

Solid Benefit Guidance ARTHUR J. GALLAGHER & CO.

Pharmacy Benefit Management Discussion

October 25, 2017 Presented by: Seth Friedman, National Pharmacy Practice Leader

Proprietary and Confidential

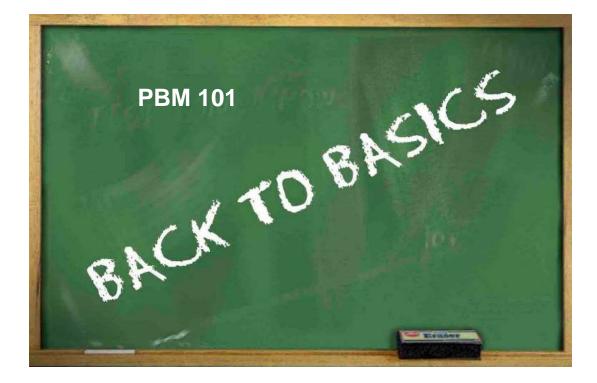














AWP

- The "Average Wholesale Price"
- Is a **list price**, not what is paid (similar to a car MSRP)
- First DataBank and Medi-Span were the two primary suppliers of this information
- Ongoing Litigation with First Databank has now forced FDB to stop publishing
- PBMs/MCOs typically offer a discount off of AWP ("AWP 15%")



MAC

- MAC stands for "the Maximum Allowable Cost"
- Represents the **maximum cost per unit of medication** (tablet, capsule, etc.) that a plan will pay for that product
- Primarily used to set pricing for similar generic products
- While Medicaid's old Federal Upper Limit is often credited with being one of the earliest and most well known MAC lists, it is no longer the industry standard.





U&C

- U&C stands for the "Usual and Customary" price
- Very different from the Medical term "U&C"
- U&C represents the price a pharmacy would sell a product to an individual consumer that did not have a prescription insurance card.
- Commonly referred to as the "cash price" for the prescription
- Each **individual pharmacy** sets it's own U&C price
- Costco and Sam's Club represent pharmacy chains that still offer deep U&C pricing discounts
- As network rates have gotten deeper, U&C has recently had less impact



GDR

- GDR is the "generic dispensing rate"
- Also known as GFR (Generic Fill Rate)
- The generic dispensing rate is calculated by taking the total number of generic prescriptions divided by the total number of all prescriptions
- Example:

42 Brand Rx

58 Generic Rx

100 Total Rx

58/100 = 58% Generic Dispensing Rate



GSR

- GSR is the generic substitution rate (measures the plan's effectiveness of moving to a generic, when possible)
- Measures effectiveness in switching to a generic product when a brand prescription is written for a product that has a generic available
- Brand drugs that have a generic available in the market are commonly referred to as "Multi-Source Brand Products"
- The GSR is calculated by taking the number of generic products and dividing by the combined total of generic products plus multisource brands
- Example: 45 Generics / (45 Generics + 5 Multisource Brands) = 90%
- Most plans will average well over 90% in terms of GSR



What are Brand Drugs?

- Compounds discovered by Brand pharmaceutical manufacturers
- Marketing Names are given to chemical compounds
- Brand Drugs are typically very expensive due the time and money needed to research product and get it approved by the FDA
- Only a fraction of the cost is actually attributable to the manufacturing of the product







What are Generic Drugs?

- Manufactured when the patent expires on the Brand drug
- Per the FDA website, the FDA requires that:

"A generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use."

- First to file gets a six month exclusivity period (Single Source Generic)
- Trademark laws prohibit the generic from **looking exactly like** the brand product.



Brand Zocor



Generic simvastatin What percent of drugs dispensed are generics? How much do they cost?

Why are Generic Drugs so Inexpensive?

- No substantial funding of drug discovery
- Increased competition
- Do not bear the burden of proving safety

- Generic
- Residual benefits of marketing from Brand companies
- Generic companies will sometimes strike deals with Brand Companies to have them manufacture the product for them
- Some popular Brand Name Drugs that are now generic
- Some argue generics are safer, as they have been market tested!

| Brand Name | Generic Name (Equivalent to the Brand) |
|------------|---|
| Zocor | simvastatin |
| Prozac | fluoxetine |
| Norvasc | amlodipine |
| Zoloft | sertraline |
| Prilosec | omeprazole |



Solid Benefit Guidance



What are Specialty Products (Drugs)?

- Very high cost medicines
- Used to treat **complex** diseases



Solid Benefit Guidance

- Rheumatoid Arthritis, Hemophilia, MS and Hepatitis C are examples
- Historically billed through medical and given in doctors office
- PBM is **building capabilities** in this area
- Sometimes require special handling (refrigeration)
- Commonly, Specialty products are thought of as "Biotech" or "Injectible" products
 - Biotech Drugs are result of companies genetically altering micro-organisms
 - Injectibles –Injected into the bloodstream directly
- Limited Distribution arrangements are starting to grow in popularity
- Orphan Drugs



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Common Specialty Drugs

| Drug | Class | Average Cost Per Rx |
|-----------|----------------------|------------------------|
| Enbrel | Rheumatoid Arthritis | \$4,500 |
| Copaxone | Multiple Sclerosis | \$4,000 |
| Avonex | Multiple Sclerosis | \$3,600 |
| Humira | Rheumatoid Arthritis | \$5,000 |
| Cellcept | Transplant | \$1,300 |
| Xolair | Asthma | \$4,000 |
| Betaseron | Multiple Sclerosis | \$4,000 |
| Gleevec | Cancer | \$9,400 |



What are "Therapeutic Alternatives?"

- Occurs when **multiple drugs** are available to treat the **same condition**
- Typically are just as safe and effective, and save the plan money

| | Description | Example |
|---------------------------------|--|--|
| Brand to Generic Alternative | A generic drug is available to treat the same condition as a more expensive brand name product (i.e. this is not the same product, but is in the therapeutic class to treat the same condition) | Generic oxybutinin xl is given to a patient instead of Brand Name Detrol LA to treat overactive bladder |
| Brand To Brand Alternative | A plan switches a member from a non-formulary product to a formulary product within the same formulary category | Brand Name Cozaar is substituted for Brand Name Benicar as a more cost effective product for the treatment of high blood pressure |



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Drug Development





So How Does it Begin?

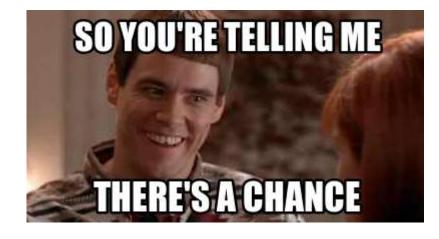
- Scientists looking for compounds to test with "targets"
- "Targets" are part of our molecular makeup that **hold the key** to disease states
- "Targets" are typically proteins that make up our DNA
- Goal: "Inhibit or Stimulate" the target
- Process is called "HTS High Throughput Screening"
- **Key is** to see how **selective** a compound is in modifying a target (i.e. impacts the target, and not other proteins)
- **Genomics** (understanding the DNA sequencing of organisms) are the future





Drug Development is a slow process, with low success rates.....

.... but huge rewards.



Odds of...

- Audited by the IRS: 1 in 100
- Dying in a car accident: 1 in 113
- Being born with 11 fingers and toes:
 1 in 500
- Being diagnosed with cancer: 1 in 2 for men and 1 in 3 for women

A potential compound from the drug discovery process actually becomes a marketable FDA approved product:

4000:1

About the FDA and Labeling

- Formed in 1906, current budget of **\$2.1B**
- Fees collected from pharma... conflict of interest?
- FDA will **review and approve** product and monitor product post launch
- Acts as **watchdog** of product marketing
- FDA becoming much more **conservative**
- Key to FDA approval is the labeling (listing of uses and warnings)
- Black Box warns of drugs with potentially serious side effects
- Pharmaceutical companies push to be assigned to a new therapeutic category



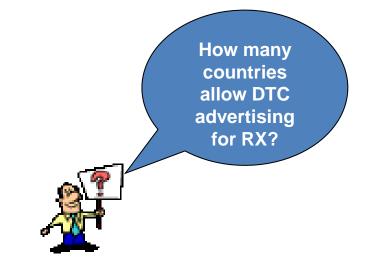


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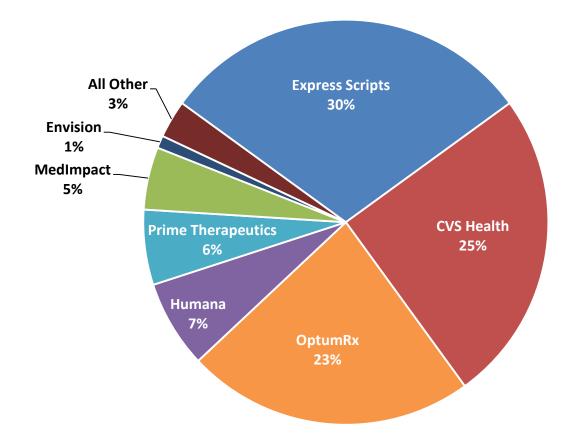
- Sales "Armies": 35k in 1995, **100k** today
- Stat: 1 US Doctor for every 1,000 citizens, but 1 Drug Rep for every 3 Doctors
- **Tier 2 Formulary Access** critical component of launch
- Formulary Access involves providing rebates to managed care organizations
- **DTC (Direct to Consumer) Advertising** heavily utilized, but with much scrutiny







Estimated PBM Market Share, 2016





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The Flow of Money

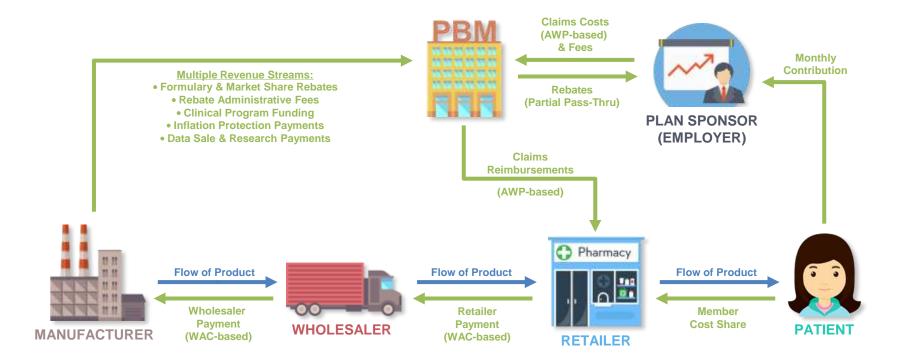






- Infographic is reflective of typical monetary flow for an oral, single-source, branded product under a usual and customary (cash price) arrangement.
- Flow of money may vary considerably based on type of drug (i.e. generic, specialty) and unique prescription characteristics (i.e. mail order, 340B).





- WAC = Wholesale Acquisition Cost (determined by Manufacturer).
- AWP = Average Wholesale Price (multiplier of WAC).
- Infographic is reflective of typical monetary flow for an oral, single-source, branded product under a traditional PBM deal with partial pass-through of rebate revenue.
- Flow of money may vary considerably based on type of drug (i.e. generic, specialty) and unique prescription characteristics (i.e. mail order, 340B).



PBMs: A Diversified Revenue Model

| BASE ADMIN FEES | | |
|----------------------------------|-------------------|--|
| ANCILLARY ADMIN FEES | CLIENT FEES | |
| CLINICAL PROGRAM FEES | CLIENT FEES | |
| FORMULARY & MARKET SHARE REBATES | | |
| REBATE ADMIN FEES | | |
| CLINICAL PROGRAM SUPPORT REVENUE | PHARMA REVENUE | |
| INFLATION PROTECTION PAYMENT5 | | |
| DATA SALE AND RESEARCH REVENUE | | |
| MARGIN ON RETAIL CLAIMS | RETAIL NETWORK | |
| NETWORK PARTICIPATION FEES | | |
| MARGIN ON MAIL ORDER CLAIMS | DISPENSING ASSETS | |
| MARGIN ON SPECIALTY CLAIMS | | |

MARGINON



What We Are Thinking About





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Specialty drug costs are spiraling out of control, with no easy solutions in sight.

Common Themes for Plan Sponsors Managing a Pharmacy Benefit in 2016 The delivery system is convoluted, and incentives are misaligned.

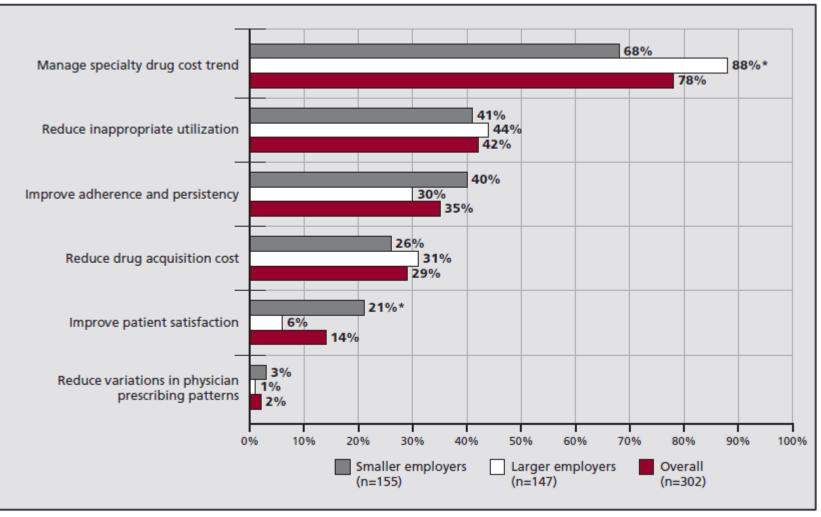
A highly consolidated PBM sector leaves fewer vendor options and diminished competition.

Questionable pricing and promotion tactics have deteriorated trust in the supply chain.

A shifting political and regulatory climate creates uncertainty about the future.



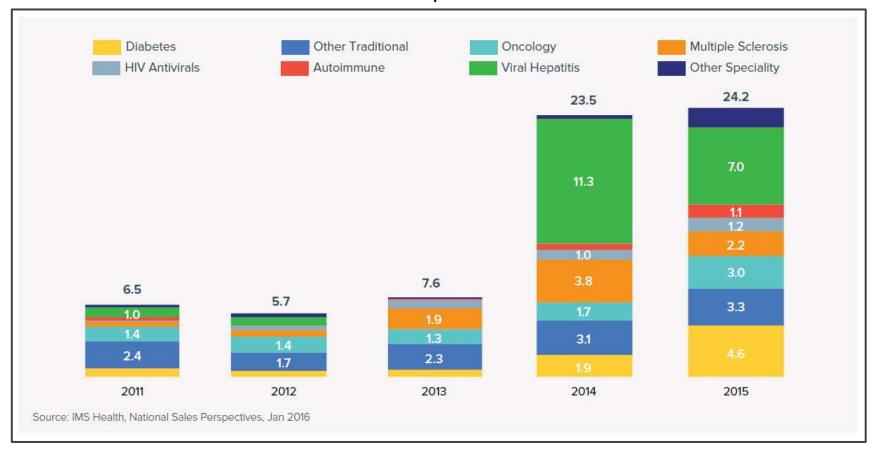
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SOURCE: 2015-2016 PBMI Prescription Drug Benefit Cost and Plan Design Report



New Brand Drug Spend Growth, By Drug Class In US \$Billion





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VIGAMOX



Coupon ID Number: 3333542H47 RxBIN: 610709 RxGroup: FDCUSC2 PATIENT INSTRUCTIONS: This coupon is pre be used immediately. Present this card/coupon pharmacy to receive a discount on prescription

PHARMACIST INSTRUCTIONS: Submit as (cannot be processed as secondary) using the processing information. For processing questi please call the Pharmacy Helpline below.





- There were 75 drugs that had copay cards on 2009. By 2015, there were **700 drugs**.
- An estimated **80% of specialty drug products** currently have copay card programs available for them.
- Copay cards were used in **10% of all prescriptions** in 2015, and this figure is increasing.
- One study suggests there will be **\$32B in additional health care costs** generated by copay cards over the next decade.



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Types of Funding

| Type of Funding | Copay Card Programs | Patient Assistance Programs (PAPs) |
|-------------------|---|--|
| Needs-Based? | Not needs-based, available to all patients (no income or financial hardship criteria). | Typically needs-based (i.e. income criteria, evidence may be required). |
| Target Market | Targeted at commercially-insured patients. Cannot be used for government-funded programs (Medicare, Medicaid). | Targeted at uninsured, underinsured, or those with financial hardship. Can typically be used for commercial or government-funded plans. |
| Source of Funding | Funding comes directly from pharmaceutical companies. | May be funded directly by pharmaceutical company foundations, or indirectly by independent foundations. |



Total Annual Assistance Value of Specialty Drug Copay Cards (Examples)

| DRUG | CLASS | TOTAL ANNUAL ASSISTANCE | PLAN MEMBER COST PER FILL |
|---------|---------------|----------------------------|------------------------------|
| Adempas | РАН | \$20,000 | \$0 |
| Exjade | Iron Overload | \$20,000 | \$0 |
| Harvoni | Hepatitis C | \$23,625 | ≤ \$5 |
| Sprycel | Oncology | \$36,000 | \$0 |
| Tasigna | Oncology | \$32,000 | \$0 |

Exhibit is courtesy of CVS Health

Copay Card Programs are offered for an estimated **80%** of specialty drugs and **50%** of traditional drugs.



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In 2014, <u>10 of the top 15</u> charitable foundations in the country were pharmaceutical company PAPs.

Largest Foundations in the U.S. by Total Giving, 2014

| Rank | Foundation | Total giving | PAP |
|------|--|-----------------|-----|
| 1 | Bill & Melinda Gates Foundation | \$3,439,671,894 | |
| 2 | Silicon Valley Community Foundation | \$956,834,000 | |
| 3 | The Abbvie Patient Assistance Foundation | \$853,356,401 | 1 |
| 4 | The Bristol-Myers Squibb Patient Assistance Foundation | \$811,433,684 | 1 |
| 5 | Johnson & Johnson Patient Assistance Foundation, Inc. | \$711,632,110 | ~ |
| 6 | Merck Patient Assistance Program, Inc. | \$686,800,564 | 1 |
| 7 | Genentech Access To Care Foundation | \$680,278,040 | ~ |
| 8 | Pfizer Patient Assistance Foundation, Inc. | \$668,050,404 | 1 |
| 9 | GlaxoSmithCline Patient Access Programs Foundation | \$625,427,284 | ~ |
| 10 | The Atlantic Philanthropies | \$521,711,000 | |
| 11 | Ford Foundation | \$518,380,000 | |
| 12 | Lilly Cares Foundation, Inc. | \$503,299,479 | 1 |
| 13 | Sanofi Foundation for North America | \$485,359,572 | 1 |
| 14 | Novartis Patient Assistance Foundation, Inc. | \$456,825,176 | 1 |
| 15 | The Susan Thompson Buffet Foundation | \$416,440,853 | |

Source: "Fiscal Totals of the 50 Largest Foundations in the U.S. by Total Giving, 2014," The Foundation Center, http://data.foundationcenter.org/#/foundations/all/nationwide/top.giving/list/2014, BROOKINGS "Under current law, corporations can deduct charitable contributions of up to 10% of their income... Companies rarely approach this limit, except in one industry large pharmaceutical companies consistently take the maximum deduction and often exceed it."

Frerick, Austin. "The Cloak of Social Responsibility: Pharmaceutical Corporate Charity." Tax Notes 153, no. 9 (2016): 1151–64.



But are they good ...?

1. DTC funding subverts plan design strategy

- Encourages use of less cost-effective therapies through copay manipulation.
- When a generic drug is available, coupons can increase brand drug utilization by more than 60%.*
- Eliminates financial barriers to off-label or inappropriate usage.

2. DTC funding distorts plan accumulator outcomes

- Processes as a member cost share from the PBM's perspective.
- Accumulates to deductibles and OOP maximums, despite the member not incurring OOP costs.

3. DTC Funding contributes to drug cost inflation

- Pharma must recoup costs of offering copay cards and PAPs through increases to AWP.
- Pharma is less inclined to offer rebate/discount incentives to PBMs for preferred tier placement.

^{*} Dafny L, Ody C, Schmitt M. When discounts raise costs: the effect of copay coupons on generic utilization. NBER Working Paper No. 22745. National Bureau of Economic Research. <u>http://www.hbs.edu/faculty/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf</u>







We know Optum Rx is not perfect but....

- Wespath has a very strong financial and contractual terms with Optum
- Optum has been a very flexible partner to work with
- Significant dollars being spent on point-of-care technology so your doctor is prepared before you go to the pharmacy
- Optum is a very stable PBM, unlike some of the others
- Optum continues to strive for service improvements by leveraging Net Promotor Score culture
- High level auditing results prove that Optum is providing strong results



Thank you!