

# **Merck Data Discredits PBM-Sponsored Study Of Brand Drug Inflation**

by

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## **Summary:**

We start with a review of the history of the opaque pharmacy benefit manager (PBM) reseller business model. We summarize our estimates of the distribution of PBM gross profits over the past decade showing that they have become dependent today on retained rebates from specialty drugs.

Next, we present numbers showing how PBMs today have painted themselves into a corner with a relatively small basis for drug rebates coupled with promises to hold their overall average rebate retention rate to a seemingly “reasonable” 10%.

We conclude the paper with a deconstruction of the growing divergence between brand drug list prices (gross) and the prices Pharma actually receive after PBM rebates (net) -- the so-called “gross-to-net price bubble”. We deconstruct data supplied by the drug company Merck to uncover the need for PBMs to drive the parameters of rebate negotiations with Pharma in order to overcome constraints on their current business model choices.

## **The “Gross-To-Net Price Bubble”**

Before 2017, there had been two well-publicized exposes of massive increases in the list price of off-patented brand drugs that were rubber-stamped by pharmacy benefit managers (PBMs). This included Mylan’s EpiPen and Martin Shkreli and his Turning Pharmaceutical’s HIV drug Daraprim.

In 2017 there have been a number of reports providing quantitative evidence of outrageous increases in list prices specialty brand drugs over the past 5 year. For example, consider this [table of list price inflation between 2012-7](#) of Multiple Sclerosis drugs taken from Congressman Michael Vounatsos' request to manufacturers for more information:

<u>Brand Name</u>	<u>Year Approved</u>	<u>Approval Price</u>	<u>2012 Price</u>	<u>2017 Price</u>	<u>Total % Increase</u>
Avonex	1996	\$8,723	\$44,781	\$86,308	889%
Tysabri	2004	\$25,850	\$49,294	\$82,366	219%
Tecfidera	2013	\$57,816	N/A	\$87,623	52%
Plegridy	2014	\$65,510	N/A	\$86,308	32%
Zinbryta*	2016	\$86,592	N/A	\$86,592	N/A

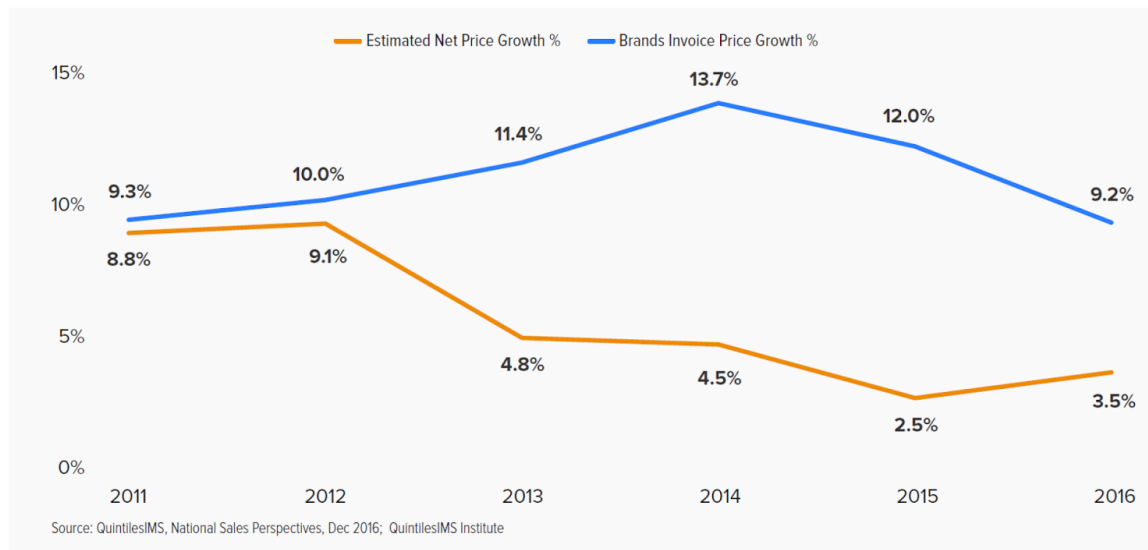
\*Zinbryta is co-promoted by Biogen and AbbVie.

In April 2017, Adam Fein first reported on his blog Drug Channels that the health information company QuintilesIMS had [just published](#) aggregate data on trends in brand name drug prices before (gross) and AFTER rebates (net) had been paid to pharmacy benefit managers (PBMs).

The data show a clear aggregate trend beginning in 2011: (1) gross prices were growing faster than net prices; (2) the divergence itself was growing.

Dr. Fein coined the term “gross-to-net rebate bubble” to describe (2) above, which has become the standard lexicon for the phenomena. Below is graph summarizing QuintilesIMS latest findings taken from [an April 2017 blog post](#) by Dr. Fein:

## Protected Brand Invoice and Net Price Growth



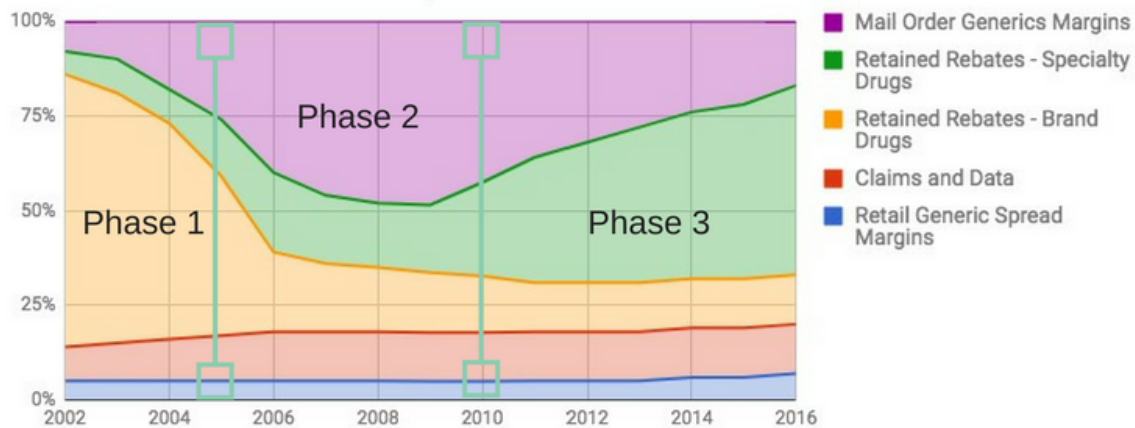
### The PBM Business Model: 2005 - 2010

[In an earlier 2017 paper](#), we presented the case that there has been three distinct phases of the pharmacy benefit manager (PBM) business model over the past 15 years. Each has been demarcated by radical shifts in their primary source of gross profits:

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

Below is graph of our estimates of the distribution of PBM gross profits over the past 15 years.

Share of PBM Gross Profits By Source - 2002-16



Source: Abrams papers on Medco to 2007, guestimates thereafter

The majority of PBMs gross profits between 2005 - 2015 came a mail order generic Rx. The [Big 3 PBMs devised a strategy](#) of tacitly colluding with their counterpart Big 3 retail pharmacies -- Walgreen, CVS, and Rite-Aid -- to hold up margins on generic Rx fills.

PBMs, essentially have the power to set their competitors' prices, an anti-competitive weapon if there ever was one. PBMs gave retailers fat margins for 30-day generics in return for promises not to compete on 90-day Rx. Then, they set the prices of generic Rx filled by captive mail order operations slightly less than retail to give the appearance of alignment with client interests. But, the supply chain hold up still allowed for fat mail order generic Rx margins.

The first blow to this scheme came in late 2006 when Walmart saw the fat retail margins and began a disruptive [\\$4 / generic Rx campaign](#). They could do this as an "outsider" retailer because their business model wasn't dependent on fat pharmacy margins subsidizing the rest of the store.

The final blow to this “hold-up” scheme came around 2008 several years after the vertical merger of the pharmacy retailer CVS and the PBM Caremark. [consistent with the business model of the merged company](#). CVS-Caremark began offering preferred provider pharmacy networks featuring lower prices at retail in return for volume.

While this managed care technique was often used successfully in reducing hospital and physician costs, it has never really been instituted by PBMs prior to the CVS-Caremark merger. This absence had been [an obvious sign to us at the time](#) of tacit collusion between the Big 3 retail pharmacies and the Big 3 PBMs.

### **The PBM Business Model: 2010 - today**

To compensate for declining mail order generic 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 were several problems with the goal of deriving a majority of gross profits from specialty drug rebates. **Reconstructing how PBMs solved these problems is the key to concluding that PBMs, not Pharma, are the drivers of the gross-to-net bubble observed in the drug supply chain today.**

First, assume that since 2010, the Big 3 PBMs needed additional gross profits each year from specialty drug retained rebates to replace incremental losses in margins from mail order generics Rx.

This creates a problem in 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. How much less? [The Pew Charitable Trust Foundation](#) sponsored a study which found that in 2015 special Rx comprised only 1% of total Rx.

[A decade ago, we estimated that about 20% of total Rx filled](#) were “rebatable” brand drugs, i.e. in therapeutic classes with a few other brand drugs that were therapeutic equivalents. So instead of 1:100 specialty Rx to total Rx basis differential, we arrive at a 1:20 “rebatable” specialty drug Rx to “rebatable” small molecule brand drug Rx basis differential.

In other words, ten years ago PBMs has 20 times the volume of Rx available to them to use as a basis for generating retained rebates as they do today.

The second constraint that PBMs have today is an the awareness by their clients that retained rebate dollars can be substantial, opaque source of PBM gross profits.

Today, there seems to be an order of magnitude more articles critical of PBMs in general, and retained rebates specifically, As a defensive move, CVS Health finally [declared publicly on its website](#) that,

“CVS Caremark was able to reduce trend for clients through... negotiation 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.

The business model of the drug companies is simple and stable by comparison. Sure, drug companies want to maximize profits just like the PBMs. But drug companies are not constrained as much as the Big 3 PBMs and don’t need a convoluted gross-to-net price scheme to achieve their targets.

It is important to remember that it takes two parties to negotiate drug rebate deals. Drug companies have some power in determining how these deals are structured, especially if there are only one or two other brands drugs that are therapeutic equivalents.

The Big 3 PBMs today have a lot of power in rebate negotiations. Drug companies have a lot to lose if negotiations fall through. Exclusion of a single drug from one of Big 3 PBMs' national lists of drugs covered by an insurance plan -- called formularies -- can cost a widely-used or expensive drug \$3+ Billion dollars in lost revenue.

It is Big 3 PBMs who drive schemes involving high-list-price / high-rebate specialty drug deals. For now, drug companies are accomplices along for the ride. They are culpable, but much less so than PBMA as drivers of the drug price inflation trend since 2010.

### **A Deconstruction of Merck's Gross-to-Net Drug Price Bubble**

In this section, we reconstruct a step-by-step sequence of how PBMs and drug companies might negotiate the parameters of a rebate deal today under the constraint that PBMs have to grow gross profit DOLLARS over time while keeping constant the rebate retention rate at 10%.

The trick is to find a win-win rebate deal structure given the above constraints. Forcing Pharma to hold list prices constant while gradually increasing PBMs' rebate percentages is a win-lose proposition to Pharma.

We lay out a step-by-step rebate negotiating process yielding a win-win outcome despite the constraint of a 10% fixed rebate retention rate. The win-win deal asks Pharma to increase brand drug list prices at double digit rates. At the same time, PBMs take list back price increases with near offsetting rebate percentages. Care is taken to choose just the right deal parameters to create a "win" for Pharma by having net prices

still go up a single digit rates. Care is also taken to choose the right parameters to create a big “win” for PBMs by having retained rebate DOLLARS increase by double digit rates even though the rebate retention rate is fixed at 10%

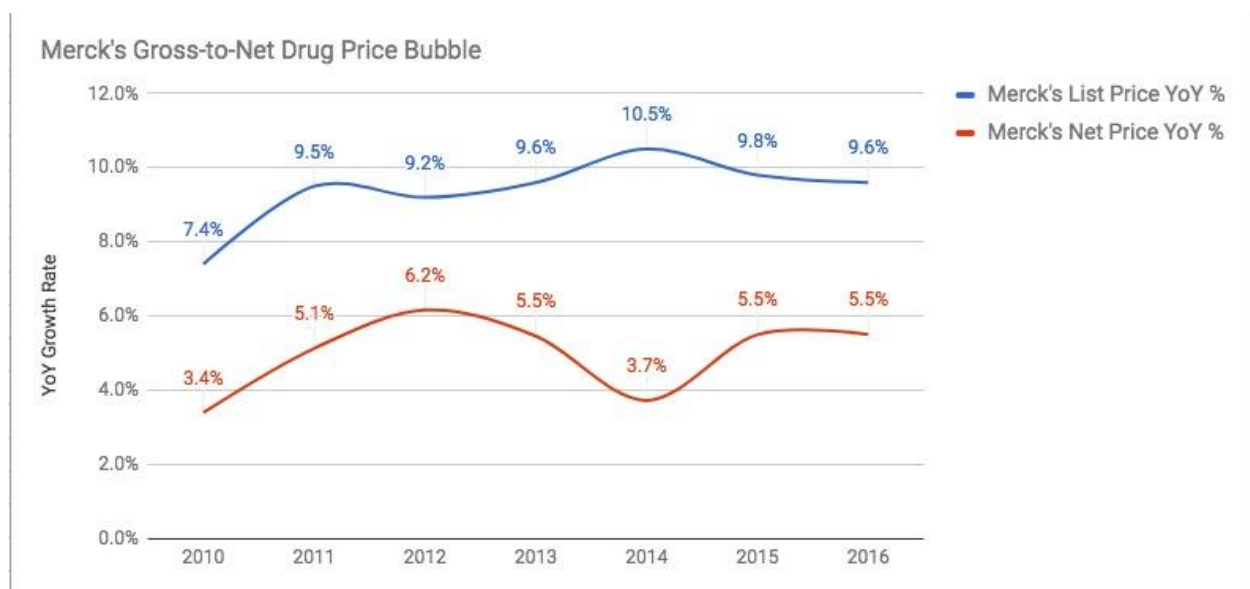
Below is a screenshot from a [Merck](#) memo laying out for all to see its “gross-to-net drug price bubble”. Other drug companies are [publishing similar data](#) as a way of defending themselves against charges of “double-digit” price-gouging tactics.

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

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

This is a graphic depiction of Merck’s gross-to-net price bubble:





Below we build a spreadsheet which “deconstructs” Merck’s bubble for a hypothetical specialty drug. It shows how PBMs can grow retained rebates dollars via a combination of growing rebate percentages while maintaining a “reasonable” rebate retention rate fixed at 10%.

A Deconstruction of Merck's List to Net Price Bubble								
	Merck's List Price YoY %	7.4%	9.5%	9.2%	9.6%	10.5%	9.8%	9.6%
	Merck's Net Price YoY %	3.4%	5.1%	6.2%	5.5%	3.7%	5.5%	5.5%
	<b>YEAR</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
1 <b>PBMs Negotiate With Merck</b>	<b>Gross Rebate %</b>	<b>27.3%</b>	<b>30.2%</b>	<b>32.1%</b>	<b>34.7%</b>	<b>38.7%</b>	<b>41.1%</b>	<b>43.3%</b>
2 Merck Reacts	List Price YoY %	7.4%	9.5%	9.2%	9.6%	10.5%	9.8%	9.6%
3 Derived from 2	Resulting Typical List Price \$	\$ 45,662	\$ 50,000	\$ 54,600	\$ 59,841	\$ 66,125	\$ 72,605	\$ 79,575
4 Derived from 1	Gross Rebate \$	\$ 12,466	\$ 15,100	\$ 17,548	\$ 20,765	\$ 25,590	\$ 29,841	\$ 34,456
5 Derived from 3 and 4	Net Price To PBMs (after rebates)	\$ 33,196	\$ 34,900	\$ 37,051	\$ 39,076	\$ 40,535	\$ 42,764	\$ 45,119
6 Derived from 5	Net Price (after rebates) YoY %	3.4%	5.1%	6.2%	5.5%	3.7%	5.5%	5.5%
7 <b>Transparent and Fixed</b>	<b>PBM Rebate Retention Rate</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>	<b>10%</b>
8 <b>But this continues to grow</b>	<b>PBM Rebate \$</b>	<b>\$ 1,247</b>	<b>\$ 1,510</b>	<b>\$ 1,755</b>	<b>\$ 2,076</b>	<b>\$ 2,559</b>	<b>\$ 2,984</b>	<b>\$ 3,446</b>
9 <b>And this continues to grow</b>	PBM Retained Rebate YoY %		21.1%	16.2%	18.3%	23.2%	16.6%	15.5%
	<b>Cumulative 6 Year Growth</b>							<b>176%</b>
10 <b>And this continues to grow</b>	Plans Net Price \$	\$ 34,443	\$ 36,410	\$ 38,806	\$ 41,153	\$ 43,094	\$ 45,748	\$ 48,565
11 <b>And this continues to grow</b>	Plans Net Price YoY %		5.7%	6.6%	6.0%	4.7%	6.2%	6.2%

A larger view of the spreadsheet above:

A Deconstruction of Merck's List to Net Price Bubble									
		Merck's List Price YoY %	7.4%	9.5%	9.2%	9.6%	10.5%	9.8%	9.6%
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		<b>YEAR</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
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<b>And this continues to grow</b>		Plans Net Price YoY %		5.7%	6.6%	6.0%	4.7%	6.2%	6.2%

Note that despite being constrained to a 10% rebate retention rate, this deal scheme give PBMs yearly retained rebate DOLLARS that is 176% greater than what they received 6 years earlier.

Some have predicted that the divergence between gross and net prices will leveled off in 2017 and thereafter. We tend to agree with that as the 2010-6 bubble was fueled by PBMs' need to REPLACE offset a declining trend in gross profits from mail order generic Rx. As long as there is stability elsewhere in sources of PBM gross profits, there will not be a need for PBMs to drive another "gross-to-net drug price bubble".