

AbbVie's Pricing of Mavyret is Disruptive to the PBM Business Model

by

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Summary:

AbbVie's pricing for its new Hep C Virus drug Mavyret is disruptive to the current PBM business model because it forces the Big 3 PBMs to consider a drug for inclusion in their national formularies that is aligned with their clients interests -- more cost-effective than Harvoni -- but not aligned with their own interest -- needing to squeeze out all the rebates they can from the specialty drug therapeutic classes.

At the very least, will Express Scripts and CVS Health open their Hep C Virus therapeutic class and add Mavyret alongside Harvoni?

Or, will they expose themselves to claims of misalignment by excluding Mavyret?

Stay tuned.

The PBM Business Model Today

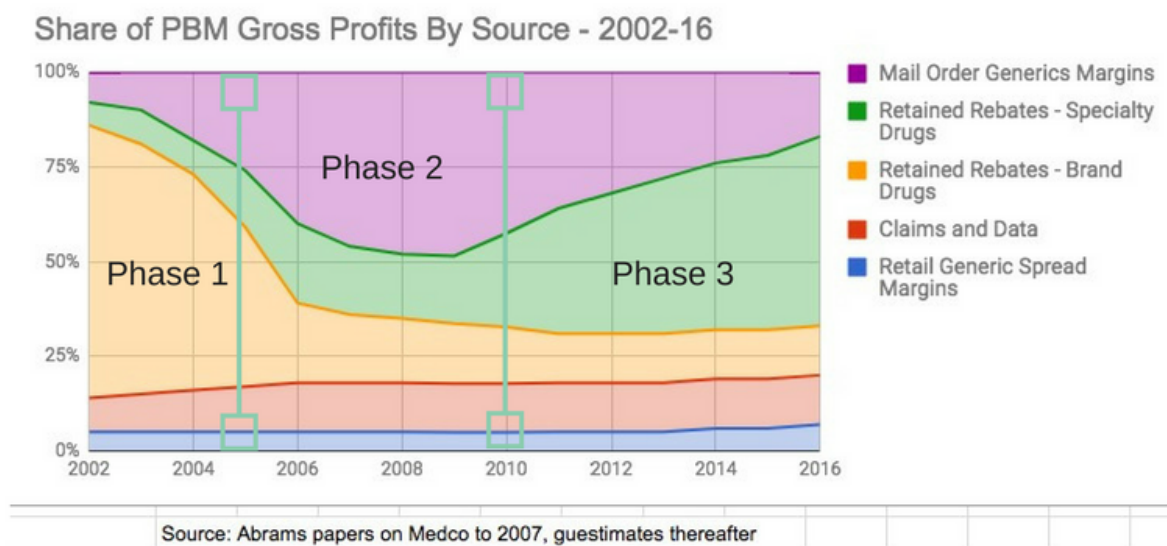
The management of the prescription (Rx) drug benefit portion of health care plans has become the domain of contracted specialists called pharmacy benefit managers (PBMs).

The three largest, independent PBMs — Express Scripts, CVS Health, and Optum Rx, (known as "The Big 3") control 73% of the total Rx claims processed in the United States in 2015.

Since the early 2000s, PBMs have continually come under attack for not acting in the best interest of their clients. We have [written a number of papers since 2004](#) pinpointing an opaque reseller business model as the source of this misalignment.

In a 2017 paper, we presented the case that [there have been 3 distinct phases of the PBM business model](#) over the past 15 years demarcated by radical shifts in the primary source of gross profits: (graph below)

1. up to 2005 — reliance on retained rebates from small molecule brand drugs;
2. 2005 – 2010 — reliance on mail order generics Rx margins;
3. 2010 – today — reliance on retained rebates from specialty drugs.



To compensate for declining mail order generics Rx margins after 2010, PBMs saw the rising trend of specialty and biotech drugs as a promising basis for a renewed reliance on retained rebates.

But there are several constraints today on a PBM business model relying on retained rebates from specialty drugs.

The first constraint is that the specialty drug Rx volume “basis” for collecting rebates today is a lot less than it was ten years ago when small molecule drugs were the basis for rebates.

The second constraint is a newfound awareness by clients that retained rebate dollars can be substantial yet an opaque source of PBM gross profits. As a defensive move, CVS Health finally [declared publicly on their website](#) that,

“CVS Caremark was able to reduce trend for clients through... negotiations of rebates, of which more than 90 percent are passed back to clients.”

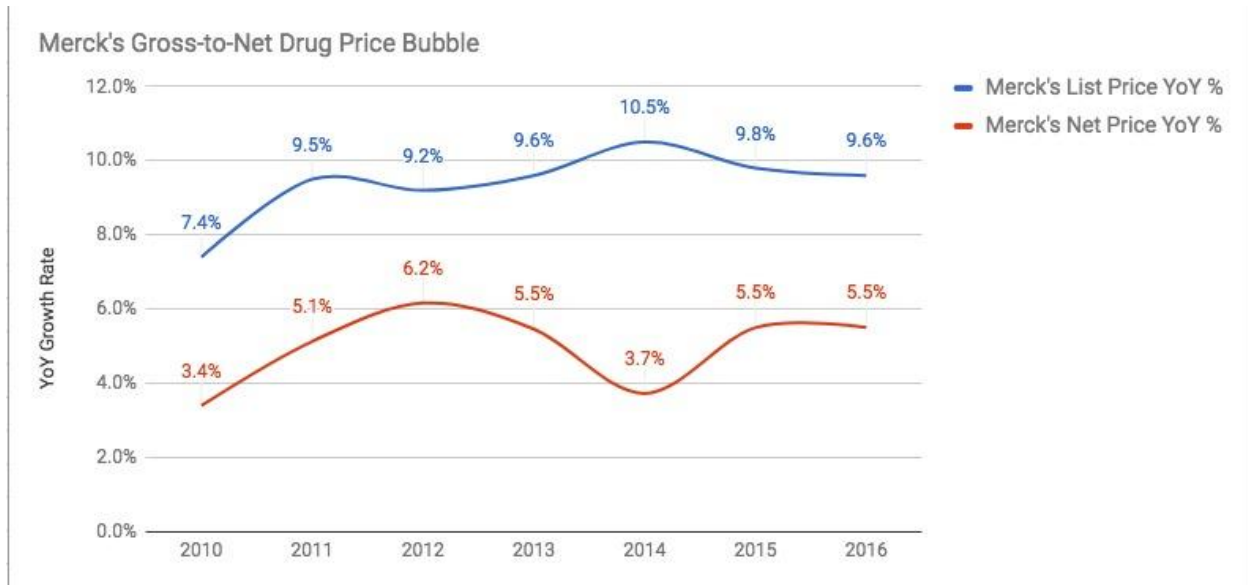
The problem facing PBMs today is how to derive a majority of gross profits from specialty Rx while maintaining a transparent rebate retention rate at 10% on average.

Using data supplied by the drug company Merck, [we reconstructed a step-by-step sequence](#) of how PBMs and drug companies might negotiate the parameters of a rebate deal under the triple constraints of (1) Pharma's net prices must grow; (2) PBMs retained rebate gross profit DOLLARS must grow; and (3) while PBM rebate retention rate must be fixed at 10%.

We found that to do this required PBMs to coax drug companies into increasing list prices for brand drugs at double-digit rates yearly while demanding that nearly all of it be rebated back to the PBMs. The result of this scheme is an occurrence now known as the “gross-to-net price bubble.” Below is a graph of the phenomenon using data supplied by Merck:

	2010	2011	2012	2013	2014	2015	2016
US Product Portfolio ¹							
% Change vs. Prior Year ²							
List Price Change (WAC) ³	7.4	9.5	9.2	9.6	10.5	9.8	9.6
Net Price ⁴ Change	3.4	5.1	6.2	5.5	3.7	5.5	5.5

	2010	2011	2012	2013	2014	2015	2016
US Product Portfolio							
Avg. Discount ⁵ (%)	27.3	28.9	29.9	32.1	37.0	38.2	40.9



PBMs and Formulary Choice

As we said in the prior section, the PBM business model relies heavily today on rebates received from specialty drug companies in return for placement on a list of drugs covered by a Rx benefit plan. That list of covered drugs is called a formulary.

The formulary is a lookup table that PBMs add to their claims processing systems that checks a Rx request against a list of therapeutic equivalents preferred by PBMs and rubber-stamped by plans. The formulary is designed to limit Rx to the most cost-effective drug(s) in each of 50-80 different therapeutic classes.

[In 2005, we were the first to conceptualize formularies](#) as a group of markets. On the sell-side are brand drug companies with close, but not perfect substitutes, called therapeutic equivalents. On the buy-side are the Big 3 PBMs representing plan sponsors and their members.

Economists call such markets bilateral oligopolies. We have [written a number of papers about the Pharma – PBM bilateral oligopoly](#) available for download free on our website.

Rebates are essentially tariffs paid by drug companies to gatekeepers for access to markets with limited competition. We have [presented that case](#) that the most “rebatable” brand drugs fall in an “oligopolistic” therapeutic class featuring a small number of patented drugs that are therapeutic equivalents. Over time, “me too” drugs enter and older drugs lose patent protection opening the door to generics or “biosimilars.” The therapeutic class becomes competitive and no manufacturer has any wiggle room left to negotiate price reductions with PBMs.

We have observed a change in PBMs’ approach to formulary design over the past 15 years. Basically, “rebatable” therapeutic classes have gone from being open -- a few approved drug -- to being closed -- a single approved drug. We are just beginning to figure out the causes of this change.

But our view of [what drives PBMs to choose open](#) versus closed therapeutic classes is this:

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he more a PBM limits competition in a therapeutic class, the more potential entrants will pay for access. Small molecule therapeutic classes tend to be open, hence less valuable to entrants. Specialty and biotech therapeutic classes tend to be closed, hence more valuable to the single favored entrant.

Today, PBMs need to squeeze everything they can from granting access to specialty therapeutic classes because there are lot fewer of these classes than the small molecule drug therapeutic classes that they relied on before 2010. Hence, this is the reason for the trend toward closed formularies and more drugs on excluded lists.

The Hepatitis C Virus Therapeutic Class

In 2013, the biotech company Gilead Sciences got FDA approval for the “innovative” Hepatitis C Virus (HCV) drug combo called Solvadi. Eight month later, an improved version of Solvadi, called Harvoni, came on the market. These drugs produced fewer side effects than first generation combo drugs requiring Interferon. Also, Solvadi / Harvoni only required regimens lasting 12 weeks, instead of 24 to 28 weeks with prior combo drugs.

[In 2016, Harvoni stood to #2](#) on the list of top selling Rx drugs at \$10.0 Billion a year, after AbbVie’s top selling biotech drug Humira at \$12.9 Billion used to treat a variety of autoimmune diseases like rheumatoid arthritis and Crohn’s disease.

In the three years since Harvoni came on there market, there have been 5 additional HCV drugs approved by the FDA, but only AbbVie’s Viekira Pak has garnered any significant sales.

The reason has been the the Big 3 PBMs have decided the make the HCV therapeutic class a “winner-take-all” proposition, coaxing competing companies to choose a high list price to be in a position to offer PBMs a “deep discount” rebate reaching 70% to 80% of list for exclusive status. Below is a summary of the Big 3 PBMs formulary choices for the HCV therapeutic class for 2017.

Big PBMs 2017 Drug Formulary for Hepatitis C Virus									
Whse Acq. Cost	Manufacturer	Drug	Formulary Placement				FDA Approved	1 pill a day weeks	Genotype
			ESRX	CVS Health	Optum Rx	Prime Theapeutics			
\$ 84,840	Gilead Sciences	Solvaldi	Excluded		Non-Preferred	Preferred	12-6-13	12	1,2,3,4
\$ 95,445	Gilead Sciences	Harvoni		Preferred	Preferred	Preferred	7-10-14	12	1,4,5,6
\$ 75,508	Gilead Sciences	Epclusa		Preferred	Preferred	Preferred	6-28-16	12	1,2,3,4,5,6
\$ 21,038	AbbVie Inc	Viekira Pak	Preferred		Non-Preferred	Excluded	12-19-14	12	1
\$ 38,710	AbbVie Inc	Technivie	Preferred	Excluded	Non-Preferred	Excluded	7-24-15	12	4
\$ 67,024	Janssen Therapeutics	Olysio	Excluded	Excluded	Non-Preferred	Excluded	11-22-13	12	1,4
\$ 63,630	Bristol-Myer Squibb	Daklinza	Excluded	Excluded	Non-Preferred	Excluded	7-24-15	12	1,3
\$ 55,148	Merck	Zepatier	Excluded	Excluded	Non-Preferred	Excluded	1-28-16	12	1,4
New Drugs Scheduled For Formulary Placement in 2018 (decision by 9-15-17)									
\$ 74,760	Gilead Sciences	Vosevi	?	?	?	?	7-18-17	12	1,2,3,4,5,6
\$ 26,400	AbbVie Inc	Mavyret	?	?	?	?	8-3-17	8	1,2,3,4,5,6

Gilead [has secured](#) exclusive preferred status for Harvoni with CVS Health and OptumRx while Express Scripts AbbVie [has secured](#) exclusive status for Viekira with Express Scripts.

Both choices are aligned with plan interests of having the most cost-effective drug included in the formulary. Both choices are also aligned with PBMs' interest of securing the most DOLLAR rebates.

Harvoni and Viekira Pak are both about equally effective so rebates become the determining factor for cost-effectiveness. For CVS Health and OptumRx, Gilead's Harvoni is more cost-effective choice because Gilead's rebate offer was greater than AbbVie's.

For Express Scripts, Viekira Pak is the most cost-effect choice because AbbVie's rebate offer was greater than Gilead's whose bid might have been constrained due to a depleted budget after the CVS Health and OptumRx wins.

AbbVie's Mavyret Drug Pricing: A Challenge to the PBM Business Model

On August 3, 2017, the FDA approved a new HCV drug call Mavyret from AbbVie. According to the [Specialty Pharmacy Times](#), this new drug had the potential to challenge the dominant position of Gilead's Harvoni on two fronts: (1) a treatment regimen requiring only 8 weeks versus 12 for Harvoni; and (2) an "disruptive" low treatment list price leaving little to no room for PBM rebates that was an estimated 15% below the NET (after rebate) price of Harvoni.

Below is our spreadsheet that summarizes the REGIMEN NET cost comparisons for Mavyret vs Harvoni:

Will Big 3 PBMs Add Mavyret as Preferred Hep C Drug in 2018?			
Pharma	Gilead	AbbVie	
Drug	Harvoni	Mavyret	
Treatment List Price	\$94,500		
Retained Rebate by PBM	\$9,450		
Net Rebate to Plan	\$64,140		
Gross Rebate	\$73,590		
Net Price	\$30,360	\$26,400	List Price
		\$26,400	Net Price
			Net Rebate to Plan = 0
			Rebate to PBM = 0
Net Plan Savings - Minimum 15%		\$3,960	

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is aligned with their clients interests -- more cost-effective than Harvoni -- but not aligned with their own interest -- needing to squeeze out all the rebates they can from the specialty drug therapeutic classes.

On July 31, 2017, [Express Scripts released its 2018 National Formulary](#), but noted:

“Please note that product placement for Hepatitis C and treatment for Inflammatory Conditions are under consideration and changes may occur based upon changes in market dynamics and new product launches. The full list of excluded products will be available on or before September 15, 2017.”

In August 2017, [CVS Health released a white paper](#) outlining the criteria it uses for formulary design and exclusion list. It stated that in January 1, 2018, we expect to remove 17 products from our Standard Control Formulary in 10 drug classes, but noted that

“We are in the process of finalizing changes for autoimmune and hepatitis C categories, which will be communicated mid-September.”

At the very least, will Express Scripts and CVS Health open their Hep C Virus therapeutic class and add Marvyet alongside Harvoni?

Or, will they expose themselves to claims of misalignment by excluding Marvyet?

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