

## **Hepatitis C Virus Formulary Choice for 2018:**

### **Will CVS Caremark Risk Looking Bad?**

By

© Lawrence W. Abrams, Ph.D.

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#### **Summary:**

AbbVie's aggressive list pricing for its new Hepatitis C Virus (HCV) drug Mavyret is disruptive to the current PBM business model. It essentially asks PBMs to align with client interests by adding a cost-effective drug to their national formularies despite little to no possibility for retained rebates.

On September 15, 2017 Express Scripts (ESRX) chose to align with client interests by opening up the HCV therapeutic class to include Mavyret as well as other HCV drugs previously excluded.

CVS Caremark has yet to announce its final choices for the HVC class despite [promising that it would do so by mid-September 2017](#).

If CVS chooses not to add Mavyret, it will be a sign that CVS is so desperate for rebate income that it is willing incur a very public case of misaligned interests.

#### **The Pharmacy Benefit Manager Business Model**

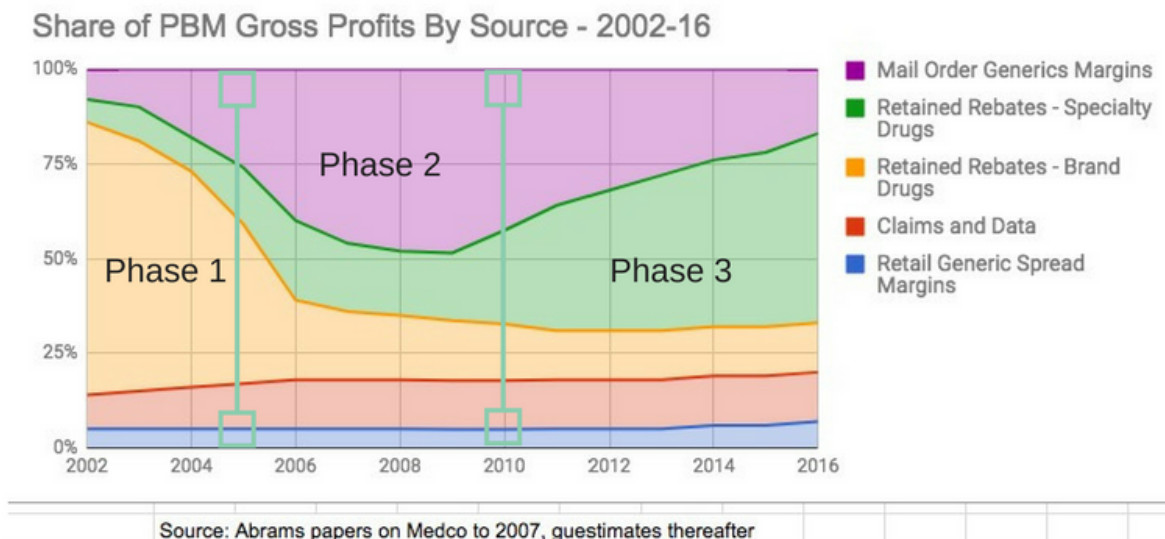
The management of the prescription (Rx) drug benefit portion of health care plans has become the domain of contracted specialists called pharmacy benefit managers (PBMs).

The three largest, independent PBMs — Express Scripts, CVS Caremark, and OptumRx, (known as "The Big 3") control 73% of the total Rx claims processed 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 generic 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 that make it difficult to rely 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 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 of 10% on average.

[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 has been an occurrence now known as [the “gross-to-net price bubble.”](#)

## **Formulary Choice and Drugs Rebates**

An important managed care function of PBMs is to develop a list of drugs that are covered by insurance. 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 the plan. The formulary is designed to limit Rx to the most cost-effective drug(s) in each of 50-80 different therapeutic classes.

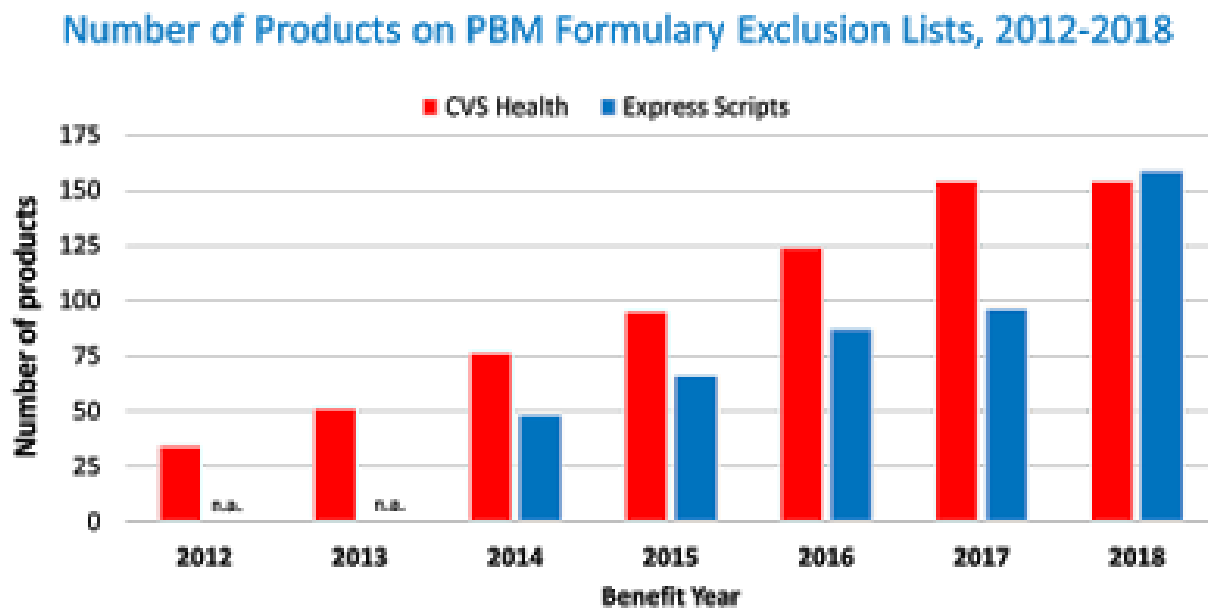
[In 2005, we were the first to conceptualize](#) formularies and their therapeutic classes as a group of markets. On the sell-side are brand drug companies with close, but not perfect substitutes, called therapeutic equivalents. On the buy-side are the Big 3 PBMs representing plan sponsors and their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

Economists call such markets bilateral oligopolies. We have [written a number of papers](#) about the Pharma - PBM bilateral oligopoly. We have also written a number of papers

[conceptualizing rebates as tariffs](#) paid by Pharma to gatekeepers (PBMs) for access to markets with limited competition.

We have observed a change in PBMs' approach to formulary choice over the past 15 years. Basically, "rebatable" therapeutic classes have gone from being open -- a number of covered drugs -- to being closed -- 1-2 covered drugs. The corollary of this trend is a growing list of excluded drugs.

[Adam Fein of the Drug Channels blog has done a great job at tracking](#) this trend. Below is his latest graph:



Note: Express Scripts did not publish exclusion lists for 2012 and 2013.

Source: Pembroke Consulting analysis of company reports

Published on Drug Channels ([www.DrugChannels.net](http://www.DrugChannels.net)) on August 3, 2017.



We are just beginning to think about the causes of this trend. But our basic view of [what drives PBMs to choose](#) open versus closed therapeutic classes is this:

The more a PBMs 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. This is the reason for the trend toward closed formularies and correspondingly more drugs on excluded lists.

### **The Hepatitis C Virus Drug Therapeutic Class**

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

[In 2016, Gilead's Harvoni stood at #2](#) on the list of top selling Rx drugs at \$10.0 Billion a year. In the three years since Harvoni came on the market, there have been 9 additional HCV drugs approved by the FDA, but only AbbVie's Viekira Pak has garnered any significant sales to date.

The main reason is that the two largest PBMs -- CVS Caremark and Express Scripts -- have decided to close the HCV therapeutic class to all but two drugs that cover all six HCV genotypes. (see table for 2017 below)

2017 Formulary Choice for Hepatitis C Virus Class - Express Scripts vs CVS									
List Price							FDA	1 pill a day	
Regimen	Manufacturer	Drug	CVS - 2017		ESRX - 2017		Approved	weeks	Genotype
\$ 84,840	Gilead Sciences	Sovaldi	Preferred		Excluded		12-6-13	12	1,2,3,4
\$ 95,445	Gilead Sciences	Harvoni					7-10-14	12	1,4,5,6
\$ 75,508	Gilead Sciences	Epclusa		Preferred			6-28-16	12	2,3
\$ 21,038	AbbVie Inc	Viekira Pak		Excluded	Preferred		12-19-14	12	1
\$ 38,710	AbbVie Inc	Technivie		Excluded	Preferred		7-24-15	12	4
\$ 67,024	Janssen T.	Olysio		Excluded		Excluded	11-22-13	12	1,4
\$ 63,630	B-M-S	Daklinza		Excluded		Excluded	7-24-15	12	1,3
\$ 55,148	Merck	Zepatier		Excluded		Excluded	1-28-16	12	1,4
\$ 74,760	Gillied Sciences	Vosevi		not FDA		not FDA	7-18-17	12	1-6
\$ 26,400	AbbVie Inc	Mavyret		not FDA		not FDA	8-3-17	8	1-6

[Source: CVS Caremark Formulary 2017](#)

[Source: CVS Caremark Formulary Exclusion List 2017](#)

[Source: Express Scripts Formulary and Exclusion List 2017](#)

## Factors Underlying Formulary Choice

The question is what were the determining factors underlying the formulary choices above. Also, given the opaqueness of the PBM business model and history of misalignment with client interests, were the above choices aligned or misaligned with client interests?

PBMs all state on [their websites](#) that the fundamental criteria governing formulary choice is drug cost-effectiveness. In the case above, a few of the nine HCV drugs may be less effective than the leader Harvoni, but effectiveness cannot account for breadth of formulary exclusion above.

The most important variable affecting HCV formulary choice above is on the cost side. Specifically it is NET costs -- Pharma's list price less gross rebates negotiated between Pharma and PBMs -- that is the determining factor.

A conflict of interest can arise if there are several therapeutic equivalents that are all cost-effective, but there is one drug with a list price so low that it affords PBMs little to no retained rebates.

Consider this hypothetical choice below:

A Test of PBM Alignment: Open or Closed Therapeutic Class?		
Therapeutic Equivalents	Specialty Drug A	Specialty Drug B
List Price (Yearly Regimen)	\$80,000	\$20,000
Negotiated Rebate (if Exclusive)	\$64,000	\$0
Net Price Before Retention	\$16,000	\$20,000
PBM Rebate Retention (10%)	\$6,400	\$0
Cost to Plan	\$22,400	\$20,000

Until AbbVie's aggressive list pricing of Mavyret appeared in August 2017 (see below), the regimen list price of all of HCV drugs was about the same. Unlike the example above, formulary choice for the HCV class did not present a potential conflict of interest prior to AbbVie's pricing of Mavyret.

The choices made by ESRX and CVS in 2017 highlighted above are aligned with interests of clients. The only question for us is why did the two PBMs close to close the therapeutic class?

We think the reason comes down to the specific rebate formulas used in rebate contracts -- a top secret element in a generally opaque PBM business model.

We speculate that the formula for placement as a preferred drug could take several general forms:

1. \$ discount / unit;
2. % price discount / unit;
3. single lump sum in \$ tens of millions as a function of market share delivered.

We think that behind closed therapeutic classes are contracts with large lump sum payouts as a function of market share. We think that behind open therapeutic classes are dollar or % discount formula with no incentives / penalties for market share delivered.

One of the reasons why PBMs want to keep rebate formulas a secret is that such formulas have been a [key element in antitrust lawsuits](#) alleging that market share rebates foreclose competition.

### **AbbVie's Mavyret Drug Pricing Is Disruptive to the PBM Business Model**

On August 3, 2017, the FDA approved a new HCV drug call Mavyret from AbbVie. According the [Speciality Pharmacy Times](#), this new drug has the potential to challenge the dominant position of Gilead's Harvoni on two fronts: (1) a regimen requiring only 8 weeks versus 12 weeks for Harvoni; and (2) a disruptive ultra-low regimen list price that leaves little to no room for PBM rebates.

Below is our spreadsheet comparison of the NET REGIMEN for Mavyret versus Harvoni:



Net Regimen Cost Comparison: Harvoni vs. Mavyret			
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	

AbbVie's pricing for 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 client interests -- as cost-effective than Harvoni -- but not aligned with their own interest of squeezing out all the rebates they can from specialty drugs.

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."

As promised, [on September 15th Express Scripts released](#) its choices for HCV class. It chose to add AbbVie's Mavyret even though the pricing afforded them little to no rebates potential.

This choice represents a clear statement by Express Scripts that it is aligned with client interests.

Surprising to us was that Express Scripts also chose to open up the HCV class to 3 other drugs as indicated in the table below.

Express Scripts Formulary Choice for Hepatitis C Virus Class - 2017 vs 2018									
List Price	Regimen	Manufacturer	Drug	ESRX - 2017	ESRX - 2018	FDA Approved	1 pill a day weeks	Genotype	
\$ 84,840		Gilead Sciences	Sovaldi	Excluded	Excluded	12-6-13	12	1,2,3,4	
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[Source: Express Scripts Formulary and Exclusion List 2017](#)

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We believe that underlying to an open therapeutic class is a movement away from a large lump sum rebate predicated on market share to a simple linear rebate as a function of volume.

CVS Health has yet to announce its final choices for the HVC class despite [promising that it would do so by mid-September 2017](#).

If CVS chooses not to add Mavyret, it will be a sign that CVS is so desperate for rebate income that it is willing incur a very public case **of misaligned interests**.