

# **Insulin Drug Price Inflation: Racketeering or Perverse Competition?**

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## **Summary**

We contend that recent insulin drug price inflation is a case of perverse competition rather than a case of illegal racketeering in violation of the RICO Act.

We will present the case that a now consolidated racketeering RICO lawsuit initiated by the law firm Hagens Berman has inverted the hierarchy of the Pharma – PBM enterprise. The lawsuit claims that the bidders — Pharma — “spearheaded” rebate negotiations and that pharmacy benefit managers (PBMs) as rebate-collecting gatekeepers are the followers. This makes no sense and is grounds for a dismissal of the lawsuit.

We concede that there was coordinated list pricing, but these were opening moves in a two-step bidding process driven by a perverse PBM business model rather than initiated by Pharma. We will present charts of formulary choices made by PBMs that are so varied that they could not be the result of collusion.

Rather the varied formulary choices in this case had to be the result of vigorous competition among insulin drug companies vying to be the highest gross rebate bidder that culminated in rational economic decisions by PBMs to award formulary exclusivity to the lowest net price bidder. In other words, there are no antitrust issues in this case.

## **Racketeers as Gatekeepers to Markets With Reduced Competition**

Racketeering is organized crime. It involves hierarchical groups of individuals working cooperatively under the direction of leaders. The organization can run the gamut from a traditional business like a trade show logistics company to a tight knit “association-in-fact” enterprise like a mafia crew.

The Racketeer Influenced and Corrupt Organizations Act (RICO) was passed by Congress in 1970 to deal with organized crime. For example, the Sopranos of HBO fame operated an ongoing “association-in-fact” enterprise involving rigged bids for suburban New Jersey garbage collection contracts. The RICO Act is ideally suited to deal with the Sopranos bid-rigging enterprise.

The Soprano scheme can be viewed as being in a class of rackets involving collecting “tariffs” in return either for opening up markets blocked by the government or for providing entrance to legitimate markets with the understanding that further competition would be limited.

Prohibition era bootlegging is the classic racket involving opening up markets blocked by government regulations. Garbage collection bid rigging is the classic racket of illegally limiting entrance to normally competitive markets.

Money laundering, loan sharking, convention center service contracts, building permits issued without inspections, drug smuggling, sports betting, arms dealing, and human trafficking are other examples of rackets involving payment for access to markets with reduced competition.

Potential entrants are willing to make substantial payments in these cases because they are cuts from super-competitive profits that normally would flow to consumers in the form of lower prices.

Potential bidders in racketeering schemes face a “prisoner’s dilemma”. On the one hand, it is in the best interest of all potential entrants to wait their turn and cooperate.

On the other hand, the best strategy for any individual bidder is go it alone, defect and enter the market secretly without paying any tariff.

The ‘prisoner’s dilemma’ is the reason why successful rackets often require threat of harm — horizontal restraints in antitrust parlance — to insure cooperation. For example, Tony Soprano regularly would dispatch his nephew Christopher Moltisanti to coach sanitation companies on upcoming municipal garbage collection contracts up for bid, and remind them of what would happen to their kneecaps if they failed to cooperate.

RICO enterprises that do not use physical force to insure cooperation look to other mechanisms to foster cooperation among bidders. In cases of price-fixing, short-term retaliation via sharp undercutting of a defector’s price is used to remind the defector of the costs of competition.

Also, bidders are more likely to cooperate long term if the racketeering gatekeeper exhibits a sense of “fairness” by distributing the rigged bid opportunities evenly across bidders.

### **Racketeering Lawsuits**

On November 3, 2016, Senators Bernie Sanders (I-Vt) and Elijah Cummins (D-Md), [asked](#) the Department of Justice and the Federal Trade Commission to investigate insulin drug manufacturers for possible anti-competitive practices in setting list prices, noting that “the potential coordination by these drug makers may not simply be a case of ‘shadow pricing,’ but may indicate possible collusion.”

Over the course of 2017, there have been [a number of class action lawsuits and state Attorney General Civil Investigative Demand \(CID\) letters](#) filed against three makers of insulin — Sanofi, Eli Lilly, and Novo Nordisk — on behalf of patients incurring high out-of-pocket costs for needed insulin drugs. The lawsuits alleged a pattern of

racketeering — repeated, organized criminal acts involving secret agreements to inflate drug prices to the benefit of drug companies.

These lawsuits all alleged that the three drug companies “spearheaded” the insulin list price inflation and that insulin list price inflation was the “proximate cause” of damages suffered by patients who could not afford to continue treating their diabetes with insulin made by these companies.

The original racketeering lawsuit was filed by the law firms of Hagens, Berman, Sobol, & Shapiro (hereafter Hagens Berman) and Carella, Byrne, Cecchi, Olstein, Brody & Agnello, P.C. on [January 30, 2017](#), amended [on March 17, 2017](#) and again [on December 27, 2017](#). Hagens Berman has been consistent in naming the three insulin drug companies — Sanofi, Eli Lilly, and Novo Nordisk — as “spearheading” the racket and as co-defendants.

Hagens Berman characterized pharmacy benefit manager (PBMs) as “knowing and willing participants” in the racketeering enterprise who helped “perpetuate” the fraud (¶ 300) and “reaped profits” ( ¶ 300) from the racket, But Hagens Berman has stopped short of naming PBMs as co-defendants. In a June 2017 interview with Bloomberg, Partner Steve W. Berman [offered this lame explanation](#) of why his law firms decided to name only drug companies as defendants:

“Rather than compete by lowering net prices, the drug companies compete by raising list prices,” says Berman, the managing partner of [Hagens Berman Sobol Shapiro LLP](#). He decided to name only the drug companies as defendants, because “they’re the ones who publish the fraudulent list prices” that directly harm patients. The two other plaintiffs’ firms that filed

In September, 2017, U.S. District Judge Brian R. Martinotti of the U.S. District Court for the District of New Jersey [consolidated all RICO lawsuits](#) and named Steve W. Berman of Hagens Berman and James E. Cecchi of Carella Byrne as interim lead counsel. There are two other RICO lawsuits [by Weitz & Lutzenberg](#) and [by Keller Rohrback LLP](#) consolidated into the Hagen Berman lawsuit by U.S. District Judge Martinotti.

These other lawsuits have named the three largest PBMs — Express Scripts, CVS Health, and OptumRx — as co-defendants. But, even these lawsuits characterize the drug companies as the masterminds of the collusion.

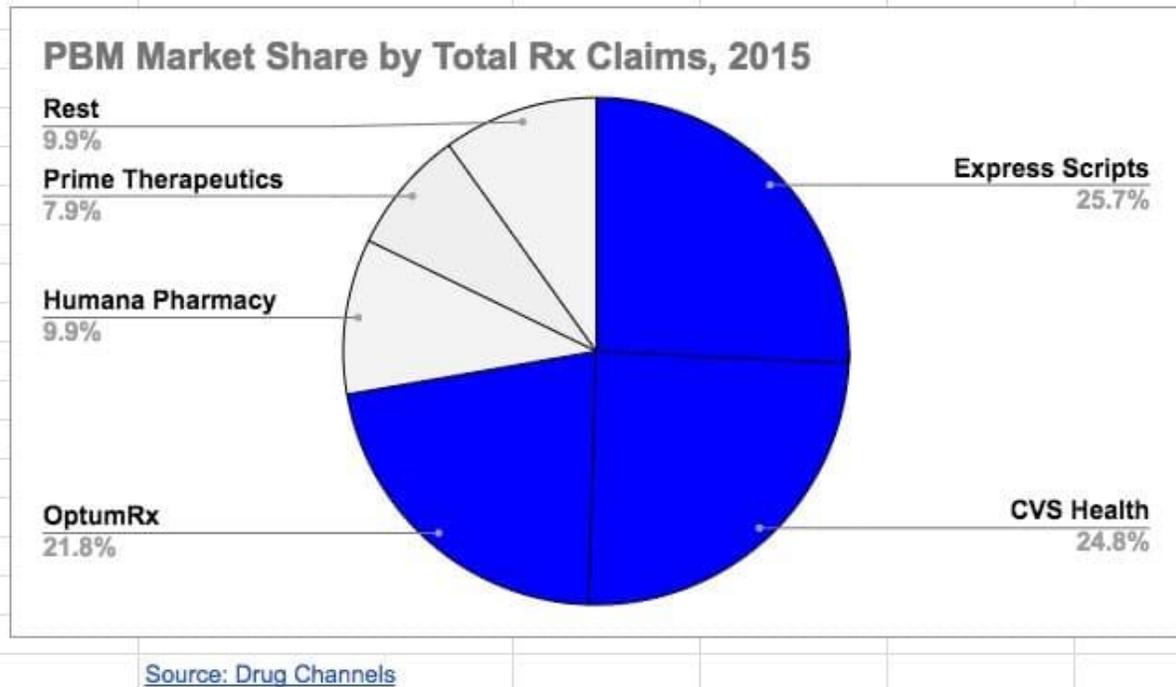
In consolidating these lawsuits, the New Jersey District Court has said that

“ the issue of joinder and/or severance of the three pharmacy benefit managers, will be addressed at a later date.”

### **Formulary Rebate Negotiations Between Pharma and PBMs**

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 OptumRx, (known as “The Big 3”) control 73% of the total Rx claims processed the United State in 2015.



We [have estimated that a majority of PBM gross profits today](#) come from retained rebates from specialty and injectable biologic drugs — infused autoimmune drugs like Humira and Enbrel and self-injectable insulin drugs like Lantus discussed below.

These rebates are paid by drug companies in return for placement in a formulary — a table of preferred drugs covered by insurance. The formulary is a lookup table that PBMs inserted into their retail drug store point of sale 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](#) PBMs as “gatekeepers” to markets with reduced competition, rebates as “tariffs” willingly paid by Pharma in return for formulary access, and formularies a set of markets with a varying degree of competitiveness (competitive, monopolistic, oligopolistic) among drugs that are “therapeutic equivalents”.

On the sell-side are brand drug companies with therapeutic equivalent drugs vying for placement in therapeutic class “markets”. On the buy-side are the Big 3 PBMs deciding which drugs among therapeutic equivalents should be listed in the formulary and covered by insurance.

Economists call such markets bilateral oligopolies. We have [written a number of papers about the Pharma – PBM bilateral oligopoly](#) available for free download on our website. In sum, rebates are tariffs paid by drug companies to PBMs for limiting access to oligopolistic therapeutic classes in formularies. That broad description — tariffs paid for access to markets with reduced competition — is the same as the Soprano bid-rigging scheme and the same as a whole class of illegal rackets. RICO lawsuits in this case have to prove an ongoing pattern of overt collusion and conspiracy involving secret plans with the intent to do something unlawful or harmful.

### **The Cause of The Recent Drug List Price Inflation**

We have written a number of papers presenting the case that it has been PBMs, not Pharma, that has driven the recent drug list price inflation.

- [Blame PBMs \(Not Pharma\) For Driving Drug Price Inflation](#) (09/17)
- [Three Phases of the Pharmacy Benefit Manager Business Model](#) (09/17)
- [Merck Data Discredits PBM-Sponsored Study of Brand Drug Price Inflation](#) (09/17)

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.

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

But there are several problems with the goal of deriving a majority of gross profits from specialty and biologic drug rebates. The first is that basis for gross rebate percentages — specialty and biologic drugs — represents only 20% of the Rx volume of the “rebateable” small molecule drugs available to PBMs a decade earlier.

The second constraint is that there is an awareness by plans and the public today that opaque retained rebates are a dominant source of gross profits. Today, articles critical of PBMs in general, and retained rebates specifically, seem to be at least ten times more numerous than a decade ago. In 2016, CVS Health has even [stated publicly on its website](#) that,

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

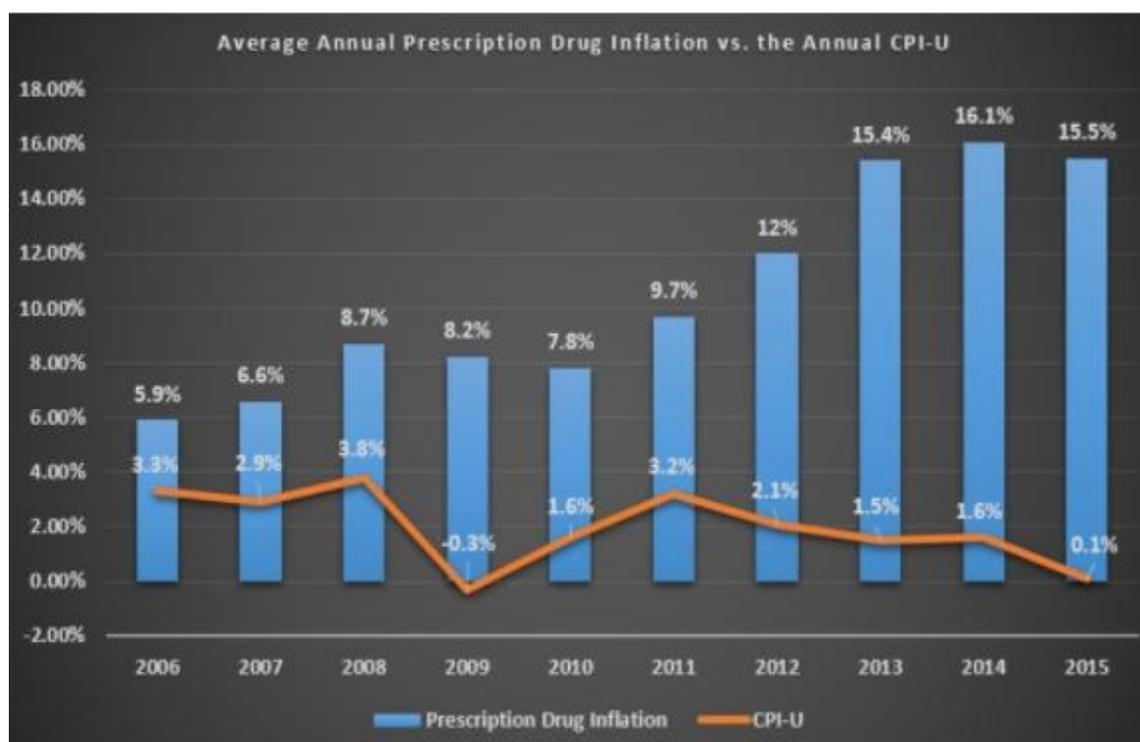
The problem facing PBMs today is how to derive around 50% of gross profits from specialty and biologic Rx while maintaining a transparent “reasonable” rebate retention rate at 10% on average.

How have the Big 3 PBMs accomplished this? Pharma knows that PBMs are desperate to make formulary choices in oligopolistic therapeutic classes on the basis of gross rebates received first and net prices second.

Pharma knows that it will disqualify itself from a chance to be the winning bidder for placement in a formulary if their first move in rebate negotiations is a low list price without any room for further rebate offers.

In sum, it is the perverse PBM business model that drives tacit cooperation among Pharma to increase list prices in lock-step. Since 2010, PBMs have required ever-increasing retained rebates to offset continuing losses in mail order generic margins. The timing of the need to offset one source of gross profits with another fits

the acceleration in drug list price inflation between 2010 and 2014 with a tailing off since then (see chart below).



[Source: Motley Fool, April 2017](#)

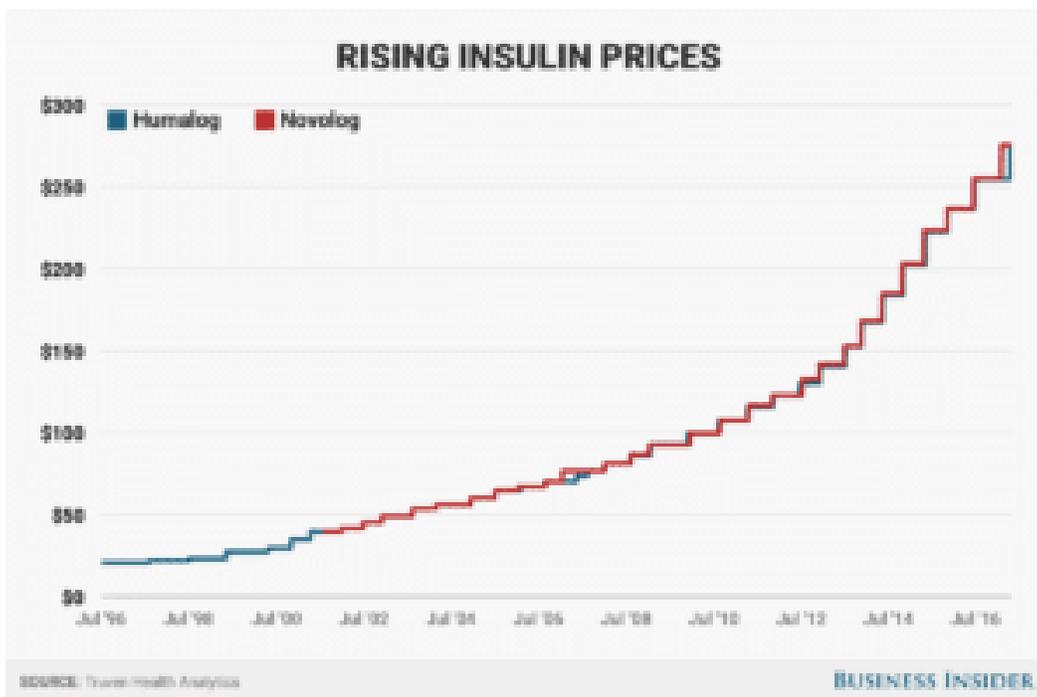
### Lock-Step Insulin Drug List Pricing

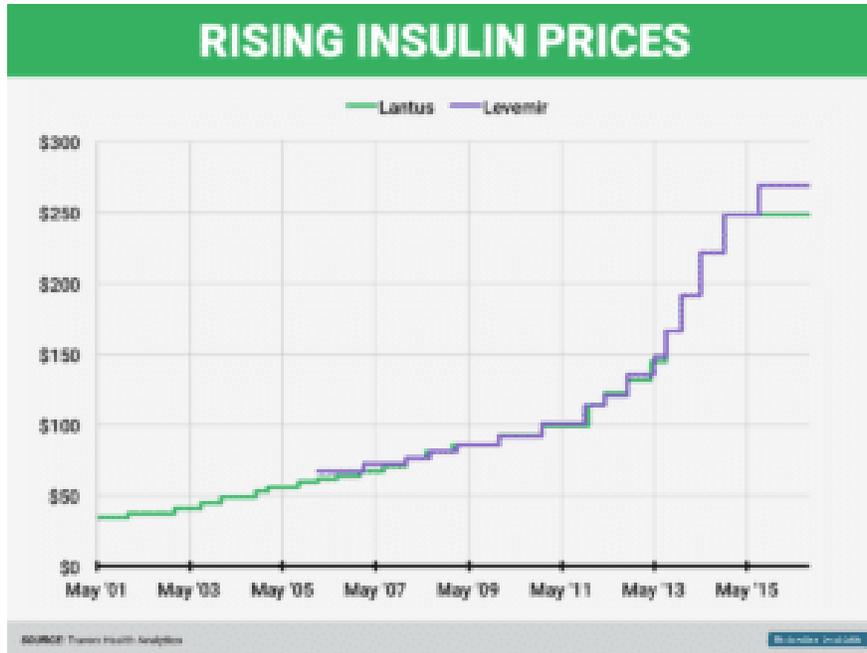
There is little question that there has been some sort of coordination among the insulin drug companies in setting list prices — formally known as wholesale acquisition costs (WAC) over the last decade.

We think the coordination is not overt, but a “follow-the-leader” understanding developed independently over the years. Pharma understands that a move to list price significantly below a competitor only reduces their ability to compete on gross rebates in the second round of this two-step bargaining process. Here is [a quote from Novo Nordisk's CEO](#) admitting that they follow closely any list price change of their competitors.

Novo Nordisk's Ken Inchausti added: "We monitor market dynamics and our competitors' pricing through public and subscription databases that track list prices."

Below are charts of lock-step increases in insulin drug prices presented by the law firm Hagens Berman in their RICO lawsuit. These charts are clearly the most damaging evidence in support of the allegations of collusion.





[Source: Business Insider, September 2016](#)

But, we believe that the insulin list price inflation is NOT an offensive move to increase gross profits, but defensive opening moves in a competitive two-step rebate negotiating game “spearheaded” by PBMs.

Negotiable prices are a hallmark of bargaining situations involving a few sellers and a few buyers. Baseball player salary arbitration starts with each party offering prices far apart from what both parties ultimately agree to.

The real estate website Zillow presents extensive historical data showing that the norm in residential home sales is a high opening list price followed by periodic price reductions until a sale is made.

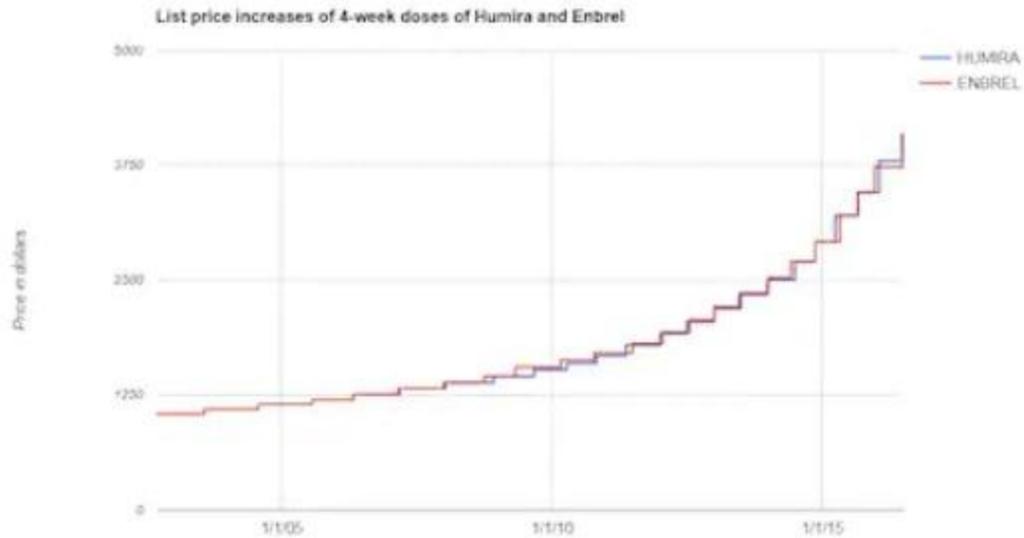
In healthcare, it is a standard practice for providers vying for preferred provider status to start negotiations with high list prices and then offer varying degrees of discounts in return for the higher volume that comes with being named a preferred provider.

What is going on between insulin drug manufacturers and PBMs is no different. High list prices are just the standard opening round in a negotiation process among companies vying for preferred status on formularies for their “therapeutic equivalent” drugs.

The practice of lock-step drug list price inflation is not unique to insulin drug makers. Below is a chart of lock-step list prices between two manufacturers of top selling autoimmune drugs — AbbVie’s Humira and Amgen’s Enbrel. Both drugs require regular infusions at clinics and hospitals. These drugs are covered by a medical benefit managed by insurance companies rather than a drug benefit plan managed by PBMs.

It is interesting to note that the lock-step drug price inflation pattern exists even though the “gatekeepers” in this case are insurance companies. Unlike PBMs, insurance companies have rational business models — 100% pass through or capitated insurance premiums — where the only consideration is net price regardless of gross rebates received.

The lock-step list pricing for autoimmune drugs managed by insurance companies is another piece of evidence that cast doubt on the claim that insulin drug price inflation is a case of organized crime rather than a standard open move in all negotiations for preferred provider status between healthcare providers and healthcare benefit managers.



Source: SSR Health, Truven Health Analytics

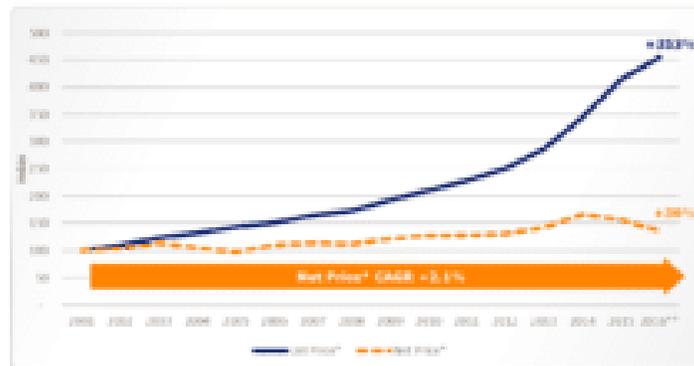
[Source: Washington Post, November 2016](#)

## The Motivation for Insulin List Price Drug Inflation

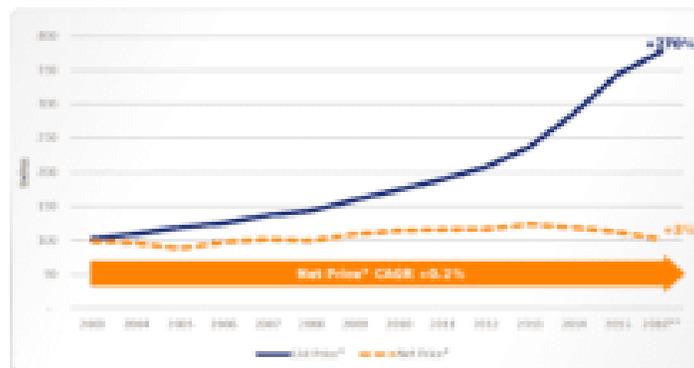
The Hagens Berman RICO lawsuit argued that insulin drug inflation was driven by drug companies motivated to increase profits. But, there is plenty of evidence that insulin drug companies received relatively small cumulative increases in net prices after a decade of substantial list price inflation.

Here are two charts provided by Novo Nordisk to show that their net price after rebates for their Novolog insulin vial has increased only a cumulative 36% over the last decade even though their list price has risen a cumulative 363%.

### NovoLog® Vial



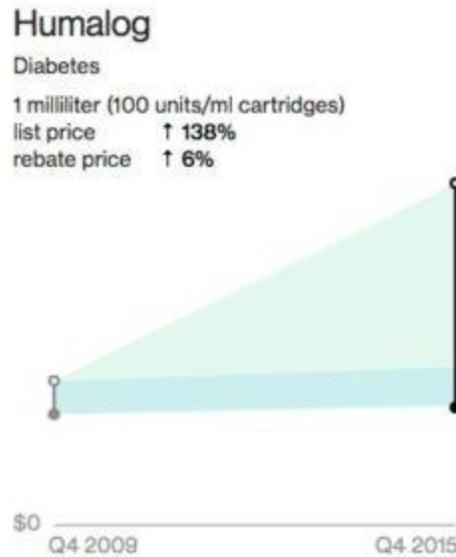
### NovoLog® FlexPen



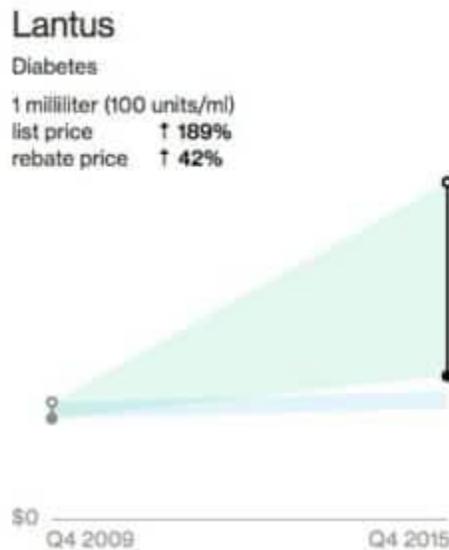
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Here are two other charts of gross to net price increases [from a June 2016 Bloomberg](#) article based on data assembled by SSR Health, an investment research company. The first is Eli Lilly's Humalog indicating cumulative list price inflation of 138% over a six year period from 4Q09 to 4Q15, but only a cumulative net price inflation of 6%



Here is another chart of Sanofi's Lantus showing a cumulative list price inflation of 189%, but a net price inflation of only 42% over a 5 year period.



Finally, here are a couple of [quotes from an October 2016 Biopharma Dive article](#) on fierce price competition among insulin manufacturers:

“Long-acting insulins have become a commodity,” said David Kliff, who publishes the industry newsletter Diabetic Investor, in an interview with BioPharma Dive. “In today’s environment, payers have the upper hand when it comes to making deals.”

That advantage is translating into pressure on insulin pricing, which all three drugmakers have begun to feel.

Novo has said average net prices for its diabetes drugs, particularly in the basal segment, are expected to be low- to mid-single digit percentages lower next year compared to 2016”.

Eli Lilly, which recently committed to averaging 5% revenue growth through 2020, has also baked in intensified pricing pressures in the U.S. to its forecasts. Lilly CFO Derica Rice, [speaking](#) on a recent earnings call, pointed to increased rebating and discounting for diabetes products as a byproduct of stepped-up competition.

And Sanofi [gave guidance](#) last October forecasting its global diabetes sales will decline by an average annualized rate of between 4% and 8% through 2018.”

These quotes run counter to the RICO lawsuit claim that insulin list price inflation has been driven by Pharma and has resulted in substantial increases in profits. Rather, we have argued earlier that the high list price / high gross rebate scheme has been driven by PBMs with a business model under stress needing more and more retained rebates to offset continuing losses in mail order generic margins since 2010.

### **Charges of Violation of Antitrust Laws**

Besides allegation of violations of the RICO Act, two RICO lawsuits [by Weitz & Lutzenberg](#) (Count ONE and TWO, pages 54-57) and [by Keller Rohrback LLP](#) ( Count

7, page 175), but not the final consolidated lawsuit of Hagen Berman, include counts of violation Sections 1 and 3 of Sherman Antitrust Act.

We believe these antitrust allegations are frivolous and should be summarily dismissed. 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.

However, in the case of PBMs you have to take out Bork's "presumptive" qualifier because the PBM business model is not rational in the traditional economics sense. While PBMs are resellers of brand drugs, their gross profits on brand Rx are derived only from retained rebate percentages. The PBM business model sets up a possible misalignment of interests between plan sponsor preferences for the lowest net cost drug in a therapeutic class and PBM preferences for the drug with the highest rebate retention DOLLARS.

But, because insulin drug list prices are in lock-step, the insulin drugs with the greatest gross rebate offer are also the drugs with the lowest net price. This means that PBM formulary choices with regard to the insulin drugs are aligned with the client's interests. There is not an antitrust issue associated with recent insulin drug price inflation.

Below is a spreadsheet of the 2016 list prices (WAC) of long-lasting insulin drugs at the time of the introduction of the Lilly's Basaglar, a follow-on biologic to Sanofi's best selling drug Lantus. Lilly chose to "play to game", not challenge the PBM business model, and took its chances competing on the basis of gross rebates.

List Price Competition in Long Lasting Insulin Therapeutic Class - 2016				
Pharma Co.	Relation To Incumbent	Drug	WAC List Price as % of Incumbent	
Sanofi	Incumbent	Lantus®	0%	SoloSTAR 1 Box WAC - \$272.75
Novo Nordisk	Therapeutic Equiv	Levemir®	6%	
Novo Nordisk	Therapeutic Equiv	Tresiba®	13%	
Sanofi	Therapeutic Equiv	Toujeo®	0%	
<b>Eli Lilly</b>	<b>Follow-on Biologic</b>	<b>Basaglar®</b>	<b>-15%</b>	
	<a href="#">Source: Lantus WAC</a>			
	<a href="#">Source: List Price Comparisons</a>			

The result was that Lilly and Basaglar were excluded by Express Scripts and OptumRx, but included by CVS Health. Per Chicago School theory, all of these choices are pro-competitive as it would be irrational for any PBM to exclude the lowest cost supplier.

2018 National Formulary for Long-Acting Insulin Therapeutic Class									
Pharma Co.	Relation To Incumbent	FDA Approved Drug	CVS Health		Express Scripts		OptumRx		
			Included	Excluded	Included	Excluded	Included	Excluded	
Sanofi	Incumbent	4-2000 Lantus®		X	X			X	
Sanofi	3X Lantus	2-2015 Toujeo®		X	X			X	
<b>Eli Lilly</b>	<b>Follow-on Biologic</b>	12-2015 <b>Basaglar®</b>	<b>X</b>			<b>X</b>			<b>X</b>
Novo Nordisk	Therapeutic Equiv	6-2016 Levemir®	X		X				X
Novo Nordisk	Therapeutic Equiv	12-2016 Tresiba®	X		X				X

Had Lilly started out with a list price for Basaglar at least 70%-80% lower than the list price of the incumbent Lantus, they might have been in a position to show that they were the lowest cost supplier in the long-acting insulin therapeutic class and merit inclusion in all 3 PBM formularies. Furthermore, they would have been in a position to

expose any of the PBMs' misaligned business models should one of them exclude Basaglar.

We have [written a paper](#) recently which compares AbbVie's aggressive list pricing of its new-to-market Hepatitis C Virus (HCV) drug Mavyret versus the incumbent biologic drug Harvoni.

AbbVie's Aggressive List Price for Mavyret Challenges PBMs to Include In Formulary Despite No Rebate			
Net Regimen Cost Comparison: Harvoni vs. Mavyret			
Pharma Drug	Gilead Harvoni	AbbVie Mavyret	% Difference
Treatment List Price	\$94,500	\$26,400	-72%
Gross Rebate - 77% of List	\$72,765	\$0	
Retained by PBM - 10% of List	\$9,450	\$0	
Net Rebate Passed On to Plan	\$63,315	\$0	
Net Price to Plan	\$31,185	\$26,400	
Net Plan Savings		\$4,785	15%
Source: <a href="https://www.specialtypharmacytimes.com/news/">https://www.specialtypharmacytimes.com/news/</a>			

Mavyret's exclusion by CVS Health created a real possibility of an anti-competitive and antitrust case of exclusive dealing despite Mavyret being the lowest cost drug available in the HCV therapeutic class. We discussed this case in more detail in another recent paper titled [Was CVS's Formulary Exclusion of Mavyret a Violation of Antitrust Laws?](#)

## **Inversion of the Pharma – PBM Enterprise**

The consolidated RICO lawsuit filed by Hagens Berman has inverted the hierarchy of the Pharma – PBM rebate negotiations relationship. This lawsuit claimed that the bidders — Pharma — “spearheaded” the rebate negotiations and that the rebate-collecting gatekeepers — PBMs — are the followers.

Here are [quotes from the consolidated RICO lawsuit](#) on how it views the hierarchy in the Pharma – PBM Enterprise:

## **The Levemir / Novolog Pricing Enterprise**

298. The persons engaged in the Levemir/Novolog Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Novo Nordisk. There is regular communication which Novo Nordisk and the PBMs share information regarding the Levemir and Novolog benchmark prices and discuss and agree on rebate amounts. Novo Nordisk and the PBMs functioned as a continuing unit for the purposes of implementing the Levemir and Novolog pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

## **The Humalog Pricing Enterprise**

270. The persons engaged in the Humalog Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Eli Lilly. There is regular communication between Eli Lilly and each of the PBMs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Eli Lilly and the PBMs share information regarding the Humalog benchmark price and discuss and agree on rebate amounts. Eli Lilly and the PBMs functioned as a continuing unit for the purposes of implementing the Humalog pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

## **The Lantus / Apidra Pricing Enterprise**

312. The persons engaged in the Lantus/Apidra Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Sanofi. There is regular communication between Sanofi and each of the PBMs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Sanofi and the PBMs share information regarding the Lantus and Apidra benchmark prices and discuss and agree on rebate amounts. Sanofi and the PBMs functioned as a continuing unit for the purposes of implementing the Lantus/Apidra pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

This makes no sense. Hagens Berman’s steadfast insistence that Novo Nordisk, Eli Lilly, and Sanofi “spearheaded” the racket is inexplicable. Generally, in cases of bidders vying for access to markets with reduced competition, it is the tariff-collecting gatekeepers that “spearhead” the scheme and the bidders are the followers.

Below is our diagram of the Hagen Berman inverted view versus the correct view of the Pharma – PBM enterprise. To highlight the nonsense of the Hagens Berman view, we compare it with two views of the Sopranos bid-rigging racket enabled by use of force to insure cooperation among bidders.

<b>The Correct RICO Lawsuit Enterprise Hierarchy:</b>		
	<b>"The Sopranos Enterprise"</b>	<b>"The PBM Enterprise"</b>
<b>Gatekeeper</b>	The Sopranos	PBMs
<b>Bidders</b>	Sanitation Co 1 Sanitation Co 2 Sanitation Co 3	Sanofi Eli Lilly Novo Nordisk
<b>Market Design</b>	Low bid wins	High rebate wins
<b>Gatekeeper</b>	Rig the bids	Rig the design only
<b>Outcome</b>	Anti-competitive	Both anti- and pro- competitive

<b>The Incorrect RICO Lawsuit Enterprise Hierarchy:</b>		
	<b>"The Sanitation Co Enterprise"</b>	<b>"The Pharma Enterprise"</b>
<b>Bidders</b>	Sanitation Co 1	Sanofi
<b>Gatekeeper</b>	The Sopranos	Express Scripts CVS Health Novo Nordisk
<b>Markets with Reduced Competition</b>	Municipal Garbage Collection Contracts	Exclusive Placement in Formulary

### **Formulary Choices as Evidence of Competition**

In all likelihood, there was a preliminary competitive round in the Soprano bid-rigging racket where Tony Soprano solicited bids from the suburban municipal garbage collection companies for the rights to be the “winning” bid on any given garbage collection contract.

In order to make the actual bidding process seem legitimate, Tony probably told other companies to participate in the actual bidding, but make their bids higher than the favored company. Obviously, the Soprano bid-rigging racket took lots of cooperation to pull it off even with threats of physical violence for defection.

Bid-rigging without threats of violence for defectors is problematic. The RICO lawsuits essentially claim that insulin drug pricing was a bid-rigging racket. Not only did the bids have to be coordinated, but according to the lawsuit, the bid-rigging was coordinated by the bidders and not the PBM gatekeepers. A racket with this inverted hierarchy of command would be extremely hard to pull off.

We acknowledge that the lock-step list-price inflation was the result of a common understanding among insulin manufacturers that the perverted PBM business model favored bidders with the highest gross rebates over bidders with the lowest net price after rebates.

But, what kind of mechanism did Pharma and PBMs use to rig the rebate offers? Unless RICO lawyers can present evidence of some sort of mechanism to enforce cooperation among insulin drug companies, the resulting pattern of formulary choices is more than likely the result of a competitive bidding process.

Below is a series of spreadsheets which show no favoritism among insulin drug companies. This evidence tends to refute the claim that there is collusion between any given PBM and the three insulin drug companies vying for preferred formulary placement.

The following formulary choices below shows Novo Nordisk winning the rights from Express Scripts for exclusivity for one of its drugs Levemir but losing the rights from Express Scripts for exclusivity for its other drugs Novolog.

"The Levemir / Novolog Pricing Enterprise		
	Novo Nordisk	
<b>Novo Nordisk in charge?</b>		
<b>PBMs cooperating</b>	Express Scripts	
<b>or forcing Novo Nordisk to compete?</b>	CVS Health	
	OptumRx	
	Long-Lasting	Rapid-Acting
	<b>Levemir</b>	<b>Novolog</b>
Express Scripts 2017	included	excluded
Express Scripts 2018	included	excluded
CVS Health 2017	included	included
CV Health 2018	included	included
OptumRx 2017	excluded	excluded
OptumRx 2018	excluded	Include

Was this achieved via just horizontal collusion among drug companies without any knowledge of the horizontal collusion by Express Scripts? Or, more likely was this a case of an all-around horizontal and vertical collusion among both bidders and PBMs? If so, the highly varied outcome depicted above would have required a ton of coordination with potential for a lot of bickering among bidders as to its fairness. And the outcome depicted above is just one of three bidding outcomes between drug company bidders and PBM gatekeepers.

The charts presented above and below depict formulary choices made by PBMs that are so varied that they could not have been the results of collusion. Rather the varied formulary choices in this case had to be the result of vigorous competition among insulin drug companies vying to be the highest gross rebate bidder and ending in a rational decision by PBMs to award formulary exclusivity to the lowest net price bidder.

<b>"The Humalog Pricing Enterprise"</b>	
	Eli Lilly
<b>Eli Lilly in charge?</b>	
<b>PBMs cooperating</b>	Express Scripts
<b>or forcing Eli Lilly</b>	CVS Health
<b>to compete?</b>	OptumRx
	<b>Humalog</b>
Express Scripts 2017	included
Express Scripts 2018	included
CVS Health 2017	excluded
CV Health 2018	excluded
OptumRx 2017	included
OptumRx 2018	excluded

"The Lantus / Aprida Pricing Enterprise"		
	Sanofi	
<b>Sanofi in charge?</b>	Express Scripts	
<b>PBMs cooperating</b>	CVS Health	
<b>or forcing Sanofi</b>	OptumRx	
<b>to compete?</b>		
	Long-Acting	Rapid-Acting
Formulary Agreements:	<b>Lantus</b>	<b>Aprida</b>
Express Scripts 2017	included	excluded
Express Scripts 2018	included	excluded
CVS Health 2017	excluded	included
CV Health 2018	excluded	included
OptumRx 2017	included	excluded
OptumRx 2018	included	excluded

Below is an alternative spreadsheet of PBM formulary choice that in our opinion indicates no overriding cooperation between drug companies and PBMs. It is indicative of a pro-competitive rebate negotiation process in which the low net cost supplier wins exclusivity on the PBM formulary of drugs covered by insurance.

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I write at the intersection of economics, finance, accounting and high tech. I have been a critic of PBMs since 2003. I have received no remuneration writing these papers.

2018 National Formulary -- PBMs In Charge  
 Pharma competes on rebates after coordinated list pricing

**Short-Acting Insulin Therapeutic Class**

Express Scripts		CVS Health		OptumRx	
included	excluded	excluded	included	excluded	included
Humalog® Eli Lilly	Novolog® Novo Nordisk	Humalog® Eli Lilly	Novolog® Novo Nordisk	Humalog® Eli Lilly	Novolog® Novo Nordisk

**Long-Acting Insulin Therapeutic Class**

Express Scripts		CVS Health		OptumRx	
included	included	excluded	included	included	excluded
Lantus® Sanofi	Levemir® Novo Nordisk	Lantus® Sanofi	Levemir® Novo Nordisk	Lantus® Sanofi	Levemir® Novo Nordisk