal rates

- Suppliers **reduce employees per shift** to ~50 – 65% of historic levels

- Manufacturers are seeing **increased costs** on raw materials and transportation

---

### Location of Generic (Gx) Manufacturing Facilities (provided by AAM)

![Graph showing the distribution of active ingredients and finished doses from different locations.](image)

**Active ingredients**

- **US**: 31%
- **China**: 31%
- **India**: 17%
- **Rest of world**: 8%
- **48% from India and China**

**Finished doses**

- **US**: 40%
- **China**: 32%
- **India**: 17%
- **Rest of world**: 8%
- **40% from India and China**

---

Supply chain is now a recognised pillar of medical innovation

Wholesalers and pharmacies are national / regional strategic assets to the system

Pre-COVID19 model
• Limited visibility to the flow of goods within the system
• Limited public awareness, and low perception

Post-COVID19 model
• Strategic asset to companies and governments
• Increasing transparency + centralised data collection
• Top-tier government priority

• Most Governments have implemented key measures
  • Approving electronic prescriptions
  • Essential status to wholesaler operations
  • Economic Incentives
• National Critical drugs list
• Stockpiling Strategy for future pandemic
• Measures to improve transparency
• Policy pressure to in-source/diversify manufacturing
• Higher security in delivery results in higher cost
• Unclear whether these initiatives will maintain momentum or fade as crisis fades
Security of supply chains has been elevated to a strategic priority

COVID-19 has exposed the fragility of global supply chains

Senator Hawley Demands Answers from FDA as Coronavirus Threatens Drug Shortage

Monday, February 24, 2020
Today U.S. Senator Josh Hawley is sending a letter to U.S. Food and Drug Administration Commissioner Dr. Stephen Hahn demanding answers for how the FDA will mitigate potential drug and medical device shortages. The letter comes after it was reported that the recent uptick of

Coronavirus (COVID-19) Supply Chain Update

For Immediate Release: February 27, 2020
Statement From: Commissioner of Food and Drugs - Food and Drug Administration

EMA announces measures to manage drug shortages as result of COVID-19

An EU Executive Steering Group will discuss how to address the impact of medicine shortages caused due to COVID-19 across the EU.

COVID-19 update: coronavirus and the pharmaceutical supply chain

With concerns rising about medicine availability during the global COVID-

Paratek Pharmaceuticals Announces Initiation of Funding from BARDA for Security Requirements and U.S. Onshoring of the Manufacturing Supply Chain for NUZYRA®

BREAKING NEWS
Paratek Gets BARDA Funding for NUZYRA Supply
To support the development and manufacturing activities of NUZYRA for the treatment of pulmonary anthrax

Sanofi to create new industry leading European company to provide active pharmaceutical ingredients (API*)

Trump vow to bring pharma firms 'back home'

US trade adviser seeks to replace Chinese drug supplies

Nevarro says coronavirus is ‘wake-up call’ to create American pharmaceutical supply chain
This means that manufacturing supply chains are at a crossroads

Technological advances become critical than economies of scale for future manufacturing

- **Resilience**
  Shorter supply chains are more resilient to disturbances

- **Pricing stability**
  Investment into quality and stability as advantage for P&MA focus of payers post-COVID

- **Quality**
  Higher manufacturing standards improve reputation and reduce chance operations are disrupted

- **Cost**
  Higher budget pressure post-COVID may demand increased cost-efficiency

- **Renewed competition**
  ‘China +1’ policies from India, and the impact of US and EU defense (e.g. Sanofi, March 2020)

- **Established structures**
  Reactivation of existing supply chains less cost intense that creating new ones

- **Evolution**
  Indian & Chinese players pressured to improve quality & resilience to protect business interests

Source: IQVIA European Though Leadership; FirstWordPharma
Weekly Vaccine Utilization: Selected Pediatric vs. Adult Weekly Sales

Weekly Volume Unit Clinic Sales for Selected Pediatric Vaccines* Through W/E 10/9

Weekly Volume Unit Clinic Sales for Selected Adult Vaccines* Through W/E 10/9

YoY Weekly Growth % – Pediatric Vaccine Market Basket

YoY Weekly Growth % – Adult Vaccine Market Basket

Source: IQVIA Weekly Sales Perspectives (WSP), February – September 2020; Note: Data reflects sales to clinic channel as defined by IQVIA – No methodology has been applied to determine VACCINE USE BY AGE

COVID-19 Market Impact - w/e Oct 9, 2020
Flu vaccinations administered at Retail pharmacies are up 64% season to date
Considerations for COVID-19 vaccine distribution center on the profiles of the vaccines in development

Key considerations for distributors of COVID-19 vaccines

1.) Vaccine profiles
   • How do the vaccines compare?
   • What characteristics make distribution complex?

2.) System challenges
   • What routes will certain vaccines take to reach patients?
   • How will the system cope with flu and COVID-19 distribution?

3.) Strategic planning
   • What are the major success factors for distribution?
   • What uncertainties remain?
   • Which clinical milestones are strong indicators?
Vaccine profiles differ most on storage needs which make distribution expensive and complex.

<table>
<thead>
<tr>
<th>Developer</th>
<th>Vaccine candidate</th>
<th>Platform</th>
<th>Dosing</th>
<th>Preclin</th>
<th>P1</th>
<th>P2</th>
<th>P3</th>
<th>P4</th>
<th>Manufacturer target /yr</th>
<th>Temp. sensitivity</th>
<th>Standard refrigeration</th>
<th>Storage (c)</th>
<th>Strategy</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxford / AZ</td>
<td>AZD1222</td>
<td>Viral vector, non-replicating attenuated adenovirus (chimp origin)</td>
<td>1 or 2</td>
<td>P3 End: Aug28</td>
<td></td>
<td>P3</td>
<td></td>
<td></td>
<td>1,000,000,000</td>
<td>Sensitive</td>
<td>Stable</td>
<td>2 - 8 c</td>
<td>Cost-pricing*</td>
<td>$3.50</td>
</tr>
<tr>
<td>Moderna NIAID</td>
<td>mRNA-1273</td>
<td>RNA</td>
<td>2</td>
<td>P3 Jul</td>
<td></td>
<td>P2</td>
<td></td>
<td></td>
<td>1,000,000,000</td>
<td>Highly sensitive</td>
<td>Stable for 7 days</td>
<td>-20</td>
<td>For profit</td>
<td>Maximum: $32 - 35</td>
</tr>
<tr>
<td>Novavax</td>
<td>NVX-CoV2373</td>
<td>Viral vector, non-replicating recombinant baculovirus (insect)</td>
<td>2</td>
<td>P2 Aug25</td>
<td></td>
<td>P2</td>
<td></td>
<td></td>
<td>1,000,000,000</td>
<td>Sensitive</td>
<td>Stable</td>
<td>2</td>
<td>-</td>
<td>$16</td>
</tr>
<tr>
<td>BioNTech / Pfizer</td>
<td>BNT162b2</td>
<td>RNA</td>
<td>2</td>
<td>P3 Jul</td>
<td></td>
<td>P2</td>
<td></td>
<td></td>
<td>1,000,000,000</td>
<td>Highly sensitive</td>
<td>Stable for 24 hrs</td>
<td>-70</td>
<td>For profit</td>
<td>$19.50</td>
</tr>
<tr>
<td>J&amp;J</td>
<td>Ad26</td>
<td>Viral vector, non-replicating attenuated adenovirus</td>
<td>2</td>
<td>P1/2 End: Jul</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,000,000,000</td>
<td>Sensitive</td>
<td>Stable</td>
<td>2 - 8 c</td>
<td>Cost-pricing*</td>
<td>$10</td>
</tr>
<tr>
<td>Merck / IAVI / Themis</td>
<td>rVSV-ZEBOV</td>
<td>Viral vector, replicating, live attenuated vesicular stomatitis virus (VSV)</td>
<td>1 or 2</td>
<td>Q4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;100,000,000</td>
<td>Highly sensitive</td>
<td>-</td>
<td>-70</td>
<td>For profit</td>
<td>-</td>
</tr>
<tr>
<td>Sanofi / GSK</td>
<td>-</td>
<td>Viral vector, non-replicating recombinant baculovirus</td>
<td>2</td>
<td>P1/2 End: Sept</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;1,000,000,000</td>
<td>Sensitive</td>
<td>Stable</td>
<td>-</td>
<td>Non-profit</td>
<td>$12</td>
</tr>
<tr>
<td>Gamaleya Research Inst.</td>
<td>Sputnik-V</td>
<td>Viral vector, non-replicating</td>
<td>2</td>
<td>P1/2</td>
<td>P3</td>
<td></td>
<td></td>
<td></td>
<td>&gt;1,000,000,000</td>
<td>Sensitive</td>
<td>Stable</td>
<td>2-8 c</td>
<td>Non-profit</td>
<td>-</td>
</tr>
<tr>
<td>CanSino Biologics</td>
<td>Ad5</td>
<td>Viral vector, non-replicated</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitive</td>
<td>Stable</td>
<td>2-8 C</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sinovac</td>
<td>CoronaVac</td>
<td>Inactivated</td>
<td>2</td>
<td>P3 Jul</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitive</td>
<td>Stable</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Wuhan Institute of Biological Products</td>
<td>-</td>
<td>Inactivated virus vaccine</td>
<td>2</td>
<td>P3 Jul</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitive</td>
<td>Stable</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sinopharm</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>P3 Jul</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sensitive</td>
<td>Stable</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: IQVIA research, Nephron insights, public sources and company reported results
Regardless of how the pandemic ends, supply is key

Perspectives on future scenarios

‘Social’ end
Societies adapt to different environment in-lieu of, or while awaiting medical treatment

Minimisation
- Testing capacity
- Effective isolation of vulnerable individuals
- Integration of detection, quarantine and treatment

Accelerated
- Disease burns out due to death of susceptible

‘Medical’ end
Virus impact minimized by development of medical interventions, or mutates

Vaccine(s)
- Scale of manufacturing and potentially complex distribution
- Potential need for multi-dose

Treatment(s)
- Scale of manufacturing and distribution
- Value of outpatient vs. inpatient therapies
- Selling PPE, home treatments and advice
- Home delivery
- Clinical trials

Self-limitation
- Disease mutates to be less virulent or infectious

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.

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