Session 16OF, Drug Pipeline Impact on Future Claims Costs

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- Do alert SOA staff and/or legal counsel to any concerning discussions
- Do consult with legal counsel before raising any matter or making a statement that may involve competitively sensitive information.

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The material in the presentation assumes the audience is familiar with the pharmaceutical marketplace and its various stakeholders. The information may not be appropriate, and should not be used, for other purposes. Nothing in this material should be construed as legal advice or strategic recommendations.

Information about unapproved medications is not an opinion predicting if these products will eventually be approved or their launch price. This information is provided to create awareness of the current status in the drug development process.
Agenda

- Background
- Problems
- FDA Approval Process
- Pipeline Overview
- Creating Solutions
- Reinsurance Impact
- Questions
Background
2013 Hepatitis C headlines...

Dec 26, 2013
“Analyst forecast Sovaldi will generate as much as $3 billion in annual sales in 2014...”

Forbes

Apr 22, 2014
“We can officially say Gilead Sciences pulled off the fastest drug launch on record... Sovaldi’s Q1 total:

$2.27 billion.”

The New York Times

Feb 4, 2015
“Together Sovaldi and Harvoni achieved $12.4 billion in sales...”

Source:
Why are we here?

Historical Overall and Rx % Spend Increases

Orphan Drugs

Are rare diseases really that rare?

Conditions that affect fewer than 200K people in the U.S. are called “orphan” or rare diseases. The individual diseases may be rare, but collectively affect 1 in 10 Americans and present critical cost and care challenges for payers as well as patients.

Alarming realities
These diseases have a high early mortality rate and cause catastrophic social, emotional and financial burdens for patients and their families.

- **Difficult to diagnose** – On average, patients wait nearly 5 years for an accurate rare disease diagnosis and see 2 physicians during that time.
- **High mortality rate** – 30% of children with rare diseases won’t live to see their 5th birthday.
- **High costs** – Annual costs per patient are more than 5x higher than non-orphan drugs.

7,000 Rare diseases
30M Patients

Good news/bad news
It’s life-changing for patients when new therapies become available, but the costs can be staggering. Here are just a few examples:

<table>
<thead>
<tr>
<th>Rare disease conditions</th>
<th>Average spend per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding disorders (factor)</td>
<td>$1,603,783</td>
</tr>
<tr>
<td>Hemophilia angiogenesis</td>
<td>$3,090,961</td>
</tr>
<tr>
<td>Rare congenital and acquired</td>
<td>$1,011,002</td>
</tr>
</tbody>
</table>

Financial exposure
Average cost per patient in 2016:

- **Top 100 orphan drugs**: $140K
- **Top 100 non-orphan drugs**: $28K

441 FDA-approved orphan drugs
35% of specialty drugs in the pipeline are orphan
95% of rare diseases don’t have an FDA-approved therapy

Rapid increase in approvals and cost
The Orphan Drug Act of 1983 created financial incentives to promote development of breakthrough therapies. Some manufacturers used these incentives to capitalize on the profitability of orphan drugs, which led to broader investigations regarding the act.

Case Study – nusinersen (Spinraza®)

Assumptions & Description
- Per Pt. Annual Cost of Spinraza - $750k
- Annual Trends: Med – 6% Rx – 10%
- SMA = Spinal Muscular Atrophy
- FDA Approved 12/23/16
- Approx. 9k patients in US have disease

*SMA AVG. PATIENT ALLOWED*

<table>
<thead>
<tr>
<th>Year</th>
<th>Med</th>
<th>Rx</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 ALLOWED</td>
<td>$4,037</td>
<td>$52,882</td>
<td>$56,919</td>
</tr>
<tr>
<td>2017 MAX VALUE*</td>
<td>$59,418</td>
<td>$754,885</td>
<td>$814,303</td>
</tr>
</tbody>
</table>

*Results based on 2015 Market Scan and Milliman Commercial data*
Why are we here – Pipeline is still robust

• Pipeline has over 7,700 products in development as of June 2018
  • 5,400 in January 2013
• Correlates to 10,800 drug-indication combinations
• 74% were potentially first-in-class in July 2017
• 1037 were orphan drug designation

Sources:
The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development, The Analysis Group, July 2017
Problems
new drugs, minimal visibility
complex to track

Source: https://media.giphy.com/media/BmmfETghGOPrW/giphy.gif [Accessed 6/18/18]
Challenges in identifying patients who may be eligible for pipeline treatments
FDA Approval Process
Drug approval process

**Pre-clinical**
- 1,000’s molecules
- toxicity
- IND submission

**Phase I**
- 20 to 100 healthy individuals
- Lasts several months
- 70% move to Phase II

**Phase II**
- 100’s with disease
- Several months up to 2 years
- 33% move to Phase III

**Phase III**
- 1000’s with disease
- Several months up to 2 years
- 25-30% get approved
- NDA/BLA submission
Drug approval process (cont.)

- Prescription Drug User Fee Act
- FDA has 10 months to approve or deny submitted application
- Expedited to 6 months under several scenarios

- Complete Response Letter
- FDA’s “denial” letter
Pipeline Overview
2017 & 2018 FDA Drug Approvals

2017H2

- Mepsevii
- Verzenio
- IDHIFA
- Vosevi
- Mavyret
- Aimovig
- Symdeko
- Tavalisse
- Palynziq
- Cystic Fibrosis
- Chronic migraines
- Immune thrombocytopenia (ITP)
- X-linked hypophosphatemia (XLH)
- Chronic myelogenous leukemia (CML)
- Mantle cell lymphoma (MCL)
- Acute myelogenous leukemia (ALS)
- Amyotrophic lateral sclerosis (ALS)
- Hepatitis C
- Breast Cancer
- Retinal dystrophy
- Morquio syndrome
- MPS VII (Sly syndrome)
- MPS VI
- MPS III
- MPS II
- MPS I

2018H1

- Luxturna
- Calquence
- Radicava
- Vosevi
- Mavyret
- Tavalisse
- Palynziq
- Aimovig
- Symdeko
- Cystic Fibrosis
- Chronic migraines
- Immune thrombocytopenia (ITP)
- X-linked hypophosphatemia (XLH)
- Chronic myelogenous leukemia (CML)
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- MPS VI
- MPS III
- MPS II
- MPS I

Pipeline Drugs to Watch

- **hATTR** = hereditary amyloidosis (transthyretin [TTR]-related)
- **NSCLC** = non-small cell lung cancer
- **AML** = acute myeloid leukemia
- **NHL** = Non-hodgkin lymphoma

**Melanoma**
- binimetinib
- encorafenib
- cemiplimab

**Hereditary angioedema (HAE)**
- gilteritinib
- lanadelumab

**Melanoma**
- bafodribler

**Hairy Cell Leukemia (HCL)**
- duvelisib

**Melanoma**
- ivosidenib

**Non-Hodgkin Lymphoma (NHL)**
- lorlatinib
- duvelisib
- ivosidenib
- tinazobulin

**NSCLC**
- molotumomab pasudotox

**AML**
- migalastat
- ibandronate
- duvelisib

**Hairy Cell Leukemia**
- duvelisib

**ALL**
- migalastat
- duvelisib

**Solid Tumors**
- larotrectinib
- Truxima
- EZN-2285

**Hairy Cell Leukemia**
- duvelisib

**NHL**
- migalastat

**ALL**
- migalastat
- duvelisib

**Solid Tumors**
- lorlatinib
- Truxima

**Melanoma**
- binimetinib
- encorafenib

**NHL**
- Truxima

**Hairy Cell Leukemia**
- duvelisib

**ALL**
- Truxima

CAR-T therapy

Increasing number of patients eligible for treatment

$475,000
Kymriah™
8/30/2017
Pediatric ALL
5/1/2018
DLBCL
CLL/SLL
MM

$373,000
Yescarta®
10/17/2017
DLBCL
MCL
Indolent NHL
ALL

$???,000
JCAR-017 & others
Multiple myeloma
ALL
DLBCL
NHL
CLL/SLL

$???,000
100+ Other CAR-T agents
sarcoma
Brain cancer
AML
NSCLC
Solid tumors


ALL = Acute lymphoblastic leukemia
DLBCL = Diffuse large B-cell lymphoma
MCL = Mantle Cell Lymphoma
MM = Multiple myeloma
NHL = Non-Hodgkin lymphoma
AML = Acute myelogenous leukemia
NSCLC = Non-small cell lung cancer
CLL / SLL = Chronic lymphocytic leukemia / small lymphocytic
Creating Solutions
<table>
<thead>
<tr>
<th>Primary</th>
<th>Secondary</th>
<th>Tertiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press releases from manufacturer</td>
<td>News or Organizations</td>
<td>Pipeline databases</td>
</tr>
</tbody>
</table>

### Primary Sources
- FDA
- ClinicalTrials.gov
- The New England Journal of Medicine
- JAMA

### Secondary Sources
- FiercePharma
- Bloomberg
- CNBC
- AMCP

### Tertiary Sources
- Biomedtracker
- DATAMONITOR Healthcare
- EvaluatePharma
Goals and considerations of projecting pipeline costs

• Focus on understanding incremental costs and/or utilization incurred by pipeline drugs

• Address the following assumptions:
  • Launch date of pipeline drugs
  • Launch price of pipeline drugs
  • Expected pipeline drug uptake within the population eligible to receive treatment

• Pipeline drug uptake should take into consideration the following:
  • Novel therapy – significantly impacts current treatment landscape
  • Add-on therapy – drug is added to current treatment protocols
  • Replacement – drug displaces current drugs used to treat condition
Timing considerations

2017 experience (baseline)

Trend development

2019 bid submission due date

2019 experience (projection)

Pipeline considerations

2017 H1  2017 H2  2018 H1  2018 H2  2019Projection

Consider list of newly approved drugs from:
• Q4 2017
• H1 2018

Consider drugs in the pipeline primarily focused on PDUFA drugs (10 month look ahead)
Client Case Study

*Results based on a random group sample from historical MarketScan and Milliman Commercial data
Sample client solution – financial impact

<table>
<thead>
<tr>
<th>Condition</th>
<th>Medication</th>
<th>Estimated</th>
<th>Total Rx Cost</th>
<th>Total Medical Costs</th>
<th>Total Cost</th>
<th>Total Rx Cost</th>
<th>Total Medical Costs</th>
<th>Total Cost</th>
<th>Total Cost of New Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amyotrophic Lateral Sclerosis (ALS)</td>
<td>Radicava</td>
<td>5</td>
<td>$26,529</td>
<td>$347,807</td>
<td>$374,336</td>
<td>$26,529</td>
<td>$533,571</td>
<td>$560,100</td>
<td>$185,764</td>
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<td>Behcet Syndrome</td>
<td>Otezla</td>
<td>7</td>
<td>$232,325</td>
<td>$221,812</td>
<td>$454,138</td>
<td>$260,325.43</td>
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<td>$459,957</td>
<td>$5,819</td>
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<tr>
<td>Immune Thrombocytopenic Purpura (ITP)</td>
<td>Tavalisse</td>
<td>27</td>
<td>$409,082</td>
<td>$2,126,049</td>
<td>$2,535,130</td>
<td>$744,541</td>
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<td>$2,870,590</td>
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<td>Cystic Fibrosis</td>
<td>Semdeko</td>
<td>15</td>
<td>$4,342,771</td>
<td>$1,460,430</td>
<td>$5,803,201</td>
<td>$5,009,079</td>
<td>$1,314,387</td>
<td>$6,323,465</td>
<td>$520,264</td>
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<tr>
<td>Duchenne's Muscular Dystrophy</td>
<td>Eteplirsen</td>
<td>11</td>
<td>$195,486</td>
<td>$1,595,193</td>
<td>$1,700,679</td>
<td>$205,486</td>
<td>$1,483,530</td>
<td>$1,689,016</td>
<td>(11,664)</td>
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<tr>
<td>Fabry's Disease</td>
<td>Migalastat</td>
<td>8</td>
<td>$1,129,068</td>
<td>$3,342,327</td>
<td>$4,471,395</td>
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<td>Leber's Congenital Amaurosis</td>
<td>Luxturna</td>
<td>1</td>
<td>$3,901</td>
<td>$5,100</td>
<td>$9,002</td>
<td>$700,000</td>
<td>$5,100</td>
<td>$705,100</td>
<td>696,099</td>
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<td>X-Linked Hypophosphatemia (XLH)</td>
<td>Crysvita</td>
<td>1</td>
<td>$6,751</td>
<td>$347,363</td>
<td>$354,115</td>
<td>$180,000</td>
<td>$347,363</td>
<td>$527,363</td>
<td>173,249</td>
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</tbody>
</table>
Downstream Impact - Reinsurance
Distribution of Stop Loss Cost by Type of Service


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Reinsurance applies across all payers

**Commercial**
- Group or individual insurance purchased by individuals or employers
- Fully insured by HMO / insurance company or self-funded by the employer
- Public exchange introduced 1/1/2014 to improve access, particularly to individuals and small employer groups
- Payors negotiate with providers for payment terms

**Medicare**
- Federal government program administered by CMS
- Health insurance for elderly or younger people with specific diseases: End Stage Renal Disease or ALS
- Government retains risk for traditional Medicare or transfers the risk to the private sector (HMOs) via Medicare Advantage
- Federal government defines Medicare Allowable payments for all participating providers.

**Medicaid**
- Jointly run by federal and state government; varies by state
- Health insurance for low income or disabled individuals
- More than half of Medicaid risk is transferred to private sector HMOs or providers (Managed Medicaid)
- States determine qualifications for Medicaid coverage and some states have expanded coverage.
- Each state defines Medicaid Allowable payments for providers
Basic insurance and reinsurance terminology

- **Health Insurance**
  A type of insurance that covers the cost of an insured person’s medical treatment, services, supplies or pharmaceutical expenses. Insurance companies or Health Maintenance Organizations (HMOs) are licensed by the states to write Health Insurance.

- **Reinsurance**
  When an HMO or insurance company passes all or part of their risk to another insurance company.

- **Self-Funded Employer**
  An employer who assumes the financial risk of providing health insurance to its employees and their dependents. The employer typically contracts with a TPA and provider network.

- **Stop Loss Insurance**
  A type of insurance sold to a Self-Funded Employer to protect against very large claims on any one person (Specific Stop Loss) or higher than expected claims overall (Aggregate Stop Loss).
3 types of reinsurance: Quota-Share, Excess, Aggregate

- **Proportional Reinsurance (Quota Share)**
  Reinsurer shares in a percentage of each risk on a underlying policy. Reinsurer shares all premiums and losses accordingly. The reinsurer shares a portion of every claim.
  
  **Example:** With a 75% quota share reinsurance agreement, the reinsurer is paid 75% of all premium (less a ceding allowance to cover the insurance company’s expenses) and the reinsurer is liable for 75% of all claims.

- **Non-Proportional Reinsurance (Excess Reinsurance or Specific Stop Loss)**
  (Re)insurer assumes liability for losses that exceed a specified retention (deductible) per person. The (re)insurer only has liability on losses for individuals who have large claims.
  
  **Example:** HMO or Self-Funded Employer retains the first $200,000 of risk per person. The reinsurer or Stop Loss carrier is liable for claims that exceed $200,000 on any one person for all claims in any 12 month period.

- **Aggregate Reinsurance (or Aggregate Stop Loss)**
  Aggregate coverage caps the aggregate amount of losses that a ceding company or self-funded employer is responsible for to an amount referred to as the attachment point.
  
  **Example:** Ceding company retains risk up to 125% of expected claims in aggregate. If expected claims for the 12 month period are $10,000,000, the ceding company’s attachment point is $12,500,000. The reinsurer is liable if total claims for all covered individuals exceed $12,500,000.
High Cost Claims – Pre ACA

- Limited coverage ($1M caps)
- Higher uninsured population

High Risk Pools

- Effective January 1 2014, the Exchanges were formed and insurers were required to provide guaranteed issue insurance with no exclusions for pre-existing conditions.
- ~35 states had High Risk Pools covering ~300,000 people across the U.S.
- These individuals had medical claims that were 3-4 times higher than the insured population.
- Following ACA, most High Risk Pools have shut down since these individuals can now buy Health Insurance either through the Exchange or directly from HMOs or Insurance Companies.
Reinsurance policy structure

Technical Features
- Reinsurer covers claims incurred by a member over a **12 month period**
- If a member is hospital confined at the end of the policy year, the Reinsurer claim terminates and client must meet their deductible again in the following policy year – if renewed (not automatic)
- Many stop loss policies will be written on an “incurred and paid” basis where the claim must be both incurred and paid in the 12 month period
- Claim reporting and submission deadlines are specified and usually do not exceed 12 months following termination date of the reinsurance policy

Contract Characteristics
- **1 year product**
- Rates & terms change annually
- Very short tail
- **High deductibles** (> $50,000 per claimant)
- Excess reinsurance is for unknown claims
- Higher deductible or exclusions included for large known ongoing claims (“lasers”)
- **“Run in” provision** reduces timing issues

![Claims Payments Frequency Distribution](image-url)
Specialty Drugs

• For new drugs entering the market, there is minimal visibility into
  • The drugs coming out,
  • The costs of these drugs,
  • What conditions they treat, and
  • Who in the member population is potentially impacted

• The number of new specialty drugs entering the market is increasing
  • Tracking pipeline movement is time consuming and complex

• When looking at a specific employer, it is difficult to
  • Identify people in a plan that are impacted by new drugs entering market, and
  • How drug and medical costs will change
New Gene Therapies create challenges for Insurance, Reinsurance and Stop Loss carriers

- Business model is to pool expected claims over a group of people.
- Reinsurance and Stop Loss Insurance are 1 year contracts covering services that are delivered in a 12 month period. Spreading the cost of Gene Therapy drugs over several years means the Reinsurer or Stop Loss Insurer would only be liable for a portion of the cost.
- While contracts are for 1 year, Reinsurers and Stop Loss Insurers desire long term relationships and are interested in treatments that reduce cost over a longer period of time.
- Reinsurers and Stop Loss Insurers need to anticipate new technologies or treatments that are high cost and may impact their expected claims. Reinsurance and Stop Loss premiums will increase if high cost new drugs are expected.
- Reinsurance and Stop Loss are intended to cover unknown claims. Ongoing known claims are typically “lasered” and remain the risk of the Health Insurer or Self-Funded Employer.
- Clients may change their Reinsurer or Stop Loss Insurer each year making longer term payment methods or refunding a challenge.
- Rebates / refunds that can be attributed to a person reduce Reinsurer or Stop Loss claims but current claim deadlines are short.
Excluding Claims

“Experimental” sample definition

• Medical services, supplies or treatments provided or performed in a special setting for research purposes, under a treatment protocol or as part of a clinical trial (Phase I, II, or III). The covered service will also be considered Experimental in any setting if the Covered Person is required to sign a consent form that indicates the proposed treatment, procedure, medical service, supply, drug, device or biological product is part of a scientific study or medical research to determine its effectiveness or safety. Medical treatment which is not considered standard treatment under the particular medical circumstances by the majority of the medical community or by Medicare, Medicaid or any other government financed programs or the National Cancer Institute regarding malignancies, will be considered Experimental. Off-label usage of any drug will be considered Experimental. A drug, device or biological product is considered Experimental if it does not have FDA approval.

“Medically Necessary” sample definition

• A treatment, service, supply or drug that:
  1. Is appropriate and essential for the diagnosis or treatment of the Covered Person’s symptoms;
  2. Is within the scope, duration or intensity of that level of care which is needed to provide safe, adequate and appropriate diagnosis or treatment;
  3. Is in accordance with generally accepted current professional medical practice, based on consultation with an appropriate service Provider;
  4. Involves only the use of drugs or substances that are not Experimental.

• A treatment, service, supply or drug will not be considered Medically Necessary if:
  1. It is part of a treatment plan that is considered to be Experimental or for research services; or
  2. It is provided primarily as a convenience to the patient or the patient’s family or the Provider.

The fact that a physician may prescribe, order, recommend or approve a treatment, service, supply or drug does not, of itself, make it Medically Necessary.
Excluding claimants - Lasering

- **What does “laser” mean?**
  - A laser is the practice of assigning a higher deductible (or excluding the individual from Reinsurance or Stop Loss Insurance completely) for an individual with a known condition that is likely to exceed the deductible.

- **Why do Stop Loss Insurers and Reinsurers “laser” individuals?**
  - Stop Loss Insurance and Reinsurance is for unknown claims
  - If an individual is likely to incur a large claim due to an ongoing condition or treatment, the Stop Loss Insurer or Reinsurer must increase their premium rates to cover these expected claims.
  - The result is that the cost to the Self-Funded Employer or ceding company is higher than it would be if they retained the risk themselves.

Laser “look back period” is generally 1 year to identify “ongoing claims”
Typical conditions / treatments that are lasered

- Hemophilia
- Hereditary angioedema
- Spinal muscular atrophy
- Leukemia
- Hodgkin Lymphoma
- Multiple Myeloma
- Cystic Fibrosis

- Duschenne Muscular Dystrophy
- Urea Disorders
- Crohn’s Disease
- Advanced Cancers
  - Breast
  - Colon
  - Lung
  - Bone
Other Issues

• Specialty inflation – leveraged trend
• Rebates
• Pay for performance contracts
  • Patient mobility
  • Payer, reinsurer, broker mobility
• Final rates → Disclosure
Cost Control Strategies

- Prior authorization
- Step therapy
- Pre-certification
- Network steerage
- Centers of Excellence
- Reference-Based Pricing (Medicare)
- Direct provider contracting
Open Discussion
Thank you!

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