THE COST OF PBM "SELF-DEALING"
UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT[1]

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I.   Executive Summary

A conference committee of the House and Senate is currently considering different versions of a Medicare prescription drug benefit. Both versions permit Pharmacy Benefits Managers ("PBMs") to administer the Medicare prescription drug plan ("PDP") in each of the Medicare regions of the country starting in 2006 and to offer government subsidized discount cards to Medicare beneficiaries in the transition period. While PBMs can be excellent plan administrators, problems can arise when a PBM is *both* the plan administrator *and* the seller of drugs (through its own mail order pharmacy) to the plan. In this paper, we calculate that the cost of that conflict of interest to the U.S. government and the Medicare beneficiaries may approach $30 billion in the period 2004-2013. This finding is consistent with the basic economic principle that markets work better in the absence of these types of conflicts of interest.

Each of the four largest PBMs owns a mail order division, and these captive mail order houses account for 77 percent of all mail order prescription business. Since mail order dispensing is more profitable for PBMs than plan administration, a PBM has a strong incentive to direct as many prescriptions as possible through its mail order pharmacy. Moreover, because PBMs receive larger rebates from pharmaceutical companies on single source brand name prescription drugs than on multi-source drugs with generic equivalents, PBMs with captive mail order houses have an incentive to sell newer and higher priced single-source drugs, even when it may be more costly for the payer.

One way in which PBMs with captive mail order houses can increase sales of single source drugs is through therapeutic switching. Because it can take several days to fill a mail order prescription, mail order dispensing provides time for PBMs to obtain the necessary physician permission to switch prescriptions to single source alternatives.[4] We find that such switching occurs more frequently in captive mail order houses than unaffiliated mail order houses, as evidenced by generic utilization being much less at captive mail order houses than at mail order houses that are unaffiliated with a PBM. Based on the best available evidence, captive mail order has a generic utilization of only 29.4 percent while independent mail order has a generic utilization rate of 38.9 percent.

PBMs with captive mail order houses can also profit by repackaging prescription drugs and selling the repackaged drugs at higher per unit AWP than the manufacturer originally charged.[5] We found 15 instances when the branded drug Celebrex was repackaged and the unit price for the repackaged drug exceeded the original manufacturer's per unit price by more than 7 percent and as much as 176 percent. Since the PBM is acting as both dispenser (through its mail order pharmacy) and claims adjudicator, it has both the

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[4] Physicians often accept PBM representations regarding the added benefits of new, single-source drugs. A self-dealing PBM may also engage in therapeutic switching from one single source drug to another in order to earn a higher rebate. If the single source drug to which the switch is made has a higher AWP, the payer's price will go up if the amount of the rebate and other discounts passed on to the payer are less than the increase in the AWP. We have not been able to determine the extent to which this happens and thus have not included this type of therapeutic switching in our model.

[5] Average Wholesale Price (AWP) is generally recognized to be the manufacturer's list price.

incentive and the ability to dispense these higher priced products to its patients and to earn profits on the difference between its acquisition costs and its inflated price. Although this process may not occur frequently, if it occurs on only 1 to 5 percent of sales it can result in substantial costs to payers and consumers.

We used a mathematical model to quantify the cost under the new Medicare program of self-dealing by PBMs with captive mail order. The results are summarized in the chart below. As discussed in the text of the report, we have not seen evidence of significant efficiencies from PBM self-dealing to offset the added costs resulting from the self-dealing, and there are reasons to question whether there are any efficiencies.

Summary of the Impact of PBMs Self-Dealing (2004-2005)		
	Using Figure 4 Generic Substitution Rates	*Using Figure 1 Generic Substitution Rates*
Under-utilization of Generics (All Payers)	$1,298,587,687	$1,958,187,781
	Using Figure 4 Generic Substitution Rates	*Using Figure 1 Generic Substitution Rates*
Under-utilization of Generics (Excluding Copayments)	$337,496,361	$508,923,084
	1% of Volume Affected	*5% of Volume Affected*
AWP Inflation (Assuming 10% AWP Inflation)	$218,624,453	$1,093,122,265
	Sum of Under-utilization (all payers) with Figure 4 Substitution Rates and AWP Inflation	*Sum of Under-utilization (all payers) with Figure 1 Substitution Rates and AWP Inflation*
Total Impact	$1,517,212,140	$3,051,310,047
Summary of the Impact of PBMs Self-Dealing (2006-2013)		
	Using Figure 4 Generic Substitution Rates	*Using Figure 1 Generic Substitution Rates*
Under-utilization of Generics (All Payers)	$11,091,782,730	$16,725,704,117
	Using Figure 4 Generic Substitution Rates	*Using Figure 1 Generic Substitution Rates*
Under-utilization of Generics (Excluding Copayments)	$10,020,742,992	$15,110,644,194
	1% of Volume Affected	*5% of Volume Affected*
AWP Inflation (Assuming 10% AWP Inflation)	$1,867,363,258	$9,336,816,288
	Sum of Under-utilization (all payers) with Figure 4 Substitution Rates and AWP Inflation	*Sum of Under-utilization (all payers) with Figure 1 Substitution Rates and AWP Inflation*
Total Impact	$12,959,145,988	$26,062,520,405

Some have suggested that, if PBMs accept insurance risk in 2006, the self-dealing abuses will disappear. However, that is not the case. As the Congressional Budget Office has recognized, the extent to which risk bearing by PBMs results in lower costs "depend[s] primarily on the degree of financial risk they would face in providing the drug benefit."[6] Our economic modeling shows that if the PBMs bear only partial risk, a significant incentive for opportunistic self-dealing would still exist. Moreover, the cost of PBM self-dealing in the non-risk bearing period (2004 and 2005) when PBMs will be offering discount cards, could well exceed any efficiencies that may result from a PBM doing business with its own mail order house. Nor will competition among PBMs eliminate the self-dealing abuses we have identified.

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[6] Congressional Budget Office Estimate, H.R. 1 and S.1, July 22, 2003, p. 13.

Just as the Federal Trade Commission found that unfettered PBM discretion over formularies was not in the consumers' interest when the PBM was owned by a drug manufacturer, so too unfettered discretion by a PBM to use its own mail order house would not be in the consumers' interest. Ending the conflict of interest at the manufacturer-PBM level has benefited consumers, and the same would be true if the conflict of interest between PBMs and captive mail order houses were prohibited in the Medicare context.

II. Background

Currently, PBMs administer pharmacy programs for their managed care clients. Among the services PBMs provide in connection with these programs are managing formularies, negotiating with drug manufacturers for discounts and rebates, negotiating with pharmacies to establish retail networks for dispensing drugs, adjudicating coverage eligibility, payment, and formulary compliance.

PBMs earn revenues from two general sources: (i) administration fees paid by managed care clients for managing prescriptions and (ii) a retained percentage of rebates, discounts, and other monies that pharmaceutical manufacturers pay to PBMs to favor the manufacturers drugs.[7] PBMs can favor a manufacturer's drugs by adding them to formularies and by therapeutic switching.[8]

Rebates on branded drugs average about 10 percent of the list price of the drug. Pharmaceutical companies generally do not pay rebates on drugs for which there are generic substitutes, because in most cases there will be automatic generic substitution. State substitution laws generally permit pharmacists to dispense the therapeutically equivalent generic version of a branded product without obtaining the prescribing doctor's permission.

PBMs typically retain about 30 percent of the rebate payments they receive from manufacturers and pass the remainder on to their end users.[9] These retained rebate dollars are a major source of PBM profits.[10] The average EBITDA to a PBM for a mail order prescription is $3.50 relative to $1.40 for a prescription filled at retail.[11] Not surprisingly, given the EBITDAs, the share of prescriptions provided through mail order has been steadily growing over time from 8.9 percent of prescription drug sales in 1992 to 14.6 percent by 2000.[12]

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[7] PBMs also generally retain a portion of the discounts pharmacies grant to join the PBM's pharmacy network.

[8] As one source notes, "drugs may be added to formularies based more on manufacturer rebates than on safety and efficacy." Pharmacy Benefit Managers, CRS Report for Congress, November 29, 2000, p. 2.

[9] See "Pharmacy Benefit Managers, Keeping a Lid on Drug Costs", Banc of America Securities, February 2002, p. 37.

[10] See "Pharmacy Benefit Managers, Keeping a Lid on Drug Costs", Banc of America Securities, February 2002, p. 39. According to this same source, discounts and administrative fees and other things account for the balance.

[11] "Pharmacy Benefit Management, Strong Fundamentals: A Winning Prescription," JP Morgan Securities, Inc., April 2, 2002, p. 6.

[12] "Pharmacy Benefit Management, Strong Fundamentals: A Winning Prescription," JP Morgan Securities, Inc., April 2, 2002, p. 24.

III. **Incentives for Opportunistic Conduct Harmful to Payers By PBMs That Are Both the Plan Administrator and the Seller of Drugs**

A. **Incentives Created by Manufacturer Rebates**

Because PBMs usually keep as profit a portion of the rebates they receive, PBMs that are *both* the plan administrator *and* the seller of drugs have a financial incentive and ability to favor drugs that pay higher rebates. As long as the costs of obtaining the physician's permission for the switch are less than the added amount the PBM can earn on the single source drug, the PBMs that are both the plan administrator and the seller of drugs have an incentive and ability to engage in therapeutic switching, even if the switch results in higher costs to the end payer (higher patient co-payment and/or third party reimbursement).

The following example demonstrates how the incentives work. Suppose a patient presents a prescription for a multi-source branded product for which there is a generic equivalent. Suppose further that there is also a single-source drug that is a close therapeutic substitute for the multi-source drug, but for which there is no generic alternative. Assume, as is usually the case, that the manufacturer of the single drug offers a rebate on the single-source drug, while the manufacturer of the multi-source drug offers no rebate on the multi-source drug. Assume further, as is usually the case, that the per unit list price of the single source drug is more than the list price of the multi-source drug and its generic equivalent. Given this commonly occurring situation, a PBM with a captive mail order house will earn significantly more money selling the single-source drug than selling either the multi-source drug or the generic equivalent of the multi-source drug. This is true even when the PBM's mail order has a higher percentage mark up on the generic product. For example, a 20 percent mark-up on $10 earns less money than a 10 percent markup on $25 even before rebates are factored in.

B. **Incentives Created for PBMs That Are Both the Plan Administrator And the Seller of Drugs to Set Higher AWPs**

PBMs with captive mail order divisions also have an incentive to dispense repackaged drugs at higher AWPs than the manufacturer has originally set. The PBM can engage in such conduct because the repackaged drug has a separate NDC code from the Food and Drug Administration. While the PBM mail order house still provides a much bigger discount than a retail pharmacist, the ultimate price to the consumer on mail orders can be higher, given the AWP markup.

The following example demonstrates how these incentives can work to harm payers and consumers. Suppose a PBM negotiates with retail pharmacies on behalf of its plans and obtains retail pricing of AWP minus 10 percent plus a $3 dispensing fee. If, as is the case with Celebrex (see figure 5, *infra*), the manufacturer's AWP is $105.34[13] for a 60 day supply ($1.76 a unit) per prescription, the plan would pay the retail pharmacy $97.81 to

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[13] Note, this number is slightly less than $1.76x60 due to rounding

fill the prescription ($94.81 plus a $3 dispensing fee). The PBM might tell the plan sponsor that it is going to offer a "better" deal on mail order to encourage members to use mail order. For instance, it might offer to fill mail order prescriptions at AWP minus 25 percent with no dispensing fee. However, if the mail order firm has inflated the AWP of its repackaged product, it can fulfill the literal terms of its contract and still make more money. The mail order firm can set its AWP at $186.13 for a 60 day supply ($3.10 per unit), as one re-labeler has done for Celebrex. In such a case, even with a 25 percent discount, the mail order firm sells the product to plan members for a net price of $142.60 ($139.60 + $3), which is $44.79 greater than without repackaging in our example. It can then pocket the difference after accounting for the relatively small cost of repackaging.

IV.   Evidence of Harm to Consumers as a Result of PBM Self-Dealing

As discussed below, empirical evidence shows that PBMs with captive mail order not only have incentives to act in ways contrary to the interests of payers and consumers, but appear to have done so.

A.   Evidence that PBMs With Captive Mail Order Have Favored Higher Priced Products

Captive mail order divisions dispense significantly fewer generic drugs than non-captive mail order companies. Approximately 39 percent of independent mail order prescriptions (using a sample of actual data from major independent mail order operations) are filled with generics, which is approximately the same amount as for third party retail.[14] In contrast, the generic substitution rate is 29.4 percent for captive mail order prescriptions, based on the best available proxy for such mail order houses. By way of comparison, the generic substitution rate is 53 percent for cash payers and 51 percent for Medicaid.

The best available proxy for captive retail is the figure for all mail order, since 77% of mail order sales are made from captive mail order divisions. Indeed, this proxy is conservative, because it includes independent mail order houses which have a higher generic substitution rate than the captives.

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[14] Since neither retail nor non-captive mail order have the same incentive as captive mail order to engage in self-dealing activities, one would expect that both retail and non-captive mail order to sell the lowest priced versions of a given drug.

Figure 1

Generic Dispensing Rate By Source of Payment
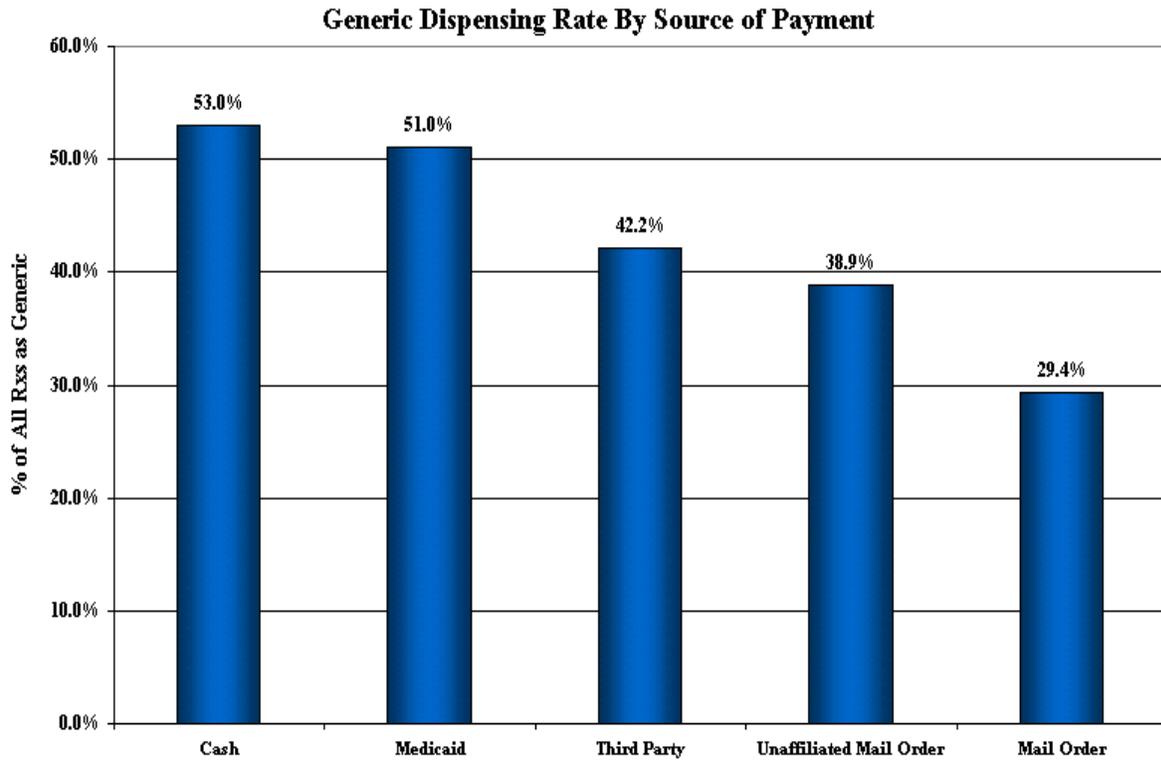
Source: Compiled by PRIME Institute, University of Minnesota from information found in Drug Store News, August 30, 2001, p. 38 and based on IMS Health data; also Medicaid data from Medicaid State Drug Utilization files with analysis and estimates by the Prime Institute. Unaffiliated mail order estimates based on conversations with retail chains

The low level of generics dispensed by PBM-controlled mail order companies appears to be due, at least in part, to the opportunity for PBMs to earn rebates by favoring higher priced drugs. As discussed below, accounting for other plausible explanations, such as differences in the type of drug dispensed ("the mix"), does not eliminate the disparity in substitution rates. [15]

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[15] Since mail order prescriptions are predominantly for products that treat chronic conditions, there may be differences in the mix of products being dispensed at retail and those being dispensed through mail order.

In Figure 2 we partially control for the differences in the mix between retail and mail order. We do so by limiting the analysis to the ten therapeutic categories most dispensed through mail order within the ten largest cities.[16] Even then, there is a lower rate of generic dispensing through mail order relative to retail as shown by Figure 2. The average generic substitution rate for mail order in these ten cities is 32.2 percent. The average retail generic substitution rate is 38 percent. Thus, the difference on average is 5.8 percent. This demonstrates that the mix is unlikely to account for the significant difference in substitution rates, and it is consistent with opportunistic self-dealing by PBMs dispensing drugs through their mail order divisions.

Figure 2
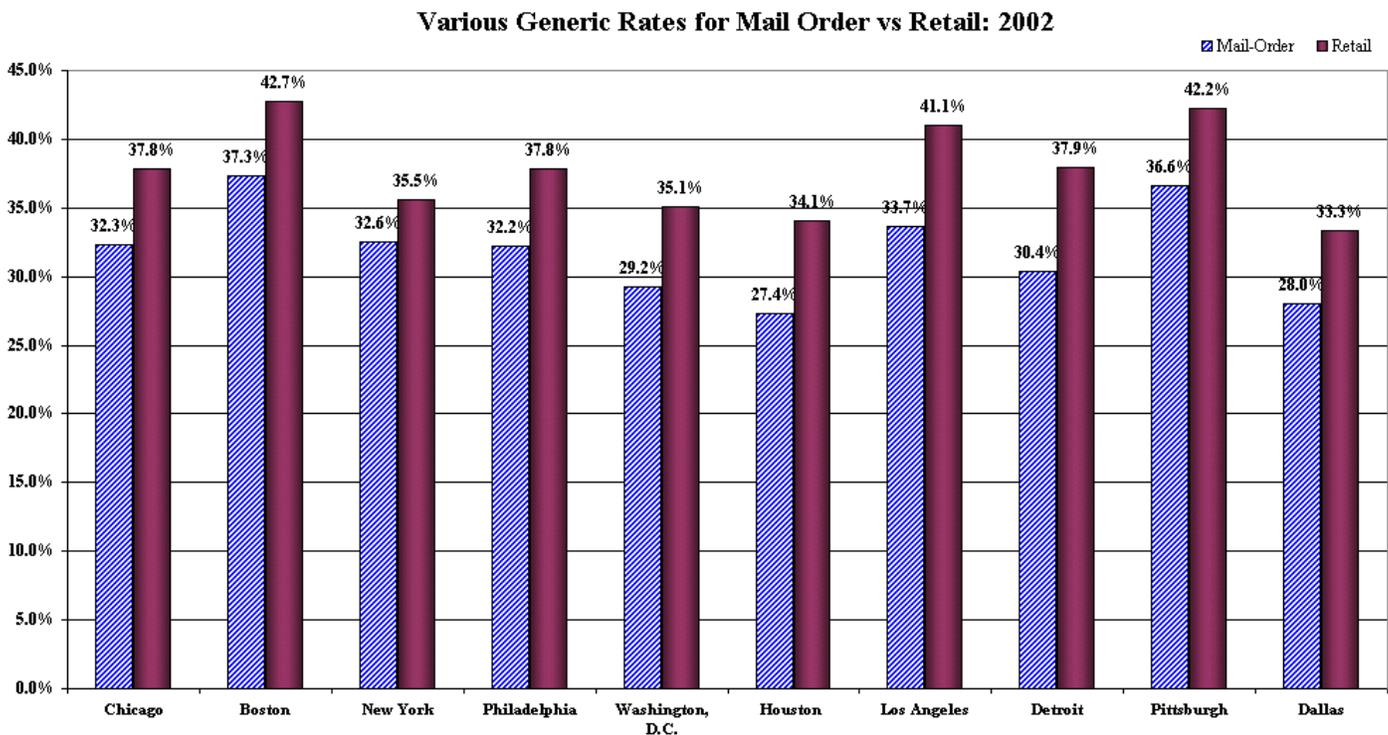
Various Generic Rates for Mail Order vs Retail: 2002

Source: Compiled by PRIME Institute, University of Minnesota from data provided by CVS Pharmacy based on IMS Health data for same mix of drugs drwn from 10 most frequently dispensed therapeutic categories of drugs in mail order pharmacy from August 2001 to July 2002

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[16] The ten drug categories included in this analysis are adrenergic blockers, systemic antiarthritics (including NSAIDS), antidepressants, anti-ulcerants, calcium blockers, cholesterol reducers, oral diabetes products, non-injectable diuretics, renin angiotensin antagonists, and sex hormones.

Figure 3 compares generic dispensing rates when all single source drugs (for which there is no generic substitute) are excluded and the analysis is confined to just multi-source drugs. In that situation, therapeutic switching to maximize rebates is unlikely to occur and the generic utilization rates should be about the same, assuming there is no significant mix effect. The data show that, with that adjustment, the average generic substitution rate for mail order in these cities is about 78 percent. The average generic substitution rate for non-captive mail order (as measured by its proxy) is about 81 percent. These data support the conclusion that differences in the mix do not explain the low level of generic utilization by PBM-owned mail order operations.

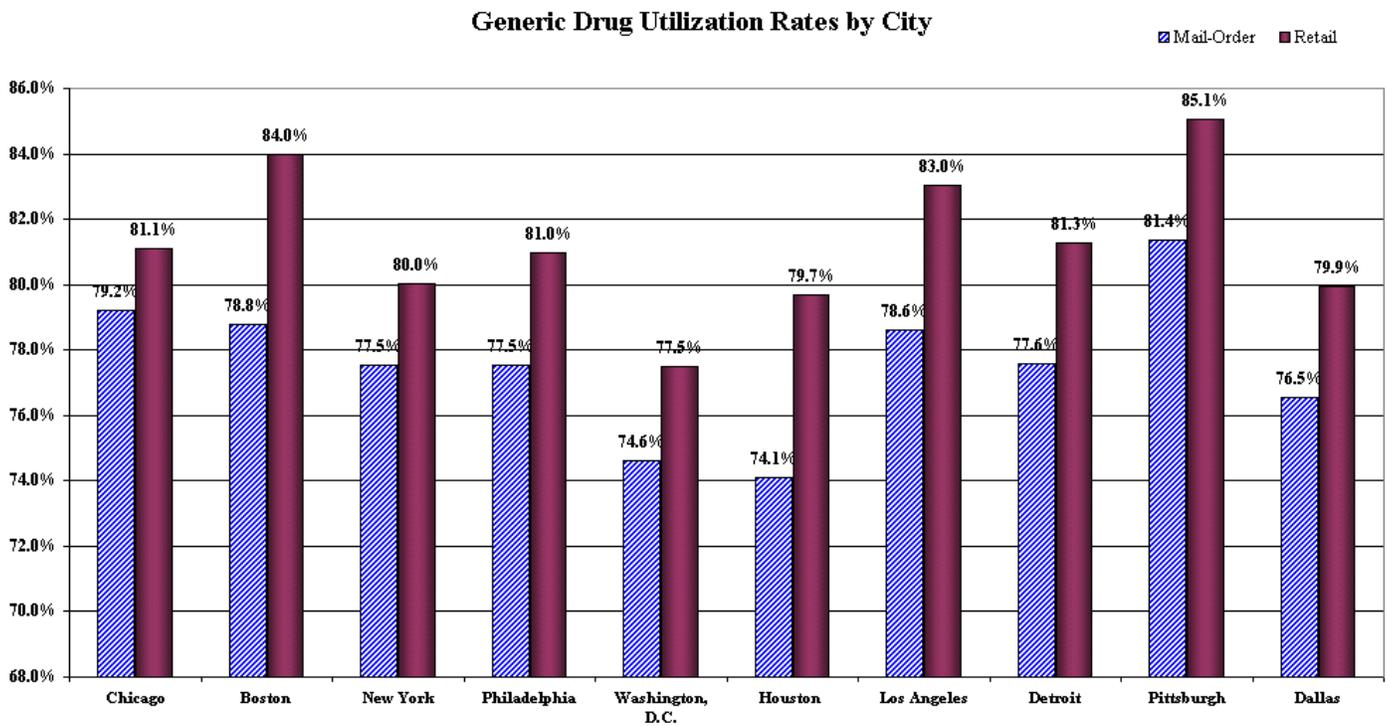**Figure 3**

Generic Drug Utilization Rates by City

Source: Compiled by PRIME Institute, University of Minnesota from data provided by CVS Pharmacy based on IMS Health data for same mix of drugs drwn from 10 most frequently dispensed therapeutic categories of drugs in mail order pharmacy from August 2001 to July 2002

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Finally, in order to further analyze the effect of the mix of products dispensed through mail order versus retail, we obtained data from IMS Health for all products in a single category of drugs—cardiovascular products. We chose cardiovascular products because they represent a large volume of sales (particularly to the elderly) and are predominantly used as maintenance products and thus are well suited for mail order distribution. We used a category of drugs rather than a specific cardiovascular drug in order to capture the possible magnitude of therapeutic switching.[17]

Figure 4 presents the percentage of prescriptions for cardiovascular products that were filled generically through mail order (the proxy for captive mail order) versus retail (the proxy for independent mail order). Within this single category of maintenance drugs, the rate of generic dispensing through mail order is significantly less than through retail. In 2002, it was 36 percent versus the retail generic dispensing rate of 42.3 percent. The differential is over 6 percent, which is very close to the differentials in Figures 2 and 3.[18]

Figure 4

Overall Cardiovascular Generic Substitution Rates

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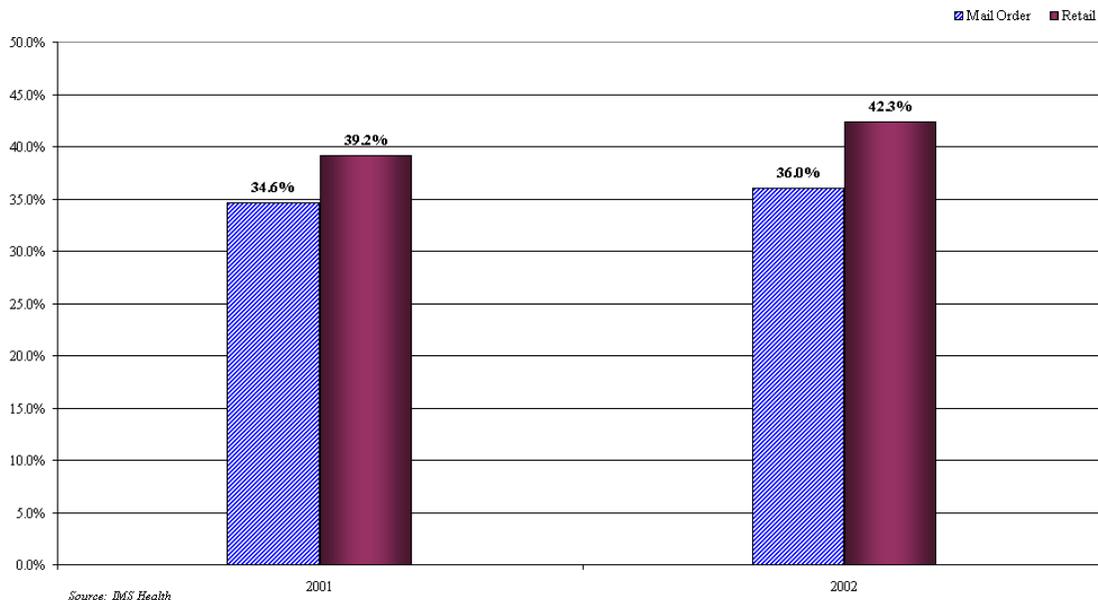
[17] This was necessary because in most instances, including for cardiovascular products, more than one single-source drug can be substituted for a multi-source drug that has a generic equivalent. The manufacturers of the single source substitutes offer rebates to PBMs, which often vary by PBM, making some single source cardiovascular drugs more attractive to some PBMs than to others. Thus, all of the single source drugs that are therapeutically similar must be considered to measure the extent of therapeutic switching caused by self-dealing.

[18] Similar differentials are present in narrower classes of cardiovascular drugs, such as beta blockers (6.2% differential), or calcium channel blockers (4.5% differential).

B.   Evidence that PBMs Have Used Captive Mail Order to Inflate AWP

There is also evidence that captive mail order firms can shift consumers to higher AWP versions of the same drug to the PBM's benefit. Figure 5 shows the higher per unit AWP prices on repackaged Celebrex 100 mg capsules.

Figure 5
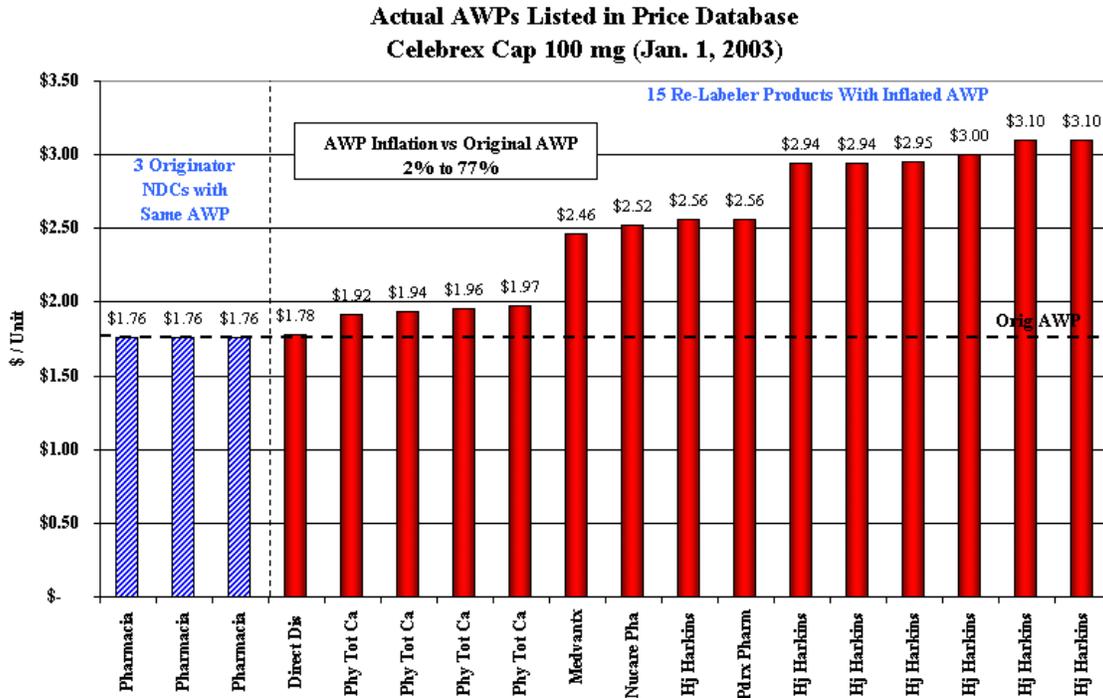
Actual AWPs Listed in Price Database
Celebrex Cap 100 mg (Jan. 1, 2003)

15 Re-Labeler Products With Inflated AWP

3 Originator NDCs with Same AWP

AWP Inflation vs Original AWP
2% to 77%

Bar	Value
Pharmacia	$1.76
Pharmacia	$1.76
Pharmacia	$1.76
Direct Dis	$1.78
Phy Tot Ca	$1.92
Phy Tot Ca	$1.94
Phy Tot Ca	$1.96
Phy Tot Ca	$1.97
Medvantx	$2.46
Nucare Pha	$2.52
Hj Harkins	$2.56
Pdrx Pharm	$2.56
Hj Harkins	$2.94
Hj Harkins	$2.94
Hj Harkins	$2.95
Hj Harkins	$3.00
Hj Harkins	$3.10
Hj Harkins	$3.10

Orig AWP

Source: Compiled by PRIME Institute, University of Minnesota from data found in PriceChek PC (Facts & Comparisons, Inc.), January 1, 2003

Some of these re-labelers are not mail order pharmacies. However, these re-labelers often sell their re-labeled products to mail order pharmacies. To the extent that mail order pharmacies are reimbursed based on the higher AWP of the re-labeled product, the potential exists for the "gaming of the system."

Figure 6 provides an example of the potential impact of AWP inflation, net of the larger discounts that generally accompany mail order dispensing. In Figure 6, we use the data from Figure 5 to calculate the list price for a 60 day supply of Celebrex at the manufacturer's price relative to the highest re-labeler price. The AWP for the manufacturer's product is $1.76 per capsule, so the AWP for a 60-day supply (one capsule per day) would be $105.34.[19] The same 60-day supply using the HJ Harkins re-labeled product would have an AWP of $186.13. This is 77 percent higher than the manufacturer's list price.[20]

Figure 6

AWP Originator & Mail Order (Re-Labeler)
Celebrex 100 mg Cap (#60)

Source: Compiled by PRIME Institute, University of Minnesota from data found in PriceChek PC (Facts & Comparisons, Inc.), January 1, 2003

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[19] Note, this number is slightly less than 1.76x60 due to rounding.

[20] Note that HJ Harkins (or the mail order pharmacy) likely acquired the product for a price at or below the manufacturer's AWP.

Figure 7 shows that even after accounting for the larger discounts available through mail order, AWP mark-ups on re-labeled drugs can result in higher prices for payers and more profit for the dispenser. In Figure 7, we assume that the typical retailer contract with the PBM sets the price at AWP minus 10 percent, plus a $3 dispensing fee. Even if the typical mail order price being offered is AWP minus 25 percent with no dispensing fee, the payers will end up paying more if the mail order dispensed the re-labeled product than if the patient had filled the prescription at a retail pharmacy ($139.60 v. $97.80).

Figure 7

Net Rx Price for Retail & Mail Order (Re-Labeler)
Celebrex 100 mg Cap (#60)

Even with the larger discount, the Re-Labeler Net Price is still higher than the Retail Net Price

In this case ... 43% More than Retail

$97.80

$139.60

A Larger Discount May Cost You More

Retail Rx

AWP - 10% + $3 Disp. Fee

Re-Labeler Rx
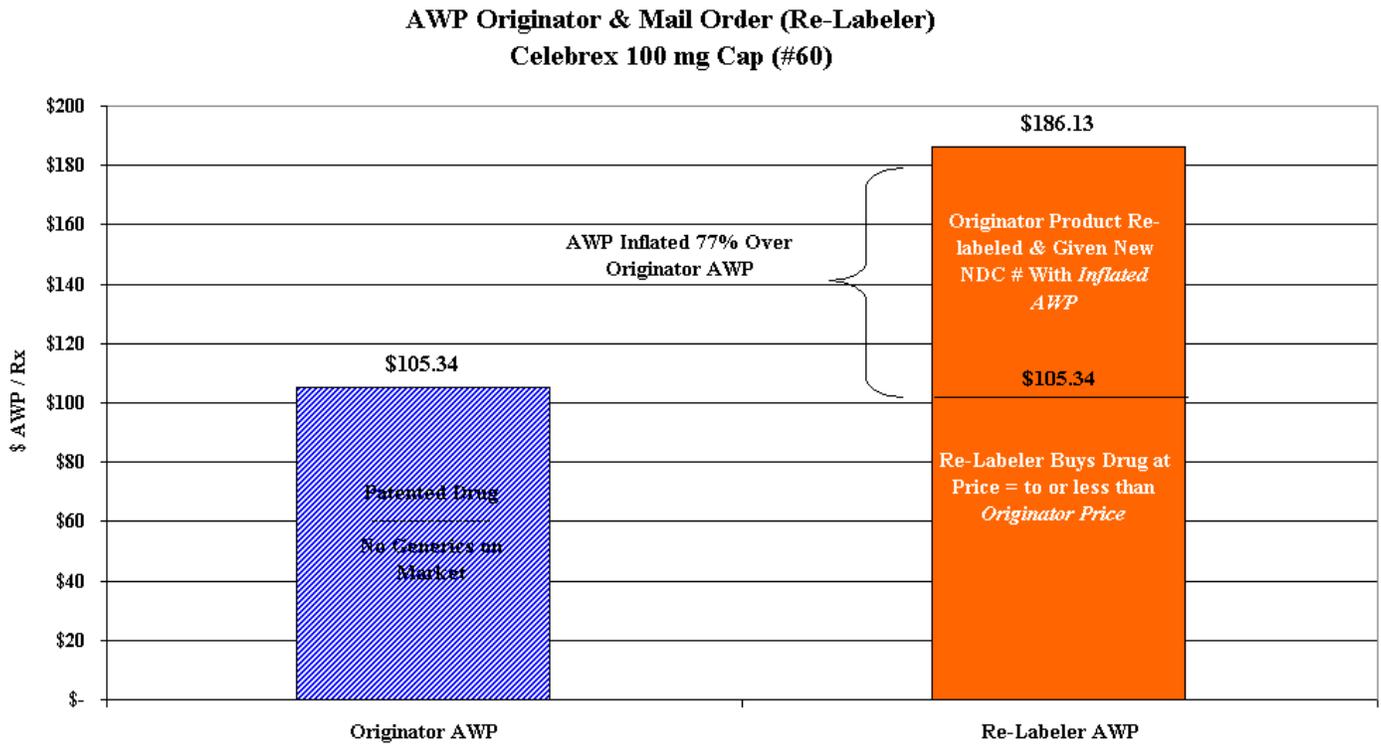
AWP - 25% + $0 Disp. Fee

Originator AWP   Re-Labeler AWP

Source: Compiled by PRIME Institute, University of Minnesota from data found in PriceChek PC (Facts & Comparisons, Inc.), January 1, 2003
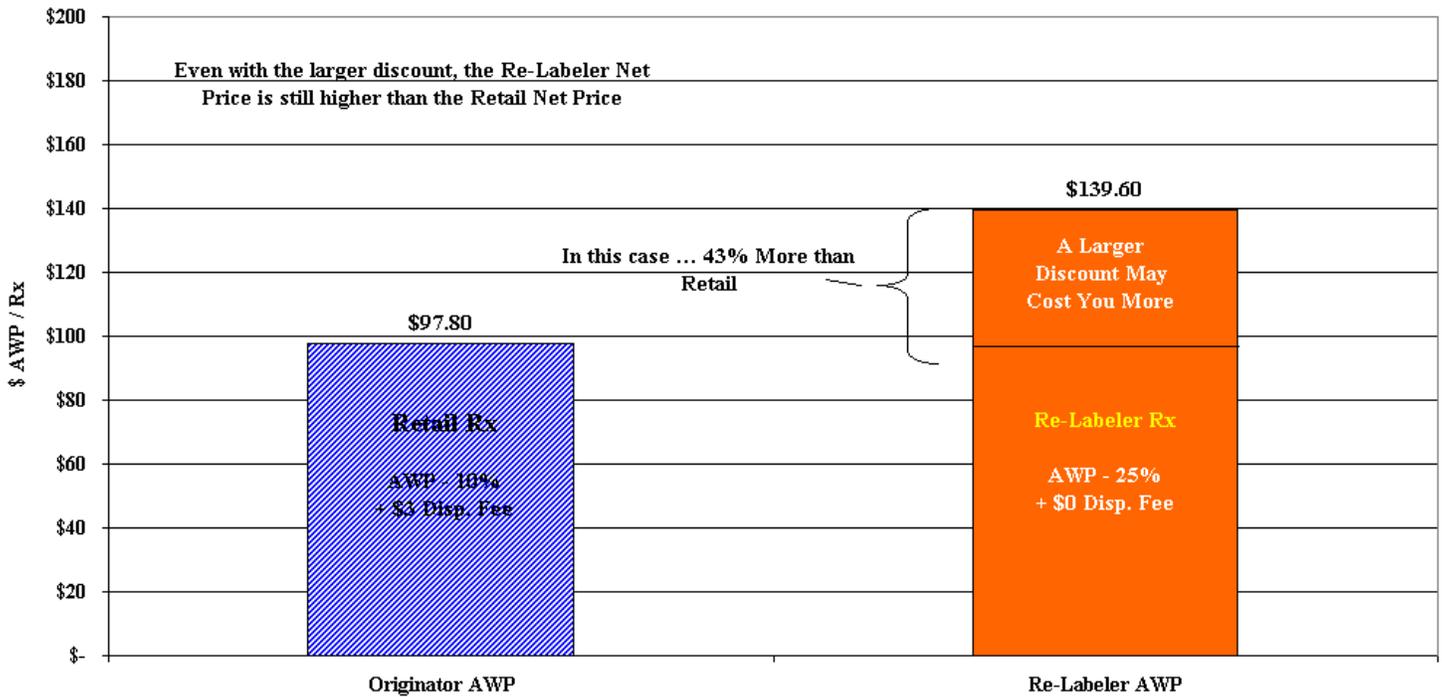
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C.   Efficiencies from Integration May Be Small Relative to the Potential Increase in Costs from PBM Self-Dealing

The fact that some plans carve out mail order and separately contract for those services in their plan design suggests that there are not likely to be significant economies of scope between PBM services and mail order services.[21] Furthermore, many PBMs have been successful using unaffiliated mail order pharmacies. If there were large economies of scope, then the costs of providing the services jointly would be lower than the cost of providing them separately, and an integrated PBM could profitably undercut the prices of firms providing the services separately and drive them out of business. The existence of successful independent PBM and mail order operations suggests that any economies of scope do not necessarily exceed the increased costs that can arise from PBM self-dealing.

Even assuming some efficiencies are achieved by combining administrative and distributive functions, there is no assurance that all, or even a significant part, of the efficiency savings will be passed on to consumers. Passing on of all efficiencies generally occurs only "(a) where the firm faces a perfectly vertical demand curve in the relevant range – something we presume never occurs; or (b) where price regulation forces the firm to pass on all cost reductions."[22]   Moreover, even if some efficiencies are earned and passed on to payers and consumers, they may not exceed the harm to payers that results from self-dealing among integrated PBMs.

In sum, efficiencies should not be assumed, nor should there be an assumption that any efficiencies result in lower costs to payers and consumers.

V.   Estimated Cost to Medicare and Beneficiaries from PBM Self-Dealing

A.   The Cost of Underutilization of Generic Products

We have developed a model to estimate the costs to the Medicare system of the self-dealing between PBMs and their captive mail order pharmacies. The model is based on several assumptions:

- We conservatively assume that 22.3 percent of Medicare prescriptions will go through mail order, the same percentage as the population as a whole. The actual Medicare percentage may be higher since the Medicare population is likely skewed towards the use of maintenance drugs that are more likely to be distributed by mail order. However, the more drugs dispensed through affiliated

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[21] "Plans reported managing mail service through a mix of internal programs, and contract with outside mail-service or pharmacy benefit management (PBM) companies." Novartis Pharmacy Benefit Report, Facts & Figures, 2001 Edition, p. 13.

[22] IVA Areeda, Hovenkamp & Solow, Antitrust Law ¶971b.

mail order, the greater the opportunity for self-dealing.[23] Thus, our assumption here is conservative.

- We assume no increased purchasing of drugs from lower cost sharing (lower co-payment) or lower prices attendant with more generic dispensing. This assumption seems reasonable since drug demand is largely inelastic.

With these assumptions in place, we apply the following equations to estimate the cost of mail order dispensing to Medicare beneficiaries with and without integrated PBM and mail order functions.

Equation (1) describes the cost of mail order when PBMs use integrated mail order.

$$\left[P_G \cdot S_M^G + P_B \cdot \left(1 - S_M^G\right)\right] Q_M \tag{1}$$

P_G is the average generic price, P_B is the average branded price, S_M^G is the share of mail order prescriptions that are filled with generic products, and Q_M is the number of Medicare prescriptions filled through mail order pharmacies.

Equation (2) describes the cost of mail order when PBMs use unaffiliated mail order.

$$\left[P_G \cdot S_R^G + P_B \cdot \left(1 - S_R^G\right)\right] Q_M \tag{2}$$

S_R^G is the share of retail prescriptions filled with generic products by unaffiliated mail order pharmacies.

Note that we assume that the prices and the number of prescriptions is the same in both regimes. Thus, the only difference between the two equations is that we assume in equation (2) that, with unaffiliated mail order pharmacies, the utilization of generics is identical to the overall rate of generic utilization of the average of the mix-adjusted rates. Figure 1 shows that the generic utilization rate for unaffiliated mail order operations is 38.9 percent and that the overall third party generic utilization rate is 42.2 percent, compared to just 29.4 percent for all mail order (which as mentioned above is mostly captive mail order).   Figure 4 shows that, even when controlling for differences in the mix by focusing on a single drug category, retail generic substitution rates are larger than mail order (42.3 percent for retail versus 36 percent for mail order).

The difference in costs between using affiliated and unaffiliated mail order pharmacies can be calculated by calculating (1) minus (2). Equation (3) is the result of that calculation.

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[23] It is also conservative because unaffiliated PBMs may use mail order less than affiliated PBMs. But, to the extent they do, it generates additional savings because of higher generic utilization at retail.

$$\left[P_G \cdot \left(S_M^G - S_R^G\right) - P_B \cdot \left(S_M^G - S_R^G\right)\right]Q_M \tag{3}$$

Rearranging equation (3) yields (3'):

$$\left[\left(P_G - P_B\right) \cdot \left(S_M^G - S_R^G\right)\right]Q_M > 0 \tag{3'}$$

From (3'), it is easy to see that affiliated mail order results in higher costs since both $\left(P_G - P_B\right)$ and $\left(S_M^G - S_R^G\right)$ are likely to be negative, or at most zero.

The estimates for equations (1) and (2) are derived from publicly available data. Tables 1-A, 1-B, and 1-C presents the data and the calculations for 2003, which are then carried forward for the period from 2006 to 2013.

We begin our calculations by estimating Q_M, the number of mail order prescriptions that will be filled by beneficiaries. According to Centers for Medicare and Medicaid Services (CMS), there are expected to be 40,800,000 Medicare beneficiaries in 2003.[24] Based on the CBO's October 2002 study, we assume that 75 percent of Medicare beneficiaries will participate in a Medicare prescription drug benefit, and that each beneficiary will fill about 30 prescriptions a year on average.[25] IMS Health estimates that 12.9 percent of prescriptions in 2002 were filled through mail order.[26] We assume that percentage holds for Medicare as well. Combining all these figures, we estimate that there would be 118,422,000 mail order Medicare prescriptions if a drug benefit were in place in 2003. (See Table 1-A). Based on CMS projections, we estimate that the number of Medicare beneficiaries will grow by 1 percent per year.[27] We also project that mail order dispensing will grow by 20 percent per year, until it reaches a peak of 22.3 percent of total prescriptions in 2006. We assume that Medicare patients will use mail order in this same proportion. Using these assumptions, we calculate Q_M for each year from 2006 to 2013. (See Table 1-A).

IMS Health estimates that the average price of a branded pharmaceutical product in 2002 was \$77.02, and the average price of a generic product was \$14.70.[28] While pharmaceutical prices have been rising rapidly in the recent past (as much as 15 percent

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[24] Medicare Enrollees, Selected Years, 1975-2003, CMS/OACT, September 2002

[25] Issues in Designing a Prescription Drug Benefit for Medicare, A CBO Study, October 2002, Table 3; We assume the amount dispensed per rx is the same for retail and mail order prescriptions (ex. 30 day supply).

[26] Kumar, Pankaj and Ana-Maria Zaugg. "IMS Review: Steady but Not Stellar", IMS Health Business Watch, May 2003

[27] Medicare Enrollees, Selected Years, 1975-2003, CMS/OACT, September 2002. Growth rate estimate from 2002-2003 HI and/or SMI Medicare enrollees.

[28] "Generic Drug Prices Rising Rapidly" CBS News http://www.cbsnews.com/stories/2002/12/27/health/main534528.shtml, data taken from IMS Health.

for generic products overall), pharmaceutical price inflation may moderate.[29] We project pharmaceutical price inflation to be 8.8 percent per year between now and 2013—the current rate of growth of branded prices.[30] Since IMS data are collected from retailers, it does not include manufacturer rebates that are paid directly to PBMs and health plans. Rebates are typically paid on branded drugs, and not on generic drugs, so we reduced the average price of branded drugs by an estimate of the amount of the rebate passed on to end payers. In a recent analysis of the PBM industry, Banc of America states that rebates on branded drugs average about 10 percent of the cost of the drug.[31] PBMs retain about 30 percent of rebate payments, and return the rest to plans.[32] Thus, rebates reduce the price of branded drugs to end payers by about 7 percent on average. To account for rebates, we reduce the estimated average branded price in a given year by 7 percent.

Finally, based on Figure 1 above, we assume that the generic substitution rate for self-dealing PBMs and mail order pharmacies will be 29.4 percent, and that the generic substitution rate with unaffiliated mail order pharmacies will be 38.9 percent, based on data we received from the mail order operations of large retail chains. Since we are comparing mail order to mail order substitution rates, there are unlikely to be material differences in the mix of drug types dispensed. Additionally, as shown in Figures 2, 3, and 4, the mix has relatively little effect, and Figure 1 covers a broader universe of products and locations than the data in Figures 2, 3, and 4.

We estimate that the total cost to all end payers (the Medicare system and patients) of mail order dispensing to Medicare drug beneficiaries from 2004 to 2005 to be about $19.9 billion, and between 2006 and 2013 to be about $169.7 billion. We arrive at that number by using available data to estimate the individual components of equation (1) for each year from 2004 to 2013. We then obtain an estimate for the total cost of mail order dispensing in the Medicare population when the mail order is unaffiliated with a PBM. As equation 2 highlights, we assume in this calculation that the only change that results from using unaffiliated PBMs is a higher rate of generic utilization. We also assume that unaffiliated mail order pharmacies will dispense generically 38.9 percent of the time, versus 29.4 percent of the time for affiliated PBMs (See Table 1-A).[33] Using this

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[29] "Generic Drug Prices Rising Rapidly" CBS News
http://www.cbsnews.com/stories/2002/12/27/health/main534528.shtml, data taken from IMS Health.; See also Kumar, Pankaj and Ana-Maria Zaugg. "IMS Review: Steady but Not Stellar", IMS Health Business Watch, May 2003

[30] "Generic Drug Prices Rising Rapidly" CBS News
http://www.cbsnews.com/stories/2002/12/27/health/main534528.shtml, data taken from IMS Health. Branded prices increased 8.8% from 2001 to 2002 while generic prices rose and average of 15% from 2001-2002.

[31] See "Pharmacy Benefit Managers, Keeping a Lid on Drug Costs", Banc of America Securities, February 2002, p. 21.

[32] See "Pharmacy Benefit Managers, Keeping a Lid on Drug Costs", Banc of America Securities, February 2002, p. 37.

[33] There are at least two alternative generic substitution rates available for captive mail order—the lowest rate we observe is the 29.4 percent rate from Figure 1 and the highest overall rate in our data is the 36 percent rate for cardiovascular products from figure 4. The 29.4 percent rate seems the most appropriate

difference, we calculate that PBM self-dealing could increase the total cost of mail order dispensing from 2004 and 2005 by $2 billion, and from 2006 to 2013 by over $16.7 billion, assuming PBMs do not bear risk. (See Table 1-A). Thus, absent self-dealing by PBMs with captive mail order, total savings from 2004 to 2013 are approximately $18.7 billion. As discussed below, even if PBMs do bear risk, they still may have an incentive to engage in self-dealing that results in higher costs to payers.

Since the analysis above is restricted to just mail order operations, there are unlikely to be differences in the overall mix of types of drugs dispensed between affiliated and unaffiliated mail order. However, as a check we recalculated the impact of self-dealing using a narrower set of drugs. In Figure 4, we report the generic substitution rates for a single class of predominantly maintenance drugs. The generic substitution rate for retail dispensing is very close to the overall retail generic substitution rate (42.3 percent v. 38.9 percent), while the mail order generic substitution rate for cardiovascular drugs is higher than the overall mail order figure (36 percent v. 29.4 percent). To be conservative, we also recalculated our model using the 42.3 percent and 36 percent substitution rates described in Figure 4. Using this narrower spread between retail and mail order substitution rates, we estimate that the cost of underutilization of generics from PBM self-dealing is about $1.3 billion between 2004 and 2005, and $11.1 billion between 2006 and 2013. (See Table 1-B).

We have used conservative assumptions regarding the rate of increase in the Medicare population, mail order usage, and pharmaceutical prices. Even if we assume a simpler method where Medicare drug expenditures grow over time by a specific percent (the CBO projects 10 percent growth), the impact of self-dealing is still substantial.[34] Table 1-C presents such a calculation using the CBO's 10 percent projection. The result is a cost increase of $1.5 billion between 2004 and 2005 and over $10.4 billion between 2006 and 2013 because of self-dealing with integrated mail order pharmacies. (See Table 1-C).

The estimates above are the cost to all end payers—both the Medicare system and patient cost sharing—and not just the increased cost to the government.[35] There are four sources of patient cost sharing. First, plan designs might include deductibles of some amount. Second, both the House and Senate versions of the plan incorporate "holes" in coverage. For instance, the House plan contemplates that patients will face 100 percent of drug costs for annual drug expenditures between $2,000 and $4,900.[36] When a beneficiary's drug expenditures exceed this amount, the plan pays 100 percent of additional drug costs.

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rate to use since it includes all drugs dispensed through mail order. However, we separately calculated the impact of self-dealing using both rates (Table 1-A below uses the substitution rates from Figure 1, and Table 1-B uses the substitution rates from Figure 4).

[34] CBO Cost Estimate, July 22, 2003, p. 9.

[35] By the Medicare system, we mean both government expenditures of tax revenues and expenditures of premiums collected from beneficiaries. In some cases, particularly for low income individuals, premiums may be subsidized by the government.

[36] CBO Cost Estimate, July 22, 2003, p. 9.

Third, patients must pay coinsurance or co-payments that likely will vary depending on which type of drug is dispensed. Fourth, under the discount card program in effect during the transitional period, patients will be responsible for charges over $600.

To estimate the portion of those costs that the government would bear in the 2006-2013 period, we assume that cost sharing takes the form of dollar co-payments.[37] Further we assume that the average co-payment for a generic product is C_G, while the average branded co-payment is C_B. The cost, net of co-payments, to the Medicare system of mail order dispensing through integrated mail order pharmacies is:

$$[(P_G - C_G) \cdot S_M^G + (P_B - C_B) \cdot (1 - S_M^G)] \cdot Q_M$$

And the cost, net of co-payments, to the Medicare system of using independent mail order pharmacies is:

$$[(P_G - C_G) \cdot S_R^G + (P_B - C_B) \cdot (1 - S_R^G)] \cdot Q_M$$

While the actual extent of cost sharing by patients will depend greatly on the details of the plans available and the specific plans in which individual patients enroll, we assume that the average Medicare co-payments will be roughly the same as the average co-payments under private health plans. Publicly available sources suggest that the average co-payment for a generic product in 2002 was $9, while the average co-payment for a branded product was $17.[38] While the extent of cost sharing has been increasing rapidly among private plans,[39] we assume that Medicare co-payments will increase at about 3 percent per year—in range with expected overall inflation for the period. All other assumptions remain the same as in the calculations above.

Using these assumptions, we estimate that the higher generic utilization rates that can be obtained by using independent mail order will save the Medicare system as much as $15.1 billion between 2006 and 2013. (See Table 1-A for the details of the calculation). These cost savings would be at risk if PBMs administering Medicare programs were

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[37] There may be other forms of patient cost sharing, such as the 100% coinsurance during the "holes" in coverage that both the House and Senate versions contemplate.

[38] The branded product co-pay used in our model of $17 is the preferred "second-tier" brand-name drug co-pay. There is a nonpreferred drug co-pay (a "third-tier" co-pay) of $26 on average. Employer Health Benefits, The Kaiser Family Foundation and Health Research and Educational Trust, 2002 Annual Survey, p.122.

[39] Growth rates in the retail setting have been increasing dramatically. Average generic co-payments (also known as first-tier) increased by 8% from 1999 to 2001. Brand-name drug or second-tier co-pays increased 20% over the same period and nonpreferred drugs or third-tier co-pays increased 23% over the period. See The Takeda Prescription Drug Benefit Cost and Plan Design Survey Report, 2002 Edition, p. 9.

permitted to engage in self-dealing in the region where they were serving as administrators.

During the 2004-2005 period, we assume that drug discount cards will be used and that the average government payment will be $200 per beneficiary, or a total of approximately $16.5 billion in the two years. Using this assumption we estimate that the higher generic utilization rate that can be obtained by independent mail order will save the Medicare system about $500 million in that two-year period if PBM self-dealing were prohibited.

Specifically, we assume the $200 cost reflects current generic substitution conditions where PBM self-dealing is permitted for mail order, and then calculate the cost of under-utilization of generics.[40] To calculate the savings of using an unaffiliated mail order we use our projected generic dispensing rate of 38.9 percent for unaffiliated mail order operations, and the difference in the average branded and generic prices for drugs, ranging from $61.00 to $67.00 over the time period. Using these values to project costs absent self-dealing, the average cost per beneficiary falls to $192 in 2004 and $191 in 2005. The cost of using unaffiliated mail order would total approximately $16 billion. Subtracting this total cost figure from the actual costs that reflect self-dealing yields a cost of under-utilization of generic dispensing under the drug card program that could result from PBM self-dealing of approximately $509 million during 2004-2005.

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[40] Generic substitution rates for PBM affiliated mail order are 29.4% as stated in Drug Store News, August 20, 2001, p. 38.

Figure 8

Projected Costs of Under-Utilization of Generics by PBM Affiliated Mail Order for Drug Card Program (2004-2005) (adjusting for manufacturer rebates)			
Variables	*2004*	*2005*	*Total 2004-2005*
# of Medicare Beneficiaries	41,208,000	41,620,080	
Average Branded Drug Price (P$_B$)	$83.80	$91.17	
Average Branded Drug Price with Rebates (of 7%)	$77.93	$84.79	
Average Generic Drug Price (P$_G$)	$15.99	$17.40	
Generic Dispensing Rate for Mail Order (S_M^G)	29.4%	29.4%	
Generic Dispensing Rate for Retail (S_R^G)	38.9%	38.9%	
Difference in Cost of Branded and Generic Drugs	$61.94	$67.39	
Difference in Generic Dispensing Rates of Mail Order and Retail	9.5%	9.5%	
New Cost per Medicare Beneficiary	$194.12	$193.60	
@ $200 per beneficiary	$8,241,600,000	$8,324,016,000	$16,565,616,000
@ New Cost per beneficiary	$7,999,126,355	$8,057,566,561	$16,056,692,916
Savings Using Unaffiliated Mail Order	**$242,473,645**	**$266,449,439**	**$508,923,084**

B.   The Cost of Potential Re-labeler AWP Inflation

We also estimated the cost to the Medicare system that could result from mail order inflating the AWP of re-labeled products. Our estimate is derived from the Celebrex example presented in Figures 5-7, where the re-labeled product's AWP is inflated by 77 percent over the manufacturer's list price. We assume that retailers offer the PBM AWP minus 10 percent plus a $3 dispensing fee, while the mail order pharmacy offers AWP minus 25 percent with no dispensing fee.[41] Even with the larger discount offered through mail order, under these assumptions the payer ends up paying significantly more using mail order than if the prescription had been dispensed through retail (See Figure 7).

While there are examples of re-labelers charging prices significantly in excess of manufacturer list prices, we do not have data on how often these re-labeled products are sold. Using a 43 percent price difference (which is derived from the 77 percent difference after adjustments for available discounts) and the data in Table 1-A, the AWP inflation from re-labeled products increases costs by $2.7 billion between 2004 and 2013, assuming that sales of these products are about 1 percent of total mail order sales. If the number of sales were as high as 5 percent of mail order sale, the figure would increase to over $13.5 billion. (See Table 2)

Even if the re-labeled products averaged only 10 percent higher actual prices than those sold through retail and these sales amounted to 1 percent of mail order sales, costs would be $2.1 billion higher.

C.   The Cost of Self-Dealing in Prior Years

To calculate the potential cost from PBM self-dealing to Medicare beneficiaries in past years, we applied the model to all prescriptions actually filled by mail order between 2000 and 2003. The total number of mail order prescriptions was about 151 million in 2000, and increased to about 175 million by 2002.[42] In addition, we collected data on generic substitution rates and drug costs between 2000 and 2003. The mail order generic substitution rate for 2000 was 28 percent increasing to 29.4% in 2003. The retail generic substitution rate was reported at 39 percent in 2000 and stayed approximately the same in

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[41] These discounts are the subject of individual negotiations and may vary. Even if the spread between mail order and retail discounts narrowed, the effect would still be an increase in net costs from using mail order.

[42] "U.S Prescription Activity by Channel", IMS Health, 2001-2003 data. Data is reported by total dispensed prescriptions including insulin dispensed through each channel. Mail service accounts for approximately 5% of total prescription dispensing in these years.

2003 at 38.9%.[43] We assume an 8.8% growth rate of generic and branded drug prices through 2000 to 2003 and adjusted prices based on 2002 data taken from IMS Health.[44]

Using these data, we calculated that the extra cost imposed on payers from self-dealing amounted to about $775 million in 2000, and we estimate that the cost of self-dealing will be $1.1 billion in 2003. The total cost of self-dealing for the 2000 to 2003 is about $3.7 billion.

VI.   Forcing PBMs to Share Risks of Cost Overruns Will Not Completely Eliminate Self-Dealing and Its Attendant Higher Costs to the Government and Beneficiaries

Although the opportunistic self-dealing identified above would lessen if PBMs start bearing the risk of cost overruns in 2006, such opportunistic conduct is unlikely to disappear. In its recent cost estimates pertaining to this legislation, the Congressional Budget Office noted that, "[t]he incentives drug plans would have to control costs depend primarily on the degree of financial risk they would face in providing the drug benefit…"[45] Thus, any reduction of the risk borne by PBMs would "weaken the plans' incentives to control cost." [46]

Even if PBMs start bearing risk in 2006, it is likely that self-dealing by integrated PBMs would continue and would cost Medicare significantly more than the $1.5 - $3 billion in increased costs that payers would suffer from PBM self-dealing in the 2004-2005 interim period when PBMs offering discount cards bear no risk. Neither the House nor the Senate version imposes full risk sharing in the post-2005 period. Both versions include reinsurance provisions to protect PBMs from excessive drug spending costs.[47] Moreover, the House version provides that the government will directly assume a significant portion

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[43] The Takeda Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition, p. 27; Takeda Prescription Drug Benefit Cost and Plan Design Survey Report, 2002 Edition, p. 11.

[44] Generic Drug Prices Rising Rapidly, http://www.cbsnews.com/stories/2002/12/27/health/main534528.shtml, 12/27/2002

[45] See Congressional Budget Office Cost Estimate, H.R.1 and S.1, July 22, 2003, p. 13.

[46] Testimony of Douglas Holtz-Eakin before the Committee on Ways and Means, U.S. House of Representatives, April 9, 2003.

[47] As the CBO has noted, reinsurance "would reduce the impact on plans of having higher-than-expected drug costs. See Congressional Budget Office Cost Estimate, H.R.1 and S.1, July 22, 2003, p. 9. Reinsurance also create "moral hazard," meaning that, because of insurance, the PBM would undertake riskier activities than it otherwise would since it does not bear the full costs of such risks. One such riskier activity is self-dealing, which may increase plan costs but also increases PBM profitability. It is unlikely that the insurance company could effectively police such behavior since the evidence above suggests self-dealing exists now in contracts between sophisticated insurers and PBMs.

of the insurance risk.[48] Similarly, both bills allow HHS to reduce the risk to PBMs to the extent necessary to ensure that there is sufficient participation by the PBMs.[49]

Even with full risk bearing, an integrated PBM engaged in self-dealing would receive the full benefit of AWP inflation, and would receive the benefit sooner than if the risk bearing integrated PBM sold the less expensive version of the drug and kept the differential. With only partial risk bearing, the incentives for AWP inflation are greater. Moreover, if manufacturers were to increase the size of their rebates in response to the large size of the Medicare patient base, then opportunistic therapeutic switching would also continue. Even at current rebate levels, opportunistic therapeutic switching would likely take place if the risk bearing takes the form of a reserve or fee hold back, as distinct from a pure capitation approach.

In sum, it is a gross oversimplification to assume that opportunistic self-dealing will cease in 2006 merely because PBMs will assume some type of risk. Indeed, the economic theory of principal-agent contracts identifies some of the pitfalls of that oversimplification.

A.   The Economic Theory of Principal-Agent Contracts

Both in the private sector and in the proposed Medicare prescription drug bills, PBMs operate as agents for the ultimate payers (beneficiaries, employers, and the Federal Government), contracting with manufacturers and pharmacies, designing drug benefit plans, reimbursing drug costs to pharmacies and so forth on behalf of these payers (principals). The economic literature recognizes that agents may pursue objectives that differ from those of the principals.[50] Opportunistic self-dealing is one way in which an agent (the PBM) can pursue its own interests at the expense of the principal it is representing (the Government and/or beneficiaries).

Standard models of principal-agent relationships demonstrate that the incentive to self-deal will not be fully eliminated until all risk is shifted to the agent. Thus, anything short of a fully capitated contract will leave the PBM with some incentive to self-deal.

Appendix 1 presents a formal, standard version of principle-agent contracting that demonstrates that risk bearing will reduce, but not eliminate, opportunistic self-dealing by PBMs. In the standard principal-agent framework, the principal (government) offers a contract to the agent (the PBM). At one end of the spectrum is a "low powered" contract, commonly a "cost-plus" contract, which is economically equivalent to the existing PBM contracts that have no risk sharing. With a cost-plus contract, the principal simply pays the agent's costs of providing the service, plus some markup or fee to allow the agent to

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[48] *Ibid.*

[49] See Congressional Budget Office Cost Estimate, H.R.1 and S.1, July 22, 2003, p. 9.

[50] See Bengt Holmstrom, "Moral Hazard and Observability," *Bell Journal of Economics*, 1979, pp. 74-91. See also, Jean Jacques Laffont and Jean Tirole, *A Theory of Incentives in Procurement and Regulation*, MIT Press, 1994.

earn a fair return. Since the principal would only hire an agent if the agent can lower costs by more than the principal can, there will always be savings compared to not using the agent (i.e., PBMs). However, with such a contract the agent has little incentive to obtain the lowest costs possible, since the principal will reimburse its apparent costs as long as they are below what the principal could obtain.

At the other end of the spectrum is a "high powered" contract, or a fixed price contract. Capitation plans fall in this category. Under a fixed price contract, the PBM is paid a flat per member, per month fee to administer the benefit. With a flat fee, or fixed price contract, any cost savings that the agent is able to generate result in higher profits to the agent. Thus, the agent would have maximum incentive to reduce costs.

In between the two extremes are a host of potential contracts that vary in the amount of risk imposed on the agent. For example, a contract might impose some percentage of the risk (λ in Appendix 1) on the agent. The more risk borne by the agent, the higher powered is the contract. It is relatively straightforward to show that the higher powered the contract, the more incentive the PBM agent has to reduce costs. (See Appendix 1). However, the agent only expends the maximal amount of cost-reducing effort when it must bear the full amount of cost. (See Appendix 1). But, even then, the agent may bid higher than it would if it were bearing less risk. In general, while higher powered contracts give more incentive to reduce costs, they also leave more profits with the agent than lower powered contracts would do.

B. The Impact of Risk Sharing on PBM Self-Dealing

In this section, we show the specific impact of opportunistic self-dealing -- both AWP inflation and therapeutic substitution -- on the three specific contract types outlined above. We find that at current rebate levels and branded and generic prices, even high levels of risk sharing may not reduce the incentive for an integrated PBM to engage in AWP inflation. Moreover, PBMs might still engage in opportunistic therapeutic switching depending on the amount of the rebates offered by the manufacturer and the amount of risk borne by the PBMs.

1) "Cost-Plus" Contracts

Current contracts between PBMs and payers do not impose risk on PBMs. As such, current contracts can be best described as cost-plus contracts, where PBMs make payments for drugs, but are reimbursed for those costs by their employer groups, plus some per prescription administration fee. As we shown above, there is strong evidence that integrated PBMs engage in self-dealing in these situations. If the government adopted such contracts for the Medicare prescription drug benefit, then self-dealing could increase costs by as much as $30 billion between 2004 and 2013 absent a substantial change in the current way the integrated PBMs do business.

2) Full Risk Sharing

A full risk bearing contract can take the form of a fixed fee per member per month. Such a contract is sometimes referred to as a capitation contract. Under such a contract, a PBM would earn profits equal to the difference between the revenues generated per member per month and its total costs including the cost of purchasing drugs, giving the PBM an incentive to keep all costs as low as possible. If drug spending exceeds the PBM's revenues, then the PBM would lose money. With full risk sharing, a rational PBM would only switch to the branded product if the price of the branded product (net of rebates retained by the PBM and copayments paid by beneficiaries) is lower than the price of the equivalent generic product (net of patient copayments). For a given capitated price, the cost to the government is unchanged if the PBM switches, but the cost to the beneficiaries could still be higher if branded copayments exceed generic co-payments.

To evaluate the effect of full risk bearing on therapeutic switching, we make the following assumptions and present the following model. First, we assume an integrated PBMs mail order pharmacy has just received a prescription from a beneficiary for a given generic product and must decide whether to fill it with the generic product or to switch the patient to a branded product for which the PBM receives a rebate. If the generic product is dispensed, PBM profits fall by P_G (the price of the generic product).[51] If the branded product is dispensed instead of the equivalent generic, the integrated PBM's profits fall by $P_B - r P_B$, where P_B is the branded price, and r is the percent rebate retained by the PBM (r is about 3% on average in our data, although there are reasons to believe additional incentives provided by the branded drug manufacturers is larger than this percentage). The PBM would prefer to dispense the branded product if doing so reduced its costs (increased its profits) more than dispensing the generic. One of the key factors that the PBM considers in making this decision is the rebate or other promotional dollars it would receive. The dollar rebate that the PBM would receive is rP_B if it dispensed the branded product. Thus, the integrated PBM mail order firm will dispense the branded product if:

$$(1 - r)\, P_B < P_G$$

Thus, with full risk sharing the PBM will dispense the drug only of the price of the branded drug (net of rebates and other promotional dollars) is less than the price of the generic drug. That is, the PBM dispenses its lowest cost alternative. The branded drug will be the lowest cost alternative if either the PBM receives large rebates or other promotional dollars (large r) and/or branded prices are close to generic prices. In mathematical terms, it pays the PBM to dispense the branded product if:

$$r > (P_B - P_G)\, /\, P_B$$

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[51]Since the PBM has already received its fixed fee, any prescription dispensed is a cost, and thus reduces profits by the price of the drug dispensed. For simplicity, we ignore the effect of patient copayments on the net price paid for the drug by the PBM.

With a small rebate and a large price difference, it would not pay the integrated PBM to switch the patient to the branded product. However, if there are large non-rebate payments by branded manufacturers, or if rebates increase as a results of forcing PBMs to accept risk, then the likelihood of self-dealing would be higher than implied by the figures we are using.

Accordingly, there may be some cases where the PBM may prefer to dispense a branded product in place of the generic even when it faces full risk under captitated contracts. In cases where the switch does occur, beneficiaries will likely be harmed, since most drug plans include higher copayments for branded products.

With respect to AWP inflation, a PBM bearing full risk is indifferent between inflating prices and not doing so, except for the cost of money which favors opportunistic self-dealing. Under our model, let m be the percentage markup or inflation, net of the mail order pharmacy discounts (the 43% in our previous example). With full risk sharing, AWP inflation would reduce integrated PBM profits by $m*P$, where P is the original price. However, dispensing the product with the inflated price increases mail order profits by exactly the same amount as the inflated price. Since the integrated PBM owns the mail order, with full risk sharing, it is indifferent between inflating AWP or not; its increase in mail order profits from doing so exactly offset its decrease in PBM profits.

3) Partial Risk Sharing

It is unclear what form risk sharing would take under the final bill, although it seems likely that PBMs will only have to bear partial risk. Such partial risk sharing will likely include a provision to share costs over some set amount (such as through a reinsurance provision). For the purposes of evaluating the likelihood of therapeutic switching, we again conservatively assume that the PBM receives a per member per month capitation, and, if drug expenditures are below that amount, it retains the full difference as its profits.[52] If, however, drug expenditures exceed the cap, we assume that the PBM will bear only a portion of the excess and that the government will share the rest. For example, assume the cap is $100 per member per month and the government shares half of any excess drug expenditures. If at the end of the month, drug expenditures equal $80 per member per month, the PBM earns $20 per member. If, however, drug expenditures equal $120 per month, the government pays the PBM half of the total loss, and the PBM loses only $10.

Again assume that the PBM receives a new prescription, which it can fill with either a branded or a generic product. With partial risk sharing, the analysis is the same as above if the PBM is below the cap. That is, there is little incentive to self-deal below the cap since profits will be lower unless the branded price is very close to the generic price, or rebates are large. Above the cap, however, the PBM has a stronger incentive to self-deal the smaller is the share of risk that it must bear.

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[52] This example is conservative because we are assuming the form of risk sharing that is most likely to eliminate self-dealing.

In particular, assume that the PBM is above the cap when the next prescription arrives, and that the PBM's share of excess costs is λ. In this case, an integrated PBM's profits fall by λP_G if a generic is dispensed, and fall by $\lambda P_B - r P_B$ if the branded product is dispensed (for which the integrated PBM receives a rebate payment of $r P_B$). The integrated PBM will dispense the branded product if:

$$(\lambda - r)P_B < \lambda P_G$$

It is possible from this equation to determine how much risk the integrated PBM must bear to make self-dealing unprofitable. Rearranging terms, self-dealing is unprofitable in this case if:

$$\lambda > r P_B / (P_B - P_G)$$

Thus, the larger the rebate and the closer the branded and generic product prices, the more risk sharing integrated PBMs would have to bear to eliminate therapeutic switching. However, there is reason to believe that manufacturers pay other promotional dollars today, so the observed rebate levels understate the "full rebate" payments. Moreover, the risk sharing imposed on PBMs would likely enable integrated PBMs to put even more pressure on branded drug manufacturers to increase rebates, again raising the level of PBM risk necessary to eliminate integrated PBMs' current self-dealing.

With respect to AWP inflation, it becomes more profitable when there is partial risk bearing than when the integrated PBM accepts full risk. With partial sharing, if the PBM is below the cap, it remains indifferent between inflating or not. If the PBM is above the cap, however, the PBM strictly prefers to sell products with inflated AWPs. As above, AWP inflation increases mail order profits by $m * P$ per prescription. However, with risk sharing, PBM profits only fall by $\lambda * m * P$. As long as $\lambda < 1$ (less than full risk bearing), the gain in mail order profits strictly exceed the loss in PBM profits, and the integrated PBM still has a profit motive for self-dealing.

VII.   The Impact of Competition Among PBMs

Competition among PBMs both to be (or to work with) a prescription drug plan ("PDP") and for enrollees once it administered a Medicare plan would not preclude self-dealing among PBMs that increased costs. With respect to upstream competition, PBMs currently compete with each other to administer non-Medicare plans and, notwithstanding that competition, generic utilization rates have remained low among captive PBM mail order houses. One explanation why the existing competition has been ineffective may be the oligopolistic structure of the PBM industry, with only four major firms that all are integrated. As Professor Areeda has noted, oligopolistic industries "depart from competitive norms, often substantially."[53]

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[53] IIA Areeda & Hovenkamp, Antitrust Law ¶404b.

With respect to downstream competition, there is also no assurance that some competition for enrollees between Medicare plans administered by different PBMs in the same region will ensure that the PBMs do not engage in cost-increasing self-dealing. Upfront bidding for contracts does not ensure that the benefits of competition carry over after contracts are in place. With complex contracts, parties have the incentive and ability to engage in post-contractual opportunistic behavior.[54] Even though up-front bidding for PBM services is the norm today, up-front bidding has not prevented apparent post-contractual opportunistic conduct. Furthermore, competition among HMOs, which would be expected to drive down premiums and keep costs low, has not eliminated self-dealing in the PBM's administration of HMO drug benefits.

VIII. The Potential Conflict of Interest from Self-Dealing Has Been Addressed in Other Health Care Settings

Economists have recognized for some time the anticompetitive incentives for self-referral in a variety of health contexts[55] and, as discussed below, policy makers have sought to limit self-dealing in order to maximize free market competition.

A. Physician Self-Referral

In 1989, the Office of the Inspector General issued a study on physician ownership and compensation from entities to which they make referrals. The study found that the patients of physicians with ownership interests in independent clinical laboratories received 45 percent more clinical laboratory services than Medicare patients in general.[56] Similarly, patients of physicians known to be owners or investors in independent physiological laboratories used 13 percent more physiological testing services than Medicare patients in general.[57]

Since then, physician ownership of imaging facilities has been extensively studied, and the published literature uniformly concludes that such ownership causes physicians to over-utilize such services relative to those without such ownership interests. An early study concluded that self-referring physicians use imaging examinations at least four times more often than those who refer to unaffiliated radiologists. Moreover, the charges

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[54] See Williamson, Oliver, *The Economic Institutions of Capitalism*, The Freedom Press, 1985, Chapter 13, pp. 326-364.

[55] See Michael Black and James Langenfeld, "Economic Theories of the Potential Anticompetitive Impact of Physician Owned Joint Ventures," *Antitrust Bulletin*, Summer 1994, 385-414.

[56] See "Financial Arrangements Between Physicians and Health Care Businesses" Office of Inspector General - OAI-12-88-01410 (May 1989).

[57] *Ibid.*

are usually higher when the imaging is done by a self-referring physicians.[58] The study further concludes that the differences could not be attributed to differences in the mix of patients, the specialty of the physicians, or the complexity of the imaging examinations performed.[59] A follow-up study by some of the same authors confirmed the result and showed that because of self-referral, average imaging charges per episode were 1.6 to 6.2 times higher for self-referring physicians than for physicians who referred to unaffiliated radiologists.[60]

The General Accounting Office also studied the impact of physician self-referrals for imaging services and found that physician owners of Florida diagnostic imaging facilities had higher referral rates than non-owners for virtually all types of imaging services. The differences in referral rates were greatest for costly, high technology imaging services-physician owners ordered 54% more MRI scans, 27% more computerized tomography (CT) scam, 37% more nuclear medicine scans, 27% more echocardiograms, 22% more ultrasound services, and 22% more complex X rays. Referral rates for simple X rays were comparable for owners and non-owners. In addition while referral practices among specialties differed, physician owners in most specialties had higher referral rates than non-owners in the same specialty.[61]

GAO also compared the imaging rates of physicians who have in-practice imaging patterns (i.e., more than 50% of the imaging services they ordered were provided within their practice affiliations) with physicians with referral imaging patterns (i.e., more than 50% of the imaging services they ordered were provided at facilities outside their practice affiliations). GAO found that physician with in-practice imaging patterns had significantly higher imaging rates than those with referral imaging patterns -- 3 times higher for MRI scans, about 2 times higher for CT scans, 4.5 to 5.1 times higher for ultrasound, echocardiography, and diagnostic nuclear medicine imaging, and about 2 times higher for complex and simple X rays.[62]

In response to concerns about physician self-dealing, Congress passed the Stark Laws that restricted Medicare reimbursement for self-referrals. The first law (the Stark I Amendment) "prohibits physicians from referring a Medicare patient to an entity for the

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[58] See Hillman BJ et al. "Frequency and Costs of Diagnostic Imaging in Office Practice - A Comparison of Self-Referring and Radiologist-Referring Physicians," New England Journal of Medicine 1990, pp. 1604-1608.

[59] *Ibid.*

[60] See Hillman B et al. "Physicians' Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population," Journal of the American Medical Association 1992, pp. 2050-2054. For further academic studies, see also, Mitchell JM and Sunshine JH. "Consequences of Physicians Ownership Of Health Care Facilities - Joint Ventures Radiation Therapy" New England Journal of Medicine, 1992, pp. 1497-1501 and Swedlow A and Johnson Q. "Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self Referral by Physicians," New England Journal of Medicine 1992, pp. 1502-1506.

[61] See Medicare: Referrals to Physician-Owned Imaging Facilities Warrant HCFA's Scrutiny (GAO Report No, B-253835; October 1994)

[62] *Ibid.*

furnishing of laboratory services if the physician or an immediate family member of the physician has a direct or indirect financial interest in the entity providing such services."[63] A later law ("the Stark II Amendment") extended this prohibition to other "designated health services," including physical therapy, radiological services, home health care, and outpatient prescription drugs.[64] The proposed restriction on PBM-mail order self-referral seeks to minimize the same type of adverse behavior for firms providing PBM services under a Medicare prescription drug plan.

B.   Pharmaceutical Companies' Acquisition of PBMs

In the mid-1990s, three large pharmaceutical manufacturers separately acquired three large PBMs— Merck acquired Medco in November 1993, SmithKline Beecham acquired DPS in May 1994, and finally Eli Lilly acquired PCS from McKesson in November 1994.[65] In addition, a few pharmaceutical manufacturers entered into alliances with various PBMs.[66]

These mergers and alliances led to concerns that the manufacturers would use their control over PBMs to cause PBMs to self-deal in favor of the parent company's drugs.[67] As one publication noted, "It's no secret that these PBMs can aid their parent drug companies by adding their products to formularies."[68] Shortly after these mergers, the GAO conducted a study to determine the extent to which PBMs had changed their behavior to favor their parent companies' pharmaceutical products. The GAO analysis showed that of the eight products that made up the bulk of Merck's sales to Medco, only one was on Medco's formulary in January 1993, before the merger period. Two months before Merck and Medco agreed to merge, the other seven were added to the formulary. After the merger, four of the eight faced less competition after competing products were removed from the Medco formulary.[69]

After investigating these concerns, the FTC imposed conditions on its approval of Lilly's acquisition of PCS. These conditions included a requirement that Lilly maintain an open formulary, maintain an independent committee to evaluate and oversee formulary decisions, and erect firewalls to prevent the parent company to gain access to

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[63] See "'Fraud and Abuse' and Stark Laws," A Guide to Legal Issues in Health Care, Office of Legal Affairs, University of Pennsylvania Health System, http://www.uphs.upenn.edu/legal/fraud.html#fn.

[64] *Ibid.*

[65] See U.S. General Accounting Office, Pharmacy Benefits Managers: Early Results on Ventures with Drug Manufacturers, (hereafter, "GAO PBM Report") p. 10.

[66] See Keating, Peter, "Why You May be Getting the Wrong Medicine: A Money Investigation Reveals How Big Drug Companies are Pressuring Doctors, Pharmacists and Insurers to Push Prescriptions that Benefit Company Bottom Lines—But May also Harm Your Health," Money Magazine, June 1997, p. 142.

[67] See GAO PBM Report, pp. 1, 11-12.

[68] "Doubts Emerge About Drug Industry Mergers", Business & Health, November 1994.

[69] See GAO PBM Report, p. 3. The GAO noted that since Medco's negotiations with Merck and other manufacturers are proprietary, it could not verify how Merck achieved its changed formulary status.

competitors' bids to PCS.[70] After investigating the Lilly-PCS merger and obtaining a consent order, the FTC reopened its investigations of the previously approved mergers and alliances between manufacturers and PBMs. As a result, other manufacturers with PBM subsidiaries adopted policies similar to those imposed in the Lilly consent.

Just as abuses resulted from the conflict of interest between pharmaceutical manufactures and captive PBMs, so too have abuses resulted from the conflict of interest between PBM and their captive mail order divisions. And just as ending the conflict of interest at the manufacturer-PBM level has benefited consumers by reducing prices, the same would be true if the conflict of interest between PBMs and captive mail order houses were prohibited in the Medicare context.

IX.   The CBO's Presumption Regarding PBM Discretion.

As the CBO correctly presumes, *when* a PBM has *no* conflicts of interest, any constraint on its cost-management tools would likely result in higher costs.[71] However, when conflicts of interest exist, costs can actually be saved by narrowly tailored restrictions that eliminate the conflicts of interest. Just as the FTC found that unfettered PBM discretion over formularies was not in the consumers' interest when the PBM was owned by a drug manufacturer, so too unfettered discretion by a PBM to use its own mail order house would not be in the consumers' interest.[72]

An example of a narrowly tailored restriction that would save substantial costs for the government is a the preclusion of self-dealing by the PBM in those regions of the country where the PBM is serving, directly or indirectly, as a Medicare plan administrator.   This restriction would not impair a PBM's ability to use all the advantages of mail order, since unaffiliated mail order companies would continue to compete for the business. Moreover, this narrow restriction would leave untouched all the other tools that a PBM can use to reduce costs. Indeed, such a restriction will likely lead to more efficient competitive bidding by unaffiliated mail order companies and thus lower costs to the government.[73]

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[70] See GAO PBM Report, p. 12.

[71] In its assessment of the costs of the pending legislation, the CBO identified the following cost management tools: "If no constraints were placed upon them, the tools a prescription drug plan could use to manage drug costs would include: enforceable limits on the number and types of drugs included in its "formulary" or list of preferred drugs; variable or tiered cost sharing to encourage beneficiaries to use less expensive generic drugs or to switch to similar but preferred drugs for which price discounts have been negotiated; and limits on the number and types of pharmacies through which coverage for prescriptions could be obtained."

[72] In the Matter of Merck & Co. Inc., a corporation, and Merck-Medco Managed Care, L.L.C., a limited liability company, File No. 951 0097, Agreement Containing Consent, See also, In the Matter of Eli Lilly and Company, a corporation, Docket No. C-3594, July 28, 1995.

[73] The CBO has already recognized in a related context that increased competitive bidding – even when it limits discretion – saves money.   See CBO letter to Hon. W.J. "Billy" Tauzin, September 24, 2002.

The best market-oriented way to prevent a Medicare PBM from exploiting its locked-in Medicare customers is to prohibit Medicare PBMs from requiring Medicare consumers to purchase mail order pharmaceuticals at through a PBM-owned facility. As FTC Chairman Muris stated in a recent speech concerning health care:

> Whenever one encounters a market problem, the correct response is to correct the market imperfection, and then allow the market to work. The wrong response is to assume the market cannot work and regulate it out of existence.[74]

A simple requirement that PBMs' deal at arm's length with independent mail order pharmacies is likely to be far more efficient than on-going government regulation of PBM self-dealing.

X.   Conclusion

In conclusion, the elimination of self-dealing between PBMs and their captive mail order pharmacies under the new Medicare drug reimbursement programs could save billions of dollars for the government and consumers, and still support the beneficial effects of free-market competition.

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[74] T. Muris, "Everything Old is New Again: Health Care and Competition in the 21st Century," Speech to the 7th Annual Competition in Health Care Forum (November 7, 2002).

Table 1-A

Projected Costs of Under-Utilization of Generics by PBM Affiliated Mail Order (2004-2013)

(adjusting for manufacturer rebates and using total mail-order rxs)

Variables	Current	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Totals (2004-2013)
# of Medicare Beneficiaries	40,800,000	41,208,000	41,620,080	42,036,281	42,456,644	42,881,210	43,310,022	43,743,122	44,180,554	44,622,359	45,068,583	
# of Medicare Beneficiaries Enrolled in Drug Plan	30,600,000	30,906,000	31,215,060	31,527,211	31,842,483	32,160,908	32,482,517	32,807,342	33,135,415	33,466,769	33,801,437	
Average Rxs Filled per Beneficiary	30	30	30	30	30	30	30	30	30	30	30	
% of Total US Sales Using Mail Order	12.9%	15.5%	18.6%	22.3%	22.3%	22.3%	22.3%	22.3%	22.3%	22.3%	22.3%	
Total Mail-Order Prescriptions in US Market (Q_M)	118,422,000	143,527,464	173,955,286	210,833,807	212,942,145	215,071,567	217,222,282	219,394,505	221,588,450	223,804,335	226,042,378	
Growth of Medicare Beneficiaries	1%											
Growth of Total US Sales Using Mail Order	20%											
Average Branded Drug Price (P_B)	$77.02	$83.80	$91.17	$99.20	$107.92	$117.42	$127.75	$139.00	$151.23	$164.54	$179.02	
Average Branded Drug Price with Rebates (of 7%)	$71.63	$77.93	$84.79	$92.25	$100.37	$109.20	$118.81	$129.27	$140.64	$153.02	$166.49	
Average Generic Drug Price (P_G)	$14.70	$15.99	$17.40	$18.93	$20.60	$22.41	$24.38	$26.53	$28.86	$31.40	$34.17	
Branded Growth Rate over Time	8.8%											
Generic Growth Rate over Time	8.8%											
Generic Dispensing Rate for Mail Order (S_M^G)	29.4%	29.4%	29.4%	29.4%	29.4%	29.4%	29.4%	29.4%	29.4%	29.4%	29.4%	
Generic Dispensing Rate for Retail (S_R^G)	38.9%	38.9%	38.9%	38.9%	38.9%	38.9%	38.9%	38.9%	38.9%	38.9%	38.9%	
Average Branded Drug Copay(C_B)	$17	$18	$18	$19	$19	$20	$20	$21	$22	$22	$23	
Average Generic Drug Copay(C_G)	$9	$9	$10	$10	$10	$10	$11	$11	$11	$12	$12	
Growth Rate for Copayments	3%											
Cost of Mail Order When PBMs Use Integrated Mail Order												
$\left[P_G \cdot S_M^G + P_B \cdot \left(1 - S_M^G\right) \right] Q_M$	$6,500,372,060	$8,571,754,620	$11,303,195,660	$14,905,026,776	$16,378,835,824	$17,998,375,110	$19,778,054,441	$21,733,708,464	$23,882,737,557	$26,244,262,646	$28,839,295,337	$189,635,246,434
Cost of Mail Order When PBMs Use Unaffiliated Mail Order												
$\left[P_G \cdot S_R^G + P_B \cdot \left(1 - S_R^G\right) \right] Q_M$	$5,859,920,187	$7,727,218,914	$10,189,543,584	$13,436,502,785	$14,765,104,180	$16,225,077,681	$17,829,413,362	$19,592,385,756	$21,529,680,859	$23,658,535,702	$25,997,891,713	$170,951,354,536
Difference In Costs												
Difference	$640,451,874	$844,535,706	$1,113,652,076	$1,468,523,991	$1,613,731,644	$1,773,297,429	$1,948,641,078	$2,141,322,708	$2,353,056,698	$2,585,726,944	$2,841,403,624	$18,683,891,898
Cost of Mail Order to End Payers with Integrated Mail Order												
$\left[(P_G - C_G) \cdot S_M^G + (P_B - C_B) \cdot (1 - S_M^G) \right] \cdot Q_M$	$4,765,726,604	$6,406,292,618	$8,599,919,516	$11,530,364,969	$12,868,175,146	$14,346,234,806	$15,978,732,883	$17,781,274,247	$19,771,020,241	$21,966,843,123	$24,389,495,807	$153,638,353,357
Cost of Mail Order to End Payers with Unaffiliated Mail Order												
$\left[(P_G - C_G) \cdot S_R^G + (P_B - C_B) \cdot (1 - S_R^G) \right] \cdot Q_M$	$4,215,275,451	$5,674,110,211	$7,626,524,804	$10,236,932,660	$11,436,591,380	$12,762,425,815	$14,227,216,626	$15,845,020,491	$17,631,296,774	$19,603,046,739	$21,778,966,544	$136,822,132,045
Difference in Cost to End Payers												
Difference	$550,451,154	$732,182,407	$973,394,712	$1,293,432,308	$1,431,583,766	$1,583,808,991	$1,751,516,257	$1,936,253,757	$2,139,723,467	$2,363,796,384	$2,610,529,263	$16,816,221,312

Assumes that amount dispensed per Rx for retail and mail-order are the same (ex. 30-day supply)

Mail order grows @ 20% as stated in "Steady but not Stellar" IMS Health Business Watch - we projected growth to cease when mail order attains 22.3% of total US sales

The average branded copay is the preferred brand-name drug copay (generally grouped in the second tier of a tiered formulary), the average nonpreferred drugs or third-tier drug copay is $26

Table 1-B

Projected Costs of Under-Utilization of Generics by PBM Affiliated Mail Order (2004-2013)

(Adjusting for Manufacturer Rebates and Using Overall Cardiovascular Drug Generic Substitution Rates from IMS Health Data)

Variables	Current	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Totals (2004-2013)
# of Medicare Beneficiaries	40,800,000	41,208,000	41,620,080	42,036,281	42,456,644	42,881,210	43,310,022	43,743,122	44,180,554	44,622,359	45,068,583	
# of Medicare Beneficiaries Enrolled in Drug Plan	30,600,000	30,906,000	31,215,060	31,527,211	31,842,483	32,160,908	32,482,517	32,807,342	33,135,415	33,466,769	33,801,437	
Average Rxs Filled per Beneficiary	30	30	30	30	30	30	30	30	30	30	30	
% of Total US Sales Using Mail Order	12.9%	15.5%	18.6%	22.3%	22.3%	22.3%	22.3%	22.3%	22.3%	22.3%	22.3%	
Total Mail-Order Rx Quantity for Medicare (Q_M)	118,422,000	143,527,464	173,955,286	210,833,807	212,942,145	215,071,567	217,222,282	219,394,505	221,588,450	223,804,335	226,042,378	
Growth of Medicare Beneficiaries	1%											
Growth of Total US Sales Using Mail Order	20%											
Average Branded Drug Price (P_B)	$77.02	$83.80	$91.17	$99.20	$107.92	$117.42	$127.75	$139.00	$151.23	$164.54	$179.02	
Average Branded Drug Price with Rebates (of 7%)	$71.63	$77.93	$84.79	$92.25	$100.37	$109.20	$118.81	$129.27	$140.64	$153.02	$166.49	
Average Generic Drug Price (P_G)	$14.70	$15.99	$17.40	$18.93	$20.60	$22.41	$24.38	$26.53	$28.86	$31.40	$34.17	
Branded Growth Rate over Time	8.8%											
Generic Growth Rate over Time	8.8%											
Generic Dispensing Rate for Mail Order (S_M^G)	36.0%	36.0%	36.0%	36.0%	36.0%	36.0%	36.0%	36.0%	36.0%	36.0%	36.0%	
Generic Dispensing Rate for Retail (S_R^G)	42.3%	42.3%	42.3%	42.3%	42.3%	42.3%	42.3%	42.3%	42.3%	42.3%	42.3%	
Average Branded Drug Copay(C_B)	$17	$18	$18	$19	$19	$20	$20	$21	$22	$22	$23	
Average Generic Drug Copay(C_G)	$9	$9	$10	$10	$10	$10	$11	$11	$11	$12	$12	
Growth Rate for Copayments	3%											
Cost of Mail Order When PBMs Use Integrated Mail Order												
$\left[P_G \cdot S_M^G + P_B \cdot \left(1 - S_M^G\right)\right]Q_M$	$ 6,055,426,548	$ 7,985,024,550	$ 10,529,500,534	$ 13,884,789,056	$ 15,257,716,997	$ 16,766,400,054	$ 18,424,261,692	$ 20,246,052,688	$ 22,247,982,377	$ 24,447,862,875	$ 26,865,267,556	$ 176,654,858,379
Cost of Mail Order When PBMs Use Unaffiliated Mail Order												
$\left[P_G \cdot S_R^G + P_B \cdot \left(1 - S_R^G\right)\right]Q_M$	$ 5,630,705,832	$ 7,424,964,030	$ 9,790,973,368	$ 12,910,925,777	$ 14,187,558,118	$ 15,590,423,865	$ 17,132,004,976	$ 18,826,017,628	$ 20,687,534,252	$ 22,733,117,638	$ 24,980,968,310	$ 164,264,487,962
Difference In Costs												
Difference	$ 424,720,716	$ 560,060,521	$ 738,527,166	$ 973,863,279	$ 1,070,158,880	$ 1,175,976,190	$ 1,292,256,715	$ 1,420,035,059	$ 1,560,448,126	$ 1,714,745,237	$ 1,884,299,246	$ 12,390,370,417
Cost of Mail Order to End Payers with Integrated Mail Order												
$\left[(P_G - C_G) \cdot S_M^G + (P_B - C_B) \cdot (1 - S_M^G)\right] \cdot Q_M$	$4,383,307,908	$5,897,618,525	$7,923,666,348	$10,631,769,891	$11,873,601,161	$13,245,904,349	$14,761,890,010	$16,436,087,427	$18,284,475,517	$20,324,626,688	$22,575,864,951	$ 141,955,504,866
Cost of Mail Order to End Payers with Unaffiliated Mail Order												
$\left[(P_G - C_G) \cdot S_R^G + (P_B - C_B) \cdot (1 - S_R^G)\right] \cdot Q_M$	$4,018,271,880	$5,412,065,981	$7,278,151,960	$9,774,020,045	$10,924,235,085	$12,195,588,913	$13,600,358,176	$15,152,045,462	$16,865,501,007	$18,757,056,454	$20,844,671,860	$ 130,803,694,943
Difference in Cost to End Payers												
Difference	$365,036,028	$485,552,544	$645,514,388	$857,749,847	$949,366,076	$1,050,315,436	$1,161,531,834	$1,284,041,965	$1,418,974,510	$1,567,570,234	$1,731,193,090	$ 11,151,809,923

Assumes that amount dispensed per Rx for retail and mail-order are the same (ex. 30-day supply)

Mail order grows @ 20% as stated in "Steady but not Stellar" IMS Health Business Watch - we projected growth to cease when mail order attains 22.3% of total US sales

The average branded copay is the preferred brand-name drug copay (generally grouped in the second tier of a tiered formulary), the average nonpreferred drugs or third-tier drug copay is $26

Table 1-C

Projected Costs of Under-Utilization of Generics by PBM Affiliated Mail-Order
With Growth Rates Assumed at CBO's Projected 10%*
(Uses Figure 1 Dispensing Rates)

Cost of Mail Order When PBMs Use Integrated Mail Order	Current	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Totals (2004-2013)
$\left[P_G \cdot S_M^G + P_R \cdot \left(1-S_M^G\right)\right]Q_M$	$6,500,372,060	$7,221,913,359	$8,023,545,742	$8,914,159,319	$9,903,631,004	$11,002,934,045	$12,224,259,724	$13,581,152,554	$15,088,660,487	$16,763,501,801	$18,624,250,501	$121,348,008,537
Cost of Mail Order When PBMs Use Unaffiliated Mail Order												
$\left[P_G \cdot S_R^G + P_B \cdot \left(1-S_R^G\right)\right]Q_M$	$ 5,859,920,187	$ 6,510,371,328	$ 7,233,022,545	$ 8,035,888,047	$8,927,871,621	$9,918,865,371	$11,019,859,427	$12,243,063,823	$13,602,043,908	$15,111,870,781	$16,789,288,438	$109,392,145,288
Difference In Costs												
Difference	$ 640,451,874	$ 711,542,032	$ 790,523,197	$ 878,271,272	$ 975,759,383	$ 1,084,068,675	$ 1,204,400,298	$ 1,338,088,731	$ 1,486,616,580	$ 1,651,631,020	$ 1,834,962,063	$11,955,863,249
Cost of Mail Order to End Payers with Integrated Mail Order												
$[(P_G - C_G) \cdot S_M^G + (P_B - C_B) \cdot (1-S_M^G)] \cdot Q_M$	$ 4,765,726,604	$ 5,294,722,258	$ 5,882,436,428	$ 6,535,386,872	$7,260,814,814	$8,066,765,259	$8,962,176,203	$9,956,977,761	$11,062,202,293	$12,290,106,747	$13,654,308,596	$88,965,897,229
Cost of Mail Order to End Payers with Unaffiliated Mail Order												
$[(P_G - C_G) \cdot S_R^G + (P_B - C_B) \cdot (1-S_R^G)] \cdot Q_M$	$ 4,215,275,451	$ 4,683,171,026	$ 5,203,003,010	$ 5,780,536,344	$6,422,175,878	$7,135,037,401	$7,927,026,552	$8,806,926,499	$9,784,495,341	$10,870,574,323	$12,077,208,073	$78,690,154,447
Difference in Cost to End Payers												
Difference	$ 550,451,154	$ 611,551,232	$ 679,433,418	$ 754,850,528	$ 838,638,936	$ 931,727,858	$ 1,035,149,651	$ 1,150,051,262	$ 1,277,706,952	$ 1,419,532,423	$ 1,577,100,522	$10,275,742,782

* CBO projects per capita drug expenditures to grow at approximately 10% annually, See Issues in Designing A Prescription Drug Benefit for Medicare, A CBO Study, October 2002, p. ix, See also CBO Cost Estimate, July 22, 2003, p. 9

Table 2			
Estimated Cost of AWP Inflation from 2004-2013 **(adjusted for manufacturer rebates)**			
	Net Markup from AWP Inflation		
% of Branded & Generic Rxs Affected	**10%**	**20%**	**43%**
1%	$ 2,085,987,711	$ 2,275,622,957	$ 2,711,784,024
2%	$ 4,171,975,422	$ 4,551,245,914	$ 5,423,568,048
5%	$ 10,429,938,554	$ 11,378,114,786	$ 13,558,920,120

Appendix 1

A1. Simple Contract Examples

Let the cost of a firm, β, take on the value of 1 or 1.1. This parameter is referred to below as the "type" of an agent or firm. This represents the idiosyncratic efficiency of the firm, regardless of any measure of effort. Let the effort expended at cost reduction, e, take on any value between 0 and 1. The adverse selection parameter is β and the moral hazard parameter is e.[1]

It is helpful to think of e as the absence of rebate taking on the part of the PBM that would distort the mix of pharmaceuticals resulting in increased cost. Assume that cost mitigating effort (choosing a minimum cost basket of pharmaceuticals) results in a cost reduction of e. Renouncing rebates is costly for the firm, so we assume that the firm bears a private cost of e^2 for this (lack of) activity.

Once the project is completed the principal, can verify (audit) the firm's accounting cost: $\beta - e$. Since effort is costly to the agent, the firm realizes total cost assumed to equal to $\beta - e + e^2$.

Consider the case where the principal observes the components of cost: β and e. In this case, the principal can maximize profit by minimizing the total cost of the firm: $\beta - e + e^2$. Since β is neither a choice variable of the agent nor principal, this minimization is done by choosing effort, e. The optimal effort is independent of β and equals 1/2. Thus in the case without any asymmetric information, the high cost type ($\beta = 1.1$) has a total cost (and is reimbursed) in the amount of 0.85. The low cost type ($\beta = 1$) has a

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[1]This appendix is based on Jean-Jacques Laffont and Jean Tirole, 1994. *A Theory of Incentives in Procurement and Regulation.* The MIT Press. Much of the theory was first introduced in David Baron and Roger Myerson, 1982. *Regulating a monopolist with unknown costs.* Econometrica 50: 911-930.

total cost (and is reimbursed) in the amount of 0.75. This outcome is efficient (optimal effort is chosen) and the principal gets all rents.

Now assume that the principal (or an impartial third party, like a court) does not observe the type or the effort level of the firm, even though the ex post (accounting) cost is observable. Note the distinction: while cost is observed, the components making up cost are not. Thus, the principal is solely reliant on a contract to incite the agent to act in the principal's interests.

Consider the lowest powered (cost reimbursement) contract offered by the principal to a single agent. Low power means that the firm does not internalize any cost reduction efforts. By definition of a cost reimbursement contract, the transfer by the principal to the agent, t, is equal to accounting cost $\beta - e$. Thus, the firm simply chooses to maximize: $-e^2$, which of course yields $e = 0$ for all β. So in this case, neither the high or low cost firms exert any effort, but neither gets any rents from the principal. The payments by the principal are 1.1 to a high cost type, and 1 to a low cost type. Note that costs are higher and effort lower in this case than in the case without asymmetric information.

Now consider the highest powered (fixed price) contract offered by the principal to a single agent. A high powered contract has the firms internalizing all cost reduction efforts. The principal must ensure that each type of agent is willing to participate, *i.e.* he must promise the agent with highest cost a profit equal to his reservation wage (assumed zero). In this case, the high cost type minimizes total cost by setting $e = 1/2$, resulting in total cost to the agent of 0.85. Thus, the fixed price contract must promise the agent a transfer of 0.85. Note that in this case each agent exerts optimal effort ($e = 1/2$), the high cost agent makes zero profit and the low cost agent

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makes a profit of 0.1.

These two examples show the two extreme high and low power contracts. Now consider a new contract which has the two extreme contracts above as special cases. Let the contract compensate the agent a fraction, λ, of its observed accounting costs plus a lump sum, t: $\lambda(\beta - e) + t$. The cost reimbursement (lowest powered) contract obtains when $\lambda = 1$ (and $t = 0$). The fixed price (highest powered) contract obtains when $\lambda = 0$ (and $t = .85$). Confronted with such a contract (chosen by the principal), the agent chooses effort to solve:

$$\max_e : \quad \lambda(\beta - e) + t - (\beta - e + e^2).$$

This is solved by setting $e = \frac{1-\lambda}{2}$. Effort level is independent of type, β, and of the lump sum transfer, t (t is chosen so that the high cost type receives no rents but still participates). Thus effort is decreasing continuously in λ. In other words effort is increasing continuously in the power of the contract. As an example, suppose $\lambda = 1/2$. In this case the level of effort by each type is equal to $1/4$.

A2. Optimal Contract and General Results

Can the principal do better than any contract considered previously? The answer is yes as the following contract shows. Suppose that it is equally likely for the firm to be high or low cost. In this instance, the principal announces to the agent: "If you are a high cost firm, then I want you exert effort 9/20. If I observe that your accounting costs are 1.1 - 9/20, I will pay you just enough to recompense your total costs (1.1 - 9/20 + 81/400 = 341/400 = .8525). If you are the low cost firm, then I want you to exert effort 1/2. If I observe that your accounting costs are 1/2, then I will pay you enough to cover your costs, plus give you a profit of 2/25 for a total payment of 332/400

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= .83."

This contract can be checked to be an equilibrium in a straightforward way. First notice that it never pays either agent to reject the contract. Now check to see if it is profitable for the high cost agent to masquerade as the low cost agent. In order to do so he would have to set $e = .6$. Thus, his total costs would be 1.1 - .6 + .36 = .86. Since he would only be recompensed .85, he would be better off giving the principal his correct type. Now check to see if it is profitable for the low cost agent to masquerade as the high cost agent. In this case his total cost would be 309/400, and he would be recompensed 341/400, for a profit of 2/25. But this leaves him just as well off as if he revealed his true type. The principal is obviously better off with this contract than the highest powered contract as he would only have to pay of $.5(.8525 + .83) < 0.85$. Also note that in this case the expected effort level is higher.

This example illustrates some general points in contract theory. **First**, the optimal contract will in general be somewhere between the two extreme contracts (fixed price and cost reimbursement). This is caused by the tension between the ability of the low power contract to extract rents from the agents, and the ability of the high power contract to increase efficiency. It is *not* true to say that all contracts can be made better (for the principal, or for overall welfare) by increasing their power. **Second**, the optimal contract, has effort decreasing with type, *i.e.* low cost types exert higher effort than high cost types. **Third**, economic profit (rents) are decreasing with type. Additionally the highest cost type receives no rents. These results are generally true, even in cases where there are more than two types of agents.

Now consider the case of a principal choosing between several agents, via an auction. For the most part, the introduction of competition leaves the re-

sults described in the previous paragraph unchanged: the optimal contract's (or auction's) power is somewhere between the two extreme contracts, effort decreases with type, and rents decrease with type. However, the additional results on auctions are well known in contract theory. **First**, if the project is realized then the optimal contract always selects the most efficient firm. **Second**, competition allows the principal to lower the rents of low cost agents. **Third**, the optimal contract sometimes does not realize a worthwhile contract. In other words, if it so happens that all the bidders are very high cost types, it may be the case that the principal does not award a contract.[2] **Fourth**, as the number of bidders grows two things happen: 1) the probability of not realizing the project decreases, and 2) the power of the optimal contract increases.

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[2]This result is similar to standard auction theory where an optimal auction generally entails the imposition of a reserve price.