Was CVS's Formulary Exclusion of Mavyret in Violation of Antitrust Laws?

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Summary

In October 2017, CVS Caremark (CVS) finally decided to exclude from its 2018 drug formulary the new-to-market Hepatitis C Virus (HCV) drug Mavyret despite it being list priced aggressively by its manufacturer AbbVie at an estimated 72% below the list price of Gilead Sciences' incumbent HCV drug Harvoni.

We estimate that Gilead Sciences had to offer CVS a minimum of a 83% rebate percentage in order for Harvoni to have a net price below Mavyret's list price. The 83% figure would represent an outlier in reported gross rebate percentages today that generally fall in the 40% to 60% range.

Had the rebate percentage been less, it sets up an anti-competitive and antitrust case that Mavyret was excluded because of lack of PBM rebate retention despite being the low cost drug in the HCV therapeutic class.

We call on CVS Caremark to issue a public statement confirming that its choice to exclude Mavyret was in the best interest of clients because Harvoni was the lower cost drug after rebates.

Pharmacy Benefit Managers and Formulary Choice

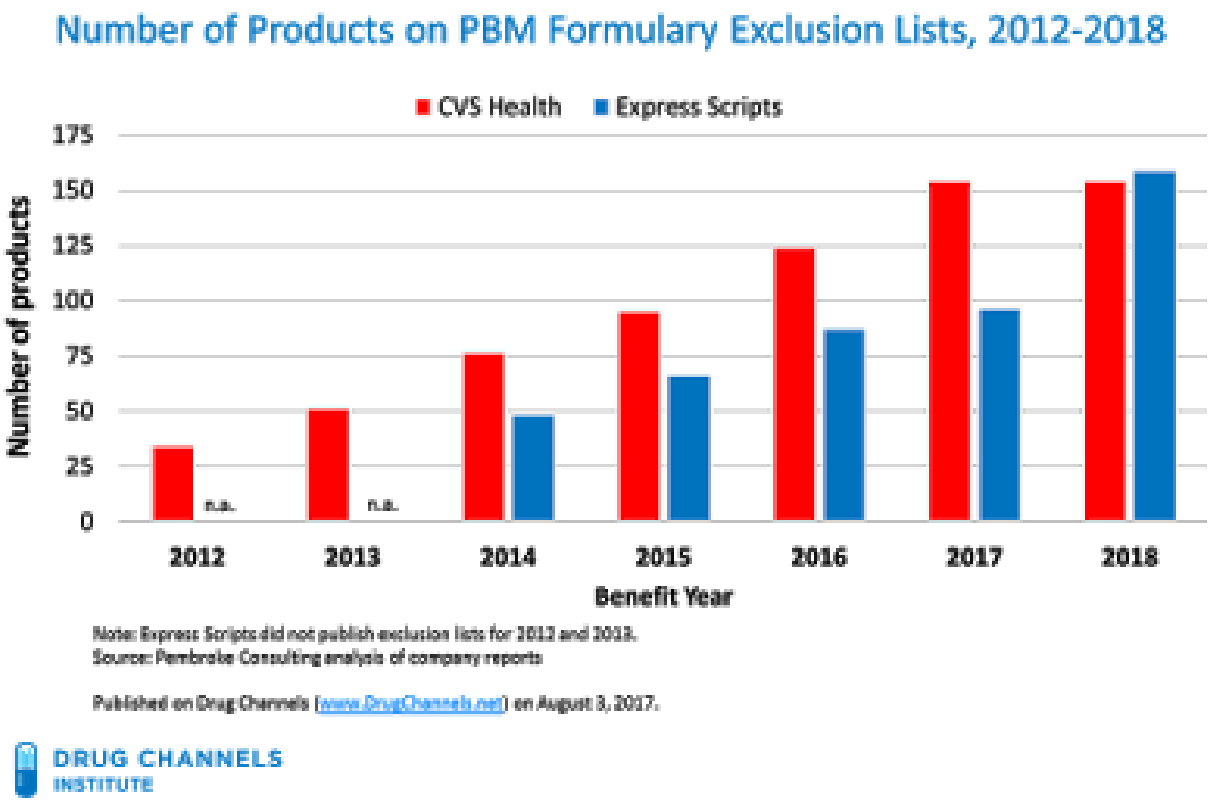
The pharmacy benefit manager (PBM) business model relies heavily today on rebates received from drug companies in return for placement on a formulary --a list of drugs covered by a prescription benefit plan.

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 drugs — to being closed — a single approved drug. We are just beginning to figure out the causes of this change, but the basic idea is this:

The 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. This is the reason for the trend toward closed therapeutic classes in formularies and correspondingly more drugs on excluded lists.

Adam Fein of the Drug Channel blog has done a great job at tracking this trend. Below is his latest graph:



Antitrust Issues In Exclusive Formulary Contracts

Following the generally accepted theories of the late legal scholar and Supreme Court nominee Robert Bork, vertical restraints such as exclusive dealing in formulary contracts are **presumptively** welfare-enhancing and procompetitive because it would not be rational for a buyer to exclude the lowest cost supplier.

Exclusionary formulary contract between Pharma and PBMs present an interesting variant to Bork's antitrust theories as the PBM business model is not "rational" in the traditional economics sense of maximizing revenue minus costs.

While PBMs are resellers of brand drugs, their gross profits on brand Rx are derived only from a retained rebate percentages on the order of 10%. As opposed to generic Rx fills, PBMs do markup, or earn a "spread margin" on, brand Rx ingredient costs however measured. A 2005 study conducted by the FTC into possible PBM conflicts of interest in excluding mail order Rx to captive operations confirmed this business model.

The PBM business model setups up a possible misalignment of interests between plan sponsor preferences for the lowest net cost drug in a therapeutic class versus PBM preferences for the drug with the highest rebate retention DOLLARS. **With PBMs, you have to take out Bork's "presumptive" qualifier to his dictum that vertical constraints are presumptively procompetitive because the PBM business model is not rational in the traditional economics sense.**

With antitrust cases involving PBM exclusive dealing in formulary contracts, you can't presume anything. But, it helps if the excluded demonstrate competitiveness from the outset.

There have been two recent lawsuits claiming that exclusive dealing in formulary contracts are anti-competitive and violate antitrust laws starting with Section 3 of Clayton Act covering exclusive dealing:

> Shire US Inc v Allergan Inc et al, U.S. District Court, District of New Jersey, Newark Office, No. 17-07716. October 2, 2017
>
> Pfizer Inc, v Johnson & Johnson et al, U.S. District Court, Pennsylvania Eastern District Court, Philadelphia Office, No 17-04180, September 20, 2017

Following Bork, we believe that both of these lawsuits are weak as it is likely that the plaintiffs (the excluded) are NOT the low cost suppliers. This likelihood is due to the fact the plaintiffs listed their new-to-market drugs at, or slightly below, the list price of the incumbent drugs. Had they started out with a list prices at least 70%-80% lower

than the list price of the incumbent, they might have been in a position to show that they were the low cost supplier of a therapeutic equivalent and merited inclusion in the formulary. Furthermore, they would have been in a position to expose PBMs' misaligned business model.

Unlike the two cases mentioned above, AbbVie's aggressive list pricing of its new-to-market HCV drug Mavyret creates a real possibility of an anti-competitive and antitrust (Section 3 Clayton Act) case of exclusive dealing due to a lack of rebate retention despite Mavyret being the lowest cost drug available in the HCV therapeutic class.

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 month later, an improved version of Sovaldi, called Harvoni, came on the market. These drugs produced fewer side effects than first generation combo drugs requiring painful stomach injections of interferon. Also, Sovaldi / Harvoni only required pill 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 prescription drugs at $10 Billion a year, after AbbVie's top selling biotech drug Humira at $13 Billion a year used to treat a variety of autoimmune diseases.

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

The two largest PBMs CVS Caremark and Express Scripts (ESRX) have a history of making 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 a “deep discount” rebate to gain exclusivity in the HCV therapeutic class.

Below is a summary of the 2017 formulary choices of CVS and ESRX for the HCV therapeutic class:

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				Excluded	12-6-13	12	1,2,3,4
$ 95,445	Gilead Sciences	Harvoni	**Preferred**				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	Gilied 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

AbbVie’s Mavyret Drug Pricing Is Disruptive to the PBM Business Model

On August 3, 2017, the FDA approved a new HCV drug called Mavyret from AbbVie. According the Speciality Pharmacy Times, this new drug had 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 of $26,400 that left little to no room for PBM rebates while still coming in at 15% below the NET price of Harvoni implying a 78% as the gross rebate percentage.

We have argued in another paper that AbbVie's pricing for Mavyret is disruptive to the PBM business model. AbbVie's aggressive pricing forces CVS and Express Scripts to consider a drug for inclusion in their national formularies that is aligned with their clients interests — lower net costs than Harvoni — but not aligned with their own interest of squeezing out all the rebates they can from specialty drugs.

Express Scripts' Choice for the HCV Therapeutic Class

On September 15, 2017 Express Scripts announced its 2018 choices for the HCV therapeutic class. It chose to add Mavyret as a preferred drug. But, surprisingly, it also chose to open up completely the HCV class by adding Gilead's existing HCV drugs. The new Gilead combo drug Vosevi was also added with a step-therapy proviso.

Below is a comparison of Express Scripts' closed formulary for 2017 versus its open formulary for 2018.

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
$ 95,445	Gilead Sciences	Harvoni			**Preferred**		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	**Preferred**		**Preferred**		12-19-14	12	1
$ 38,710	AbbVie Inc	Technivie	**Preferred**		**Preferred**		7-24-15	12	4
$ 67,024	Janssen T.	Olysio		Excluded		Excluded	11-22-13	12	1,4
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CVS Caremark's Choice for the HCV Therapeutic Class

In August 2017, CVS Health released a white paper reiterating the criteria it uses for formulary choices and exclusion lists.

> "We remove drugs only when clinically-appropriate, lower-cost (often generic) alternatives are available.

CVS stated that it expected to remove 17 products from its 2018 Standard Control Formulary, but noted that

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

On September 28, 2018, we noted in a blog post that CVS was two weeks late in making its decision on Mavyret. We also tweeted about it to CVS.

On October 1, 2017 CVS released its drug exclusion list for 2018 with no mention of its decision on Mavyret. Replicating its 2017 choices, CVS preferred the Gilead drugs and excluded the rest.

Sometime after October 1, 2017 and before October 10 201,7 CVS released an "undated" Advanced Control Formulary for 2018 that indicated that it finally did decide to exclude Mayvet:

EXCLUDED DRUG NAME(S)	PREFERRED OPTION(S)*
LUXIQ	*clocortolone, hydrocortisone butyrate, mometasone, triamcinolone*, LOCOID LOTION
MACRODANTIN	*nitrofurantoin*
Matzim LA	*diltiazem ext-rel* (except generic CARDIZEM LA)
MAVYRET	EPCLUSA (genotypes 1, 2, 3, 4, 5, 6), HARVONI (genotypes 1, 4, 5, 6), VOSEVI [2]

It is interesting to consider the question of why CVS chose to keep the the HCV class closed while ESRX choose to open it up. Obviously, CVS received more from Gilead for exclusive placement of Harvoni than ESRX received in return for subjecting Harvoni to competition.

A less obvious reason is that, because of CVS's sagging "front store" drugstore convenience business, CVS has to rely on retained rebates from specialty drugs more than the pure play PBM ESRX. This forces CVS to squeeze all the rebates it can from specialty drug companies by offering exclusivity on its formulary.

On the other hand, ESRX's gross profits from rebate retention do not have to subsidize low to negative gross profits from the "front stores" of vertically integrated retail drugstore chain. ESRX can afford to be more "open" about formulary design than CVS.

Was CVS's Exclusion of Mavyret Anticompetitive?

Based on list prices reported by Speciality Pharmacy Times and CVS' own reported average rebate retention rate of 10%, we present an estimate below of the rebate

percentage Gilead had to offer CVS Caremark in order for Harvoni to come in at a lower net price than Mavyret's list price.

If our estimate of 83% was what actually transpired, then both Gilead and CVS would have a solid case that this exclusive dealing rebate contract was procompetitive and in the best interest of plan sponsors and consumers.

Estimate of Gilead's Rebate Offer to CVS Caremark To Win Exclusive Formulary Placement for Hep C Drugs				
Net Regimen Cost Comparison: Harvoni vs. Mavyret				
Pharma	%	Gilead	AbbVie	% Difference
Drug		Harvoni	Mavyret	
Treatment List Price		$94,500	$26,400	-72%
Estimated Gross Rebate	-83%	-$78,435	$0	
PBM Rebate Retention Rate	10%	$7,844		
Net Price To Plan		$23,909	$26,400	
Winning Margin $		-$2,492		
Winning Margin %		-9.4%		
Source: AbbVie Pricing for Mavyret				

On the other hand, our 83% estimate seems to an outlier for rebates negotiations today.

Merck has published data on average gross rebate percentages given to PBMs and others. For 2016, Merck's average gross rebate percent stood at 40.9%, far below our estimate of 83% that Gilead would have had to pay CVS to undercut AbbVie's list pricing for Mavyret. The Merck data cast doubt on the likelihood that Gilead would given anywhere near 83% rebate.

If the gross rebate was slightly less, say 75%, then Mavyret would be the low cost drug.

In this case, the Bork presumption of the pro-competitiveness of vertical restraints breaks down. Here a “rational” PBM buyer would exclude the low cost supplier because of a misaligned business model based on retained rebates. A buyer with a normal reseller business model would NOT have excluded Mavyret.

Case Where Exclusion of Lowest Cost Drug Is "Rational" Due To Misaligned PBM Business Model				
Net Regimen Cost Comparison: Harvoni vs. Mavyret				
Pharma	%	Gilead	AbbVie	% Difference
Drug		Harvoni	Mavyret	
Treatment List Price		$94,500	$26,400	-72%
What If Gross Rebate	-75%	-$70,875	$0	
PBM Rebate Retention Rate	10%	$7,088	$0	
Net Price To Plan		$30,713	$26,400	
Mavyret's Lower Cost By			-$4,313	-14%
Source: AbbVie Pricing for Mavyret				

We call on CVS Caremark to issue a public statement confirming that its choice to exclude Mavyret was in the best interest of clients because Harvoni was the lower cost drug after rebates.

While there is no prize for second place here, we all benefit from AbbVie’s competitive effort. It’s aggressive pricing has forced PBMs to consider a low cost specialty drug that offers no rebate potential. If Gilead’s Harvoni was in fact the low cost drug, then AbbVie

forced Gilead to pay an outlier gross rebate percentage of around 83% to gain exclusivity and plan sponsors using CVS as their PBM all benefited.

In addition, AbbVie's aggressive pricing was likely a factor in other drug companies halting wasteful R&D spending on "me-to" HCV drugs. In September 2017, both Merck and Johnson & Johnson announced that they would be abandoning further development of HCV drugs. Merck said that it would be writing off a full $2.9 Billion in HVC R&D "due to competition."

Finally, while AbbVie's aggressive list pricing might not have been enough to undercut Gilead's outsized rebate offer, we believe AbbVie might have planted the seed in other specialty drug companies, especially one with biosimilars in development, that you cannot beat out incumbents by matching their high list prices and out rebating them for formulary placement.

Like AbbVie with Mavyret, we believe strongly that a company with a new-to-market "me-too" or biosimilar specialty drug must start out today with a list price at least 70% lower than the incumbent in the therapeutic class.

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