

**'Sins of Omission':
A Review of the FTC Study of PBM Conflict of Interest**

**By
Lawrence W. Abrams, Ph.D.**

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Abstract

On September 6, 2005, the Federal Trade Commission (FTC) released a long awaited study of potential conflicts of interest by independent pharmacy benefit managers (PBMs). (Available at <http://www.ftc.gov/os/2005/09/index.htm#>) Like any good study of alleged wrongdoing, the FTC examined both motive and performance.

The FTC's analysis indicated that it is in PBMs' own interest to favor mail order generics over brands. This analysis failed on two counts.

The FTC failed to realize that potential wrongdoing is limited to situations involving "rebateable" brands and that rebate averages across all brands are significantly less than rebate averages across rebateable brands. They also failed to realize that business segment profitability is due as much to transaction volume as average unit margin. It turns out that mail order generics are a relatively high average margin, but relatively low volume business for PBMs. When these failures are corrected, the result is that PBMs earn more per rebateable transaction and in the aggregate from brand name drugs than mail order generics.

The FTC concluded that there was strong evidence that PBMs "did not disadvantage" their clients. This conclusion was based on flawed tests based on comparisons of generic substitution and generic dispensing rates by fulfillment channel and mail order business model.

The FTC failed to understand that it is the corporate structure of PBMs – independent or captive of insurance companies – that affects business model bias and performance rather than the corporate structure of mail order operations. They also failed to understand what decisions truly are at the discretion of PBMs. Finally, the FTC failed to consider that rebates are paid to PBMs as much for what they don't do, as what they do.

What could have been the definitive study of the effect of corporate structure on PBM performance has become just another failed test for PBM 'sins of omission'.

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I have not received any remuneration for this paper nor have I financial interest in any company cited in this working paper.

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No, you never get any fun
Out of things that you haven't done,
But they are the things that I do not like to be amid,
Because the suitable things you didn't do
Give you a lot more trouble than the unsuitable things you did.

From poem by Ogden Nash

Introduction

On September 6, 2005, the Federal Trade Commission (FTC) released a long awaited study of potential conflicts of interest by independent pharmacy benefit managers (PBMs). (Available at <http://www.ftc.gov/os/2005/09/index.htm#>) Congress had specifically requested that the FTC conduct this study in anticipation that PBMs would play a major role in the newly passed Medicare Modernization Act that extended outpatient drug benefits to Medicare recipients. There had been widespread allegations of a conflict between client interests in containing overall drug costs and PBM interests in earning rebates from brand name drug manufacturers. In addition, there were concerns about PBM use of exclusionary practices to steer business to their own captive mail order operations.

Like any good study of alleged wrongdoing, the FTC examined both motive and performance.

As to the question of motive, the FTC found that "...generic dispensing at own mail order pharmacies generally is more profitable than brand dispensing." (p.74) and concluded that the interests of independent PBMs are indeed aligned with their clients.

As to the question of performance, the FTC found no significant differences in generic substitution and dispensing rates between mail order operations owned by large independent PBMs and rates

at independent mail order operations they occasionally used. The FTC concluded that "... PBM ownership of mail order pharmacies generally did not disadvantage plan sponsors." (p.x)

The FTC analysis of both questions is fundamentally flawed. Their conclusion about the orientation of the PBM business model is wrong. The conclusions about PBM performance must be nullified because of design flaws. What could have been the definitive study of the effect of PBM corporate structure on performance has become just another failed test for PBM 'sins of omission'.

Background

There are a variety of corporate structures under which PBMs operate. In 2005, the three largest PBMs were publicly held independents – Caremark Rx, Medco Health Solutions, and Express Scripts, (known as "The Big 3"). Together, they control approximately 50% of all outpatient prescriptions filled through retail and mail order channels. There are also independent PBM operations owned by CVS and Walgreen, both large drugstore chains. Some of the largest insurance companies have found it economic to have their own captive PBM operations rather than contract out. Wellpoint, Aetna, CIGNA, Pacificare and Prime Therapeutics (owned by Blue Cross-Blue Shield licensees), are the premier examples of insurance companies that have set up their own captive PBM operation. Other large insurance companies such as United Healthcare, Humana, and Mutual of Omaha have found it economic to contract out PBM functions to the Big 3.

PBMs use a variety of techniques to contain costs. While clients have final approval over the design of cost containment plans, independent PBMs exercise discretion in the following areas of formulary and rebate management: (1) the initialization of the formulary design process with their "owned" national formulary; (2) the "granularity" of the formulary; (3) the use of proprietary financial modeling software to assist clients in customizing their own plan formulary and choosing co-payments; (4) the actual formula used to re-distribute rebates to clients after rebate retention;

(5) the extent to which PBM call centers engage in, or abstain from, persuading physicians to switch prescriptions to therapeutic equivalents.

In the area of pharmacy network management, PBMs exercise discretion in: (1) deciding the extent of preferred provider networks, including sole source contracting of mail order to their own captive operations; (2) advising clients on the use of exclusionary practices such as mandatory mail order and limiting 90-day prescriptions to mail order; and (3) setting retail-mail order price differentials.

Alignment of Interests: Generics Vs. Brands

Independent PBMs have been on the defensive lately countering claims that their interests are not aligned with clients'. As long as a company's interests are aligned with their customers, there is nothing wrong if a company's business model is not so well aligned. Bundle pricing and tied product offerings are commonly used in business today as way of deflecting competitive price comparisons and cherry picking. Such practices create all sorts of misalignment of prices and costs.

Take, for example, General Motors. It aspires to build great cars, yet it earns more on car finance than car sales. McDonalds aspires to offer customers with a great tasting hamburger, yet the company has a higher mark-up on a soda that it does on a hamburger. Best Buy recoups slim margins on consumer electronics products with fat margins with extended warranties.

PBMs could have admitted business model misalignment while stressing that their overriding interests are aligned with clients'. This admission might be tolerable to customers of fast food or consumer electronics. But, the relation of PBMs to their customers is different. There are issues of agency and fiduciary duty between PBMs and their clients. Hamburger lovers have never accused McDonalds of breach of fiduciary duty.

The FTC was wise to include an investigation of motive in its study of alleged PBM wrongdoing. It gathered data on average unit margins, or spreads in their terminology, for generic and brand drug ingredients by channel of distribution for the Big 3 independent PBMs. The spread earned on drugs dispensed by retail outlets represents the difference between what the PBMs reimburse pharmacies and what they receive as reimbursement from clients. The spread earned on captive mail order operations is fundamentally different. Instead of a reimbursement spread, PBMs earn a much larger mark-up for value added on prescriptions filled by their captive mail order operations.

In addition to reimbursement and mark-up spreads, PBMs negotiate and receive rebates from brand name manufacturers. The FTC included an amount equal to the average rebate retained per brand drug in their margin analysis.

Brand name drug manufacturers pay these rebates even though their products are patented. This is because they face competition from other chemically different, but patentable, brands and from generics of off-patented brands that have been deemed therapeutic equivalents. Brand name drug manufacturers negotiate rebates with PBMs because they know that the power to affect the demand for brand drugs rest with PBMs and not with pharmacies who have no say in formulary design and compliance.

On the other hand, generic drug manufacturers negotiate discounts with pharmacies, and not PBMs, because they know that pharmacies are empowered to fill any particular generic prescription from an array of manufacturers selling FDA-certified, perfect substitutes. Exhibit 1 presents the FTC data on average unit spreads, including retained rebates, by drug type and by channel for the Big 3 in 2003.

		Normalized (30 Day Rx)	
		Generic	Brand
Big 3 Captive Mail Order	Table IV-5 p. 73	\$ 8.82	\$ 4.75
Big 3 Retail Network	Table IV-3 p 72	\$ (0.01)	\$ 2.01

The results indicate that, on average, captive mail order generics are more profitable to PBMs than brands.

The FTC analysis seems to support the Big 3's contention, echoed by Wall Street, that their business model is aligned with any shift from brands to generics, either at micro-level of individual prescription switches or at the macro-level of drug trends.

The FTC analysis fails on two counts. When these failures are corrected, the result is that PBMs earn more per "rebateable" transaction and in the aggregate from brand name drugs than mail order generics. The current business models of the Big 3 PBMs are **not** aligned with client's interests.

One fatal flaw in the FTC analysis is the use of rebate averages to represent what PBMs stands to gain and lose on discretionary choices involving brands versus generics. The FTC was aware of large variations in rebate rates by drug. The following three quotes are important:

"Regardless of the PBM category, a majority of these payments were derived from a limited number of brand drugs. The data show that, in 2003, each of PBMs' top 25 brand drugs (in terms of total rebates received) accounted for approximately 71% of its total pharmaceutical payments, on average." (p.48)

When a unique, pioneer drug enters the market, it may be considered to be in a therapeutic class by itself. Market share payment is not provided for such drugs and formulary payments are either small or non-existent because the manufacturer does not need to offer incentives for formulary placement (p.53)

"The brand name manufacturers generally stopped making payments upon generic entry. (p.54)

The FTC failed to understand how this variability might impact their analysis of PBM motivation.

Economic bargaining theory suggests that drug companies would pay the highest rates for top selling drugs under conditions of "bilateral oligopoly". That is, the highest rebates are paid for brand drugs in therapeutic classes where there are a few sellers **and** where there are a few large buyers capable of "moving markets" or at least present a credible threat to do so.

The fact that PBMs stop giving rebates once a therapeutic class faces competition from low-cost generics is consistent with bargaining theory. At the other extreme, it is to be expected that brand name drug manufacturers with monopoly positions would not feel compelled to offer rebates.

Market power on the sell side is also a factor that explains variability of rebates. For example, it is doubtful that substantial rebates are offered for central nervous system drugs such as anti-depressants and anticonvulsants even though there are a number of potential substitutes in each class. Drug companies realize that the threat of PBM action in these classes is reduced because PBMs are hesitant to override physicians' decisions when there is such a variety of individual reaction to any given drug.

In addition, it is to be expected that rebates are generally higher on drugs for chronic illnesses such as high cholesterol than for drugs for acute illnesses such as infections. The reason has to do with the potential buy-side power to affect demand. PBMs rarely engage in concurrent therapeutic interchange, a key finding (p.84) reported by the FTC. If PBMs engage in any discretionary prescription switching among therapeutic equivalents, it is retrospective – or made on renewals. Because prescriptions treating acute illnesses are rarely renewed, PBMs ability to affect demand is limited. On the other hand, the potential of PBMs to affect the demand for drugs treating chronic illnesses is enormous because prescriptions are renewed over and over again.

Individual economic decisions are based on marginal, not average, consequences. The areas where PBM discretion matters most are concentrated in top selling classes of drugs treating chronic illnesses. Drugs in these classes are the most “rebatable” –facing both limited competition on the Pharma sell side and willingness, whether exercised or not, on the PBM buy side to affect demand through discretionary formulary design and compliance.

The FTC failed in its analysis when it used a broad average for rebates. An estimate of the average rebate on rebatable brands would have been a more accurate reflection of what PBMs stand to gain and lose in any given discretionary choice.

The most rebatable therapeutic classes are: statins (cholesterol lowering), proton pump inhibitors (anti-ulcer), COX-II inhibitors (anti-inflammatory), and 2nd generation antihistamines (seasonal allergies). A few years ago, ACE inhibitors (hypertension) and H2-receptor antagonists (anti-ulcer) were highly rebatable classes, but their “rebatability” has diminished, if not ended, as an

increasing number of brands in these classes have lost their patent protection. Indeed, therapeutic classes can go through a rebatability life cycle with a monopolist phase (no-rebates) followed by an oligopolist phase (rebatable), and then a competitive phase with many generics (no-rebates). The FTC also saw signs that therapeutic classes went through a rebatability life cycle. (p.53-54)

The FTC's had specifically requested that each PBM in the study provide data on gross rebates received per drug. But, they failed to disclose any detail other than the quotes above. While one can respect the FTC's need to maintain confidentiality about rebate rates per drug, disclosing average rebate rates per therapeutic class would not have revealed anything about individual firms. Such data might have provided confirmation that bargaining theory, as opposed to price theory, is best at explaining the variation in pharmaceutical rebate rates.

In any case, we can reconstruct an estimate of the variability of rebates from two disclosures made by the FTC. The first key statistic is the FTC finding that the Big 3 received on average \$6.34 per brand drug in 2003. (p.vii and p.47) The second key statistic is contained in the quote from above that 71 % of all rebates received were concentrated in 25 brand drugs.

A conservative assumption, from an estimating point, is that the top 25 rebate receiving drugs referenced in the FTC quote represents about 20% of the volume of all brand drugs prescriptions.

Then, the overall average rebate of \$ 6.34 can be viewed as the following weighted average: $20\%*(X) + 80%*(Y)$ where X represents the average rebate for the top 25 rebate receiving drugs and Y represents the average for the rest. The next step is to realize that, if 71% of the total rebates come from 20% of the rebatable drugs, then 71% of the average rebate of \$6.34 also comes from the same 20%.

Algebraically, this means that $20\%*(X) = 71\%* 6.34$ or X, the average rebate rate for the top 25 selling brand drugs is \$22.51. The average rebate for the rest of the rebatable drugs, Y, is \$2.30.

These new results have been derived using only FTC supplied data and the conservative assumption that 25 brands drugs represents about 20% of brand drug prescription volume.

The average rebate of \$22.51 per rebatable brand represents a rebate rate 31.9% of wholesale acquisition costs (WAC) for on-patent brands of \$70.50. The WAC figure represents a 11% discount – 3% for wholesale margin and 8% for retail margin -- of FTC study supplied data that the average ingredient price of an on-patent brand prescription filled through retail channels was \$78.26 (p.29).

Converting the overall average of \$ 6.34 converted to a percentage of WAC would only amount to 9.0%.

This difference highlights the weakness of using broad averages as a measure of the rebate negotiating power of the Big 3 PBMs. It also highlights the weakness of using broad averages when comparing the rebate negotiation power of the private sector with the rebate negotiating power of the Federal government as measured by the Medicaid “best price” rebate rate. (See “PBMs as Bargaining Agents” available at www.nu-retail.com)

The Exhibit 3 below presents a revision of the FTC analysis in light of our estimate of the variability of rebates rates. Exhibit 2 summarized those results. It turns out that PBMs gain more by favoring a rebatable brand prescription over a generic therapeutic equivalent across all fulfillment channels. Alternatively, PBMs stand to gain (lose less) by abstaining from retrospective brand-to-generic therapeutic interchange. At the micro level, the PBM business model is **not** aligned with clients’ interest in overall drug cost containment.

	Normalized (30 day)		
	Generic	Top 25- Brand	Rest-Brand
Big 3 Captive Mail Order	\$ 8.82	\$ 11.21	\$ 3.13
Big 3 Retail Network	\$ (0.01)	\$ 8.47	\$ 0.39

Exhibit 3: Distribution of Ingredient + Rebate Spreads			Normalized (30 day)		
Big 3 Captive Mail Order Operations, 2003			Generic	SSB-Top 25	SSB-Rest
Ingredient+Rebate Spreads	R1	Table IV-5 p. 73	\$8.82	\$4.75	\$4.75
Ave Retained Rebate / Brand Rx	R2	estimate above		\$2.54	\$2.54
Ingredient Spreads	R3	R1-R2	\$8.82	\$2.21	\$2.21
Distribution of Retained Rebates	R4	estimate above		\$9.00	\$0.92
Distribution of Ingredient+Rebate Spreads	R5	R3+R4	\$8.82	\$11.21	\$3.13
Big 3 Retail Network, 2003			Reported (30 Days)		
			Generic	SSB-Top 25	SSB-Rest
Ingredient+Rebate Spreads	R1	Table IV-3 p 72	-\$0.01	\$2.01	\$2.01
Ave Retained Rebate / Brand Rx	R2	estimate above		\$2.54	\$2.54
Ingredient Spreads	R3	R1-R2	-\$0.01	-\$0.53	-\$0.53
Distribution of Retained Rebates	R4	estimate above		\$9.00	\$0.92
Distribution of Ingredient+Rebate Spreads	R5	R3+R4	-\$0.01	\$8.47	\$0.39

R1 is what the FTC found for average ingredient + rebates spreads for generics and single source brand (SSB) drugs for mail order and retail. R2 is the estimate of the average of rebates retained by the Big 3. It is equal to the \$6.34 average of gross rebates received as reported by the FTC (p. vii and p. 47) times a 40% average rebate retention rate as reported by the FTC (p. 59). R3 = R1 – R2 and represents the average spread net of rebates. R4 is the decomposition of the average retained rebate of \$ 2.54 based on the same algebraic technique used above to decompose gross rebates. R5 = R3 + R4 and represents the average ingredient + rebate spreads for generics and single source brands (SSB) taking into the account the variability of rebate rates.

Again, to be fair, business model misalignment does not necessarily mean a misalignment of interests. And, a motive for wrongdoing does not necessarily lead to wrongdoing itself.

Alignment of Interests: Retail vs. Captive Mail Order

The above analysis dealt mainly with alignment of interests by drug type. We turn our attention briefly to the question of alignment of interests by fulfillment channel – retail or mail order. It is obvious what fulfillment channel is preferred by the Big 3 PBMs. They make more on a prescription filled by their captive mail order operations than one filled by some retail outlet or one filled by an independent mail order pharmacy.

The FTC provided a comparison of prices paid by plan sponsors for drugs filled by various channels as evidence of what channel is best for plan sponsors. But, these results merely confirmed earlier, credible studies by the GAO and the AARP. The key result was that the average retail prices were higher than the captive mail order prices by 23.9% and 13.9% for generic and on-patent brand drugs, respectively. (p.34) In addition, the average price paid by plan sponsors for prescriptions filled by independent mail order pharmacies was higher than the price they paid for drugs filled by captive mail order operations of the Big 3. (p.23)

While the results seem straightforward, caution must be exercised in drawing any conclusions due to the fact that the Big 3 employ a bundle pricing strategy with all sorts of cross-subsidies. PBMs have found it advantageous in contract negotiations to price services like mail order and claims processing low while recouping margin deficiencies through secretive rebate retention. This PBM strategy has been analyzed elsewhere. (See “Exclusionary Practices in the Mail Order Pharmacy Market” available at www.nu-retail.com).

The trend toward a transparent PBM business model with greater pass-through of rebates will force PBMs to begin to reverse their bundle pricing strategy. The price superiority of mail order reported by FTC for 2002-2003 is less today and will shrink even further in the future. The Big 3 will no longer be able to use mail order price superiority as a justification for such exclusionary practices as mandatory mail order and no 90-day prescriptions at retail.

Alignment of Interests: Macro Drug Trends

FTC failed to use their data to investigate the question of business model orientation at the aggregate level. A business segment's profitability can be viewed as the product of average unit margin, or spread to use the FTC terminology, multiplied by transaction volume. Even if a business segment has relatively high average unit margins, its contribution to the overall profitability of the company can be low if its volume of business is low.

It is possible to use FTC data on transaction volume by channel and drug type to derive a 2 X 2 matrix of the share of total transaction volume by business segment. Multiplying this matrix by the matrix of average unit spreads presented earlier in Exhibit 1, when normalized, yields a matrix of the share of total spread earnings by business segment. These calculations are presented below in Exhibit 4.

The result is that mail order generics represent only 13.7% of the Big 3's business by volume while brands across all channel represents 59.5% of their volume. Even though mail order generics yield a relative high average unit spread --\$8.82 versus the \$4.75 on mail order brands and \$2.01 on retail brands – it is a relatively low margin business for the Big 3. When spread margins are combined with volume data, the result is that contribution of mail order generics represents only 39.0% to the Big 3's total spread earnings whereas the contribution of brands across all channels represents 61.1% to total spread earnings.

Exhibit 4: Share of Aggregate Spread by Channel and Drug				
		Generic	Brand	
M1: Average Unit Spreads by Channel and Drug				
Table IV-5 p. 73	Mail Order	\$8.82	\$4.75	
Table IV-3 p. 72	Retail	(\$0.01)	\$2.01	
M2: Share of Volume within Channel by Drug Type				Totals
p.77	Mail Order	35.0%	65.0%	100.0%
p.77	Retail	44.0%	56.0%	100.0%
M3: Share of Volume by Channel				
	Mail Order	39.0%	39.0%	
	Retail	61.0%	61.0%	
	Totals	100.0%	100.0%	
M4: Share of Volume by Channel and Drug				Totals
M2 x M3	Mail Order	13.7%	25.3%	39.0%
M2 x M3	Retail	26.8%	34.2%	61.0%
	Totals	40.5%	59.5%	100.0%
M5: Share of Total Spread by Channel and Drug				
		Generic	Brand	Totals
M1 x M4	Mail Order	39.0%	39.0%	78.0%
M1 x M4	Retail	-0.1%	22.1%	22.0%
	Totals	38.9%	61.1%	100.0%

It is obvious that macro drug trends that favor generics are in the best interest of plan sponsors. The Big 3 PBMs suggest that such trends are also in their own best interests. Wall Street analysts have echoed this sentiment. But, this is incorrect.

For example, it has been widely reported that in 2006 there will be an unusually large number of blockbuster drugs losing patent protection, including Zocor, the drug with the 2nd highest sales. Wall Street financial analysts believe that such events will help, rather than hurt, PBM profitability.

But, this conclusion is based on a consideration only of data on average unit spreads such as presented in Exhibit 1. The reality is that the replacement of the Zocor by its relatively higher generic, simvastatin, benefits a PBM business segment representing only 13.7% of total volume.

While the lawyers at the FTC can be excused for failing to see that business segment profitability depends as much on transaction volume as average unit margin, there is no excuse for the Wall Street financial analysts making the same mistake.

Tests Using Generic Substitution Rates

The purpose of the next two sections is to examine two tests designed by the FTC to measure the effect of potential business model bias on PBM performance. Do large independent PBMs “disadvantage” (FTC’s word) their clients because of potential business model bias that favors brands over generics?

One test used the generic substitution rate as a measure of PBM performance. The FTC compared generic substitution rates across fulfillment channels. Generic substitution is a concurrent switch of a generic for its higher cost off-patent brand. It is the ratio of the number of generic drug prescriptions dispensed divided by the sum of generic and off-patent brand prescriptions that are bio-equivalents.

The FTC study found that the captive mail order operations of large independent PBMs had generic substitution rates of 92.5% and 93.3% for 2002 and 2003, respectively. The generic substitution rates were about the same – 91.9% and 93.1% for 2002 and 2003, respectively -- for retail networks controlled by the same PBMs.

These results prove nothing about the effect of business model bias on PBMs performance for two reasons. The most important reason is that brand manufacturers do not pay rebates once a

drug loses its patent. There is no potential business model bias when it comes to choices between off-patent brands and their generic substitutes.

The second reason why the FTC test here proves nothing is that generic substitution rates measure pharmacy performance more than PBM performance. There is no question of therapeutic equivalency in switches involving generic substitution. As a result, many states have granted pharmacies the power to do generic substitution without prior approval either from the prescribing physician or from the managing PBM. Furthermore, as the FTC data indicates, generics are far more profitable to pharmacies than off-patent brands. Pharmacies are the drivers of generic substitution, not PBMs.

Tests Using Generic Dispensing Rates

The FTC also developed a test using generic dispensing rates as a measure of performance. The generic dispensing rate is the ratio of the number of generic drugs dispensed divided by the number of all drugs dispensed – generics, off-patent brands, and on-patent brands.

Using generic dispensing rates as a measure of PBM performance has its pluses and minuses. On the one hand, the generic dispensing rate captures the effect of a broad range of PBM discretionary activity designed to contain client costs. On the other hand, the rate is affected by other factors not under control of PBMs.

The most confounding is the “drug mix - channel effect”. Drugs for chronic illnesses such as high cholesterol tend to be filled by mail order. At the same time, drugs for chronic illnesses tend to be under patent protection as new drug development is predominately aimed at chronic illnesses. This means that, even without any PBM intervention, the generic dispensing rate at mail order operations would be less than that at retail operations.

Failure to account for the “drug mix - channel effect” nullified the first test of potential PBM conflict of interest by Langenfeld and Maness. (Available at <http://www.mpaginc.com/news/pbmreport.pdf>)

A second test by Wosinska and Huckman also compared rates by channel but used additional variables to account for the “drug mix - channel effect”. (Available at

<http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.409v1.pdf>) The reason Wosinska and

Huckman gave for their expectations that channel could be used as a proxy for business model

bias was as follows:

“The conflict of interest argument builds on the mail delivery feature. With several days to fill a mail order prescription, mail pharmacies could use that time to obtain the necessary physician permission to switch medications.” (p. W4-410)

However, data provided by the FTC study cast serious doubt on the contention that mail order fulfillment time delay is a contributing fact to biased switching. One of the key findings of the FTC study was that almost all therapeutic interchanges are retrospective, not concurrent.

“..TI affected less than one-half of one percent (.5%) of prescriptions dispensed at retail and at PBMs own mail-order pharmacies. (p. 84)

Because almost all therapeutic interchanges are retrospective, the Wonsinska and Huckman test using fulfillment channel as the proxy for business model bias must also be nullified.

There was high hope that the FTC study would be the definitive study of the effect of business model bias on PBM performance. They did see the importance of using business model rather than channel as the independent variable. They FTC placed validity only in one test that compared the rates of the Big 3’s own captive operations with rates of independent mail order operations. Their finding of no significant difference was a key result behind their conclusion that the Big 3 PBMs do not “disadvantage” clients.

The problem with the FTC test was that they used mail order corporate structure, and not PBM corporate structure, as the independent variable. One group was composed of PBM-managed plans using captive mail order pharmacies. The other group allegedly contained PBM managed plans using independent mail order pharmacies. Although the later group was unified by mail

order corporate structure, it was a mixed bag of PBM corporate structures. It included captive PBMs of insurance companies such as Aetna and Cigna as well as small independent PBMs such as INSTAT and National Medical Health Card.

The problem with this grouping is that mail order dispensing pharmacy personnel – whether at PBM-owned operations or independent operations -- are not empowered to initiate retrospective therapeutic interchange. Such switches are initiated at PBM-owned call centers. A biased PBM controls the extent to which the call center engages in retrospective therapeutic interchange. The results are spread out over all channels.

The FTC study represents another failed test of potential PBM conflict of interest.

PBM ‘Sins of Omission’

The failure is doubly frustrating because the FTC study could have been the definitive test for what we call PBM “sins of omission”.

There are two fundamental ways PBMs can fail clients when making decisions that affect generic dispensing rates and, in turn, overall client drug costs. We have labeled the two types of failure ‘sins of commission’ and ‘sins of omission’ after theological discussions. Sins of commission occur when PBMs use their discretion in formulary design and compliance to promote prescription switching from lower cost drugs – generic or brand – to higher costs brands that are therapeutically equivalent. Sins of omission occur when PBMs abstain from promoting switches to lower cost drugs that are therapeutically equivalent.

Sins of commission are fairly easy to detect given access to company records and the assistance of specialized audit companies armed with IT software to do the “heavy lifting”. It is the domain of whistle blowers and *qui tam*. It has been the focus of attention of lawyers from both the public and

private sector. Data from full disclosure fiduciary laws are not necessary to prove sins of commission because such switches are never cost-effective, even with rebates fully known and accounted.

There are many other alleged sins of commission other than cost-increasing switches. This includes PBMs assigning payment to Medicaid, the payer of last resort, rather than doing a little more investigation to see if the claim might be assigned elsewhere. It includes allegations of short counting prescriptions, deceptive re-labeling, and hiding failures to fulfill mail order prescriptions on time. These other allegations have nothing to do with the potential of rebates to bias decisions and are likely covered by contract law.

Sins of omission are not easy to detect, and therefore hard to deter through contract. It is an area where trust must be established as an alternative to contract. It is the domain of statisticians and *ceteris paribus*. It has been the focus (unknowingly) of only three statistical studies, all failures in design as noted above. Data from full disclosure fiduciary laws would not help detect PBM sins of omission.

In 2003, the Big 3 managed approximately 1.4 billion prescriptions. The FTC tests were so aggregate and general that a one-percentage point difference in rates was deemed insignificant. But, this “insignificant” difference represents a swing either way of 14 million brand prescriptions that could have been filled by lower cost generic equivalents. The cost to clients of this “insignificant” wrongdoing is approximately \$800 million. It is entirely appropriate that the FTC qualify its conclusion that PBMs “generally” do not disadvantage their clients because their conclusion is entirely consistent with a number of alleged occurrences of wrongdoing.

Even though the FTC test design was flawed, every effort should be made to continue testing for Big 3 bias based on comparisons of generic dispensing rates. We offer three reasons. First, if the Big 3 stray at all, it is far more likely to be sins of omission than sins of commission. Second,

harmful inaction can only be detected through comparative statistical tests. Third, the success of the “purple pill” Nexium, the 4th highest selling drug in the United States in 2003, is circumstantial evidence of PBM sins of omission. Indeed, the continuing success of all brand drugs in the proton pump inhibitor therapeutic class in the face of the loss of patent protection by Prilosec and the availability of its generic, omeprazole, is circumstantial evidence of significant inaction that is not in clients’ best interests.

The expectation that, if PBMs fail clients in areas affecting drug mix utilization, it is far more likely to be by omission than by commission is based on an economic theory of criminal behavior. The basic idea is that the decision to do right, do wrong, or do nothing, is a rational decision based on benefits and costs. We have demonstrated earlier that potential for rational wrongdoing by PBMs exists because of a misaligned business model that favors brands over lower cost generic therapeutic equivalents.

The next step is to delve deeper into the nature of rebate negotiations and the exact structure of rebates to show that benefits of doing nothing are the same as the benefits of doing wrong. Since it is obvious that the cost of inaction – as measured by probability of getting caught – is a lot less than the cost of wrongdoing, any PBM, who is so inclined to stray, is far more likely to commit sins of omission than sins of commission.

How does an incentive structure come to be where the benefits of inaction equal the benefits of wrongdoing? The key is realize that rebates are not price concessions in return for exclusive commitments for volume purchases, but economic rent-shifting tariffs paid for access to markets protected from further competition other than from direct-to-consumer advertising and physician “detailing”. It is a mistake to conceive of PBMs as purchasing agents and “middlemen”. They should be conceived as bargaining agents and “gatekeepers”.

PBMs are not the populist countervailing force as conceptualized by Galbraith in the late 50s. They are not Robin Hood rent-shifters, taking surplus from the Pharma oligopoly and sharing it with the masses. They are enablers of Big Pharma. They help to create economic rent, or surplus, in the first place. They shelter markets from price competition in return for rebates.

The FTC study has confirmed that PBMs are paid two types of rebates: access or formulary rebates and market share rebates. Formulary rebates are paid for placement in the national formulary of PBMs. Formulary rebate receipts are equal to the product of drug volume times the rebate rate, or allowance using FTC terminology. But, unlike most price discounts, the formulary rebate rate itself is fixed and not a function of volume. It is a function of the perceived competitive advantage that placement confers.

The clearest example of this are the Medicaid “best price” rebates paid by brand name drug manufacturers to the government for placement in the Medicaid formulary. The law establishing the Medicaid “best price” guaranteed payers that Medicaid will not engage in any concurrent or retrospective therapeutic interchange – brand-to-brand or brand-to-generic – however cost-effective it might be. Wisely, no such guarantees are offered in the private sector by PBMs. Placement in the Medicaid formulary has more value to Pharma than placement in private sector formularies. Pharma pays more to the government, but gets more. On the other hand, the government gets more, but gives up more. This trade-off goes unrecognized by those who say that the government is a better at negotiating with Pharma than the private sector.

Preferred placement by PBMs in their national formulary comes with no promises of exclusivity or advantage. Rather, PBMs often grant “Tier 2” preference to several brands. They create re-distribution formulas with weak incentives for clients to mirror the national formulary. (See “The Effect of Corporate Structure on Formulary Design: The Case of Large Insurance Companies” available at www.nu-retail.com)

The FTC examined rebates contracts of major brand name drug manufacturers. Their overall sense of these contracts was that

“...PBMs agreed not to disadvantage the manufacturer’s drug relative to other brand drugs (e.g. with regard to co-payment or coinsurance levels, treatment guidelines such as step-therapy protocols, or promotion of a competing product.)” (p. 48)

Beside the characterization of the exchange as rebates for not disadvantaging, there are two other aspects to the quote that bear noting. First, the FTC states that the contracts specified other **brand** drugs as the competition. Second, the FTC was not clear whether or not “promotion” included specific limits on therapeutic interchange.

Based on the FTC examination, it appears that these contracts contain no explicit language that shelters brands from cost-effective brand-to-generic therapeutic interchange. However, formulary rebate formulas embodied in these contracts, unintentional or otherwise, make such switches less likely. If rebates were specifically a reward for choices that were advantageous to a brand drug, this would eliminate the problem. PBMs would be paid rebates only for actual brand-to-brand therapeutic interchanges. The incentive not to make cost-effective brand-to-generic therapeutic interchange exists only because rebates are rewards for choices that do not disadvantage a brand, rather than for choices that advantage a brand.

This is also true for market share rebates, the other type of rebate paid by Pharma to PBMs. On the surface, market share rebates seem designed to “move markets” or to promote advantageous behavior. But, the FTC provide details on the formula for this rebate suggesting that it is also a payoff for not disadvantaging a brand drug, that unintentionally or not, provides an incentive not to engage in brand-to-generic switches.

The key is how the “market” is defined in market share rebate contracts. The numerator is the combined volume of an individual brand drug filled by retail and mail order pharmacies managed by a PBM. The denominator is the volume of all therapeutic equivalents and potential

competitors. The therapeutic class, or “market”, could have been limited to all brands that are therapeutic equivalents. But, the FTC reported otherwise,

“Brand manufacturers more frequently included generic products equivalent to competitors’ drugs in defined markets for calculation of market share.” (p.55)

Unlike formulary rebates, market share rebates provide extra incentives for advantageous behavior that favors one brand over another. But, market share rebates are not neutral with respect to generics. Market share is lost when generics are substituted for favored brand.

If PBM business model bias has any effect on discretionary therapeutic interchange, we have tried to show that the risk-reward ratio favors inaction over outright wrongdoing. Even though the FTC’s test was flawed, comparisons of generic dispensing rates across groups with different business models remain the most promising way to test for PBM sins of omission.