An Assessment of the Federal Trade Commission
Conflict of Interest Study

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Prepared for:
The National Community Pharmacists Association

PharmaBio Strategy Consulting

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Executive Summary

In November of 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The MMA provides senior citizens and other Medicare beneficiaries with a voluntary prescription drug benefit beginning in January 2006. As part of the MMA, Congress requested that the Federal Trade Commission determine whether pharmacy benefit managers (PBMs) that own a mail-order pharmacy act in a manner that maximizes competition and results in lower prescription drug prices for its plan sponsor members.

The request came about because of concerns over potential for conflicts of interest between PBMs and their plan sponsor customers. PBMs are tasked to manage and lower the cost of pharmacy benefits. However, the retention of pharmaceutical payments by PBMs can create situations where the PBM has incentives to dispense higher cost drugs in order to generate additional profits for itself, while increasing costs to the plan sponsor. These concerns were most notably expressed in, The Cost of PBM “Self-Dealing” Under a Medicare Prescription Drug Benefit by James Langenfeld and Robert Maness, 9 September 2003 (hereinafter, the Self Dealing Study).

The FTC study (hereinafter, The Study), was released in August 2005. In The Study the FTC acknowledges that, “in theory they (PBMs) could have incentives to increase costs and generate additional profits through mail-order pharmacies. However, the FTC concludes that, in 2002 and 2003, PBM’s ownership of mail-order pharmacies generally did not disadvantage plan sponsors” (The Study, Executive Summary, p. ii). The FTC further posits that, “these data suggest that competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests.” Finally the FTC states that, “the allegations (in the Self Dealing Study) are without merit” (The Study, Executive Summary, p. ii).

However, many industry commentators have expressed concern that the FTC conclusions do not provide a balanced perspective adequate to inform Congress and policymakers in their endeavors to protect the fiscal integrity of the MMA prescription drug benefit program. In particular, rather than investigating further, the FTC seems to ignore and set aside the evidence that they themselves have surfaced that would have supported the issues raised in the Self Dealing Study. Further, the FTC methodology has looked at these issues in general terms and using averages rather than considering specific transactions. In doing so, the FTC has masked the underlying conflicts of interest that occur on a transaction-by-transaction basis. The methodologies chosen by the FTC, the degree to which the FTC probed or did not probe in the face of the evidence surfaced and the choice of conclusions relative to the underlying evidence have led to concern as to the balance with which the FTC approached The Study.
PharmaBio Strategy Consulting's\(^1\) analysis of the FTC’s methodologies and conclusions will demonstrate that:

- Many of the key analyses in *The Study* contain methodological flaws, making any conclusion difficult without correction of the analyses.

- The FTC surfaces abundant evidence of potential conflict of interest but fails to investigate further and ignores their own findings.

- The FTC often mischaracterizes its analyses in such ways as to mislead the reader who is not an expert in the industry and unable to examine the analyses in detail.

- The information and evidence that the FTC present do not support the conclusions presented and, in fact, support altogether different conclusions.

The FTC appears to have misunderstood the fundamental concern of economists and indeed of Congress in requesting *The Study*. It is well understood that, all other things being equal, PBMs make more profit on higher cost drugs than on lower cost drugs. The concern is over PBMs encouraging the use of higher cost drugs on which they receive significant manufacturer rebates versus lower cost drugs (particularly generics) on which they receive no manufacturer payments.

Our assessment surfaces many issues in *The Study* of particular importance:

- The sample that the FTC uses to assess costs and Generic Dispensing Rates for owned-mail order (vertically integrated), not owned (independent) mail order and retail pharmacy is skewed by the representation of each individual PBM in each channel. Without correction for this potential skewing, it is impossible to draw accurate conclusions as to price differentials.

- In the FTC comparison of costs charged by PBM-owned mail-order vs. not-owned retail pharmacy, the FTC adjusted out the effect of drug mix, the very effect that Congress had intended the FTC to analyze. By comparing cost on a weighted average drug-by-drug basis rather than on a therapeutic class basis, the FTC has ignored the potential that PBM-owned mail order may dispense a higher proportion of higher cost drugs than does retail pharmacy, where PBMs exercise less discretionary control.

- The FTC claims that competition in the industry affords plan sponsors with sufficient tools to safeguard their interests and that pharmaceutical payments retained by PBMs may get passed onto plan sponsors through discounts in other

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\(^1\) See Appendix I for background on PharmaBio Strategy Consulting and the credentials of the authors.
areas due to competition between PBMs for plan sponsor business. However, the FTC presents no specific evidence to back up this claim beyond anecdotal evidence from selected PBM plan sponsor contracts. By direct contrast, commercial industry experience suggests that commercial customers have difficulty protecting their interests. The PBM industry is highly consolidated, collects high profit margins and, as we will show, captures an unusually high rate of return on invested capital. None of this suggests that competition for plan sponsor business bids away PBM profits retained from pharmaceutical manufacturer payments.

• In assessing differences in Generic Dispensing Rates (GDRs) by therapeutic class between mail order and retail, the FTC found that mail-order GDRs were 5% lower than those at retail. This result is roughly consistent with the prior findings of the Self Dealing Study. This is evidence of PBMs using their discretionary influence at mail order to encourage brand rather than generic drugs. However, rather than investigate further, the FTC discards the result and asserts the unlikely claim (with no additional evidence) that this could be the result of differences in benefit design within mail and retail.

• The FTC claims that because a comparison of Generic Substitution Rates (GSRs) shows little difference between mail and retail that this is evidence that pharmaceutical manufacturer payments do not have an effect on PBM drug mix in their vertically integrated mail-order pharmacies. But GSRs measure the ratio of generic drugs to multi-source brand drugs (MSBs) on which PBMs receive no pharmaceutical manufacturer payments not the ratio of generics to single-source brand drugs (SSBs) for which PBMs receive and retain significant manufacturer payments.

• The FTC claims that it is more profitable for PBMs to dispense generic drugs at mail-order than to dispense single-source brand drugs even when the effect of pharmaceutical manufacturer payments are included. However in its comparison of profitability the FTC considers brand drugs on average thus applying pharmaceutical payments to all brand drugs not to the preferred SSB drugs on which they receive the bulk of their pharmaceutical payments. By appropriately adjusting the FTC data to account for unequal distribution of rebates, we demonstrate that preferred single-source brand drugs are on average more profitable than generic drugs. In any case, the misalignment of incentives is most significant on a transaction-by-transaction basis rather than on an average basis. We identify many representative transactions which demonstrate clear misalignment of incentives.

• The FTC claims PBM’s use of brand-to-brand therapeutic interchange is limited. They have little data to back up this assertion. Where they present data they have not considered the impact that an individual therapeutic interchange of one prescription for a chronic condition will have on future refills and renewals. We estimate that therapeutic interchange programs have an effect on approximately
10% of brand drugs dispensed at PBM-owned mail-order. It is widely understood and acknowledged by the FTC that therapeutic interchange occurs much less frequently at not-owned retail pharmacies. Therapeutic Interchange is a prevalent practice at PBM-owned mail-order pharmacies and a fundamental component of the PBM business model.

- In its assessment of therapeutic interchange (TI), the FTC identifies numerous approved TI programs (about 34% of total in the 10 categories examined) whose effect would be to increase plan sponsor costs. Rather than further investigating these instances, the reasons they occur, and their potential impact on plan sponsor costs, the FTC sets aside this evidence because the majority of TI programs do appear to benefit the plan sponsors. At issue, however, is not what PBMs do when their incentives are aligned with those of plan sponsors, but rather what occurs when these incentives are not aligned. It is clear that PBMs deploy TI programs when it increases their profits despite the impact to plan sponsor costs.

- The FTC also identifies numerous instances of approved TI programs where multi-source brand drugs are interchanged to more expensive single-source brand drugs rather than to less costly generic alternatives. Rather than further investigating these instances and their potential impact on GDRs and plan sponsor costs, the FTC labels these occurrences as “rare”. However, as best we can determine from the data presented, these programs appear to represent about 10% of TI activity. The fact that these programs exist at all is evidence of PBM activity to increase profits to the detriment of plan sponsor costs and is consistent with the FTC’s own findings of depressed GDRs at PBM-owned mail-order pharmacy.

- While the FTC uncovers but largely dismisses evidence of PBM activity to the detriment of plan sponsor costs, the FTC does not consider the extent to which PBMs forgo activity that will decrease the PBMs profit but would nonetheless lower the drug costs of plan sponsor customers. For example, one explanation on the lower GDR at mail order compared to retail is that PBMs may favor therapeutic interchange from brand drugs to other preferred brand drugs rather than to alternative generic drugs within the therapeutic class.

- Finally, the FTC does not assess the extent to which the assumption of risk might alleviate the misalignment of incentives and fails to provide any assessment of the adequacy of risk sharing in the context of Medicare Part D legislation. We will show that because prescription drug plans (PDPs) in Medicare retain 100% of pharmaceutical payments, the incentives are particularly misaligned. The level of risk assumed by PDPs in Medicare Part D does not alleviate the problem, particularly when enrollees are in the “donut hole” or reach the level of catastrophic coverage. Because tax payers bear the majority of drug costs in catastrophic coverage, any increase in SSB utilization or shift in drug mix resulting from this misalignment of incentives will have the primary effect of increasing costs to the government and tax payers.
The authors of this assessment do not have access to the internal PBM information aggregated by the FTC. The FTC has not yet fully responded to our requests for relevant data. Without the data requested, we cannot yet provide a complete study as intended by Congress which fully and properly investigates PBM conflicts of interest and their effects on drug costs. However, to the extent possible, we attempt to correct errors in The Study and provide conclusions consistent with the actual evidence in an effort to better inform Congress and policymakers in developing relevant legislation and policy.

The FTC has indicated that they may provide some of the information requested, but it is unclear what they will provide or when it will be provided. Based on any additional information we receive, there may be an addendum provided to this assessment.

**The Congressional Request**

Congress requested that the FTC obtain and analyze internal information from PBMs to address the issues raised in the Self Dealing Study. Specifically, Congress requested in the MMA that the FTC undertake a “Conflict of Interest Study” to examine “differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers,” including:

1) An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers compared to mail-order pharmacies not owned by pharmaceutical benefit managers and community pharmacies.

2) Whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.3

The Conference Report on the legislation further specified that the FTC consider the following:

1) whether mail-order pharmacies that are owned by PBMs (or entities that own PBMs) dispense fewer generic drugs compared to single-source drugs within the same therapeutic class than mail order pharmacies not owned by PBMs.

2) whether mail-order pharmacies that are owned by PBMs (or entities that own PBMs) switch patients from lower priced drugs to higher priced drugs (in the absence of clinical indication) more frequently than mail order pharmacies that are not owned by PBMs.

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2 See Appendix II for relevant correspondence.
3) whether mail-order pharmacies owned by PBMs (or entities that own PBMs) sell a higher proportion of repackaged drugs than mail order pharmacies that are not owned by PBMs

4) whether mail-order pharmacies owned by PBMs (or entities owned by PBMs) sell repackaged drugs at prices above the manufacturers wholesale price.

5) other factors deemed relevant by the FTC.\(^4\)

Finally the conference report specified that, “[i]n conducting this Study, the FTC shall consider whether competition or drug pricing behavior by PBMs would be affected if PBMs were to bear financial risk for drug spending.”\(^5\) The FTC reiterated these directives into a set of six questions for which it provided responses.

**Response to Questions in the MMA and Conference Report**

**Question 1: Assessment of Price Differences in Payment Amounts Incurred by Plans and their Members for Prescription Drugs Dispensed by Mail Order Pharmacies Owned by PBMs Compared to Non-Owned Mail-Order Pharmacies and Retail Pharmacies.**

The specific concern raised in the Self Dealing Study and elsewhere is that PBMs have incentives to dispense higher cost drugs and so the mix of drugs at PBM owned mail order is skewed to drugs with higher costs.

The FTC suggests that PBMs do not favor higher priced alternatives, but the approach the FTC employs is flawed. The FTC failed in its comparison of costs across different channels because it failed to adjust for the potential skewing associated with the representation of each PBM in the sample used to calculate the average for each channel. In addition, in the comparison of PBM-owned mail order costs to non-owned retail pharmacy costs, the FTC adjusted out the effect of drug mix, the very effect that Congress had intended that it analyze.

The only way to get an actual comparison of costs as intended by Congress would be to redo the FTC analysis, which cannot be done without access to the underlying confidential data held by the FTC. This having been said, given what we know, it would be reasonable to assume that the cost difference between mail order and retail pharmacy is minimal once drug mix (by therapeutic class) is taken into account. This can be estimated by calculating the weighted average cost of dispensing at retail under a few different assumptions with respect to drug mix:

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\(^5\) Id at 520
Table E-1: Comparison of Average Cost of Drugs Mail-Order vs. Retail

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Avg. Prices Mail</th>
<th>Mail Mix of Types(^6)</th>
<th>Avg. Prices Retail</th>
<th>Mix of Types(^6)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Large PBMs Mail(^*)</td>
</tr>
<tr>
<td>Generic</td>
<td>$45.00</td>
<td>39.0%</td>
<td>$48.06</td>
<td>39.0%</td>
</tr>
<tr>
<td>MSB</td>
<td>$98.63</td>
<td>2.8%</td>
<td>$114.02</td>
<td>2.8%</td>
</tr>
<tr>
<td>SSB</td>
<td>$195.00</td>
<td>58.2%</td>
<td>$217.04</td>
<td>58.2%</td>
</tr>
<tr>
<td>Avg. Cost per Rx</td>
<td>$133.80</td>
<td></td>
<td>$148.25</td>
<td>$139.23</td>
</tr>
</tbody>
</table>

\(^*\) Large PBMs dispensing through owned PBM-owned mail-order

\(^**\) Large PBMs dispensing through not-owned retail

\(^***\) Retail-owned PBMs dispensing through owned retail

If anything, dispensing at retail may result in a lower total cost when mix of products is taken into account. At the same time, retail pharmacy provides benefits that cannot be delivered through mail order, including face-to-face counseling and medication management, which are especially important for elderly patients taking multiple drugs.

We expect that PBMs cross-subsidize mail-order prices today in order to attract volume to the channel where they are able to maximize the rebates they receive and retain. Rebate retention by PBMs causes the conflict of interest between PBMs and plan sponsors. In the absence of rebate retention there would be less opportunity for cross-subsidization of mail prices. Therefore, we would expect mail prices (to the extent that they are lower than retail prices today) to gravitate towards retail prices. At the same time, since PBMs would no longer have such incentive to dispense higher cost drugs, the difference in drug mix (on a therapeutic class level) would also go away.

**Question 2: Whether Plans are Acting in a Manner that Maximizes Competition and Results in Lower Prescription Drug Prices for Enrollees**

PBMs suffer from a conflict of interest created, to a large extent, by retention of pharmaceutical manufacturer payments. An analysis of PBM margins shows that retention of these rebates is the primary source of margin in the current predominant PBM business model, accounting for about 64% of gross profits and an even higher proportion of net profits.

The FTC argues that plan sponsors have the ability to protect themselves from PBMs through contractual remedies and that competition for plan sponsor business should protect plan sponsors from potential abuse. However commercial plans have had to resort

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\(^6\) Generic percentages equal to GDRs (*The Study*, p. 77). MSB percentages equal to (GDR/GSR) – GDR (*The Study*, pp. 66,68). SSB percentage equal to 1-Generic-MSB.
to legal and legislative remedies and have not been protected by competitive forces in the industry.

The FTC argues that even though PBMs do not explicitly pass on all of pharmaceutical manufacturer payments to their plan sponsor clients they might ultimately pass on these benefits through lower fees charged elsewhere to sponsors. However, analysis of PBM profitability does not suggest that PBMs deliver these savings to customers in other areas. In adjusting PBMs’ accounting methodology from a gross basis to a net basis (i.e., not including in Cost of Goods Sold the cost of drugs for which PBMs never takes title) we see that PBMs enjoy excellent profit margins—higher than all other industry participants:

Chart E-1: PBM 2003 Operating Margin, Gross Basis vs. Net Basis Accounting

This argues strongly against the FTC hypothesis that competition among PBMs forces them to deliver improved terms to their plan sponsor customers.

The FTC case for fierce competition unravels further if the level of consolidation in the PBM industry is considered. The industry is highly consolidated and becoming more so over time. There is no evidence that other PBM entities or business models are able to make headway against these dominant players.

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7 Calculated from company annual reports (see Appendix IV for detailed calculations) including: PBMs: Medco Health Solutions, Caremark Rx, AdvancePCS, and Express Scripts; Wholesale & Distribution: Cardinal Health, McKesson Corporation, and AmeriSourceBergen Corp.; Large Retail Chain Pharmacy: Rite Aid Corporation, CVS Corporation, Walgreen Company, and Longs Drug Stores Corp.; Health Plans: Aetna Inc. CIGNA Corporation, PacifiCare Health Systems, WellPoint Inc. Humana Inc., UnitedHealth Group Inc., and WellChoice Inc.
An examination of the three large PBMs’ (four in 2003) return on investment further underlines the point that PBMs make unusually high margins for relatively little capital investment. These returns suggest an industry that wields consolidated power to collect upstream discounts without the corresponding competitive pressure to pass on those discounts to their downstream customers (health plans, employers, their covered enrollees and the government).

Chart E-2: Average Return on Invested Capital (ROIC) for Largest Companies\(^8\) in Pharmaceutical Benefits & Distribution Value Chain, 2003 (see Appendix V for calculation)

Mail order integration may provide for lower prices on a drug-by-drug basis. But it also increases the misalignment of incentives between PBMs and their plan sponsor clients and increases the PBMs’ ability to influence the mix of drugs dispensed to maximize its own profits, potentially to the detriment of plan sponsor clients. Industry performance simply is not consistent with the FTC assertion that PBMs compete fiercely to earn client contracts and suggests that the profits that PBMs receive and retain from manufacturer payments are not ultimately passed on to plan sponsors through competition.

**Question 3: Whether Mail-Order Pharmacies that Are Owned by PBMs (or Entities that Own PBMs) Dispense Fewer Generic Drugs Compared to Single-Source Drugs within the Same Therapeutic Class than Mail-Order Pharmacies that are Not Owned by PBMs**

\(^8\) PBMs: Medco Health Solutions, Caremark Rx, AdvancePCS, and Express Scripts; Wholesale & Distribution: Cardinal Health, McKesson Corporation, and AmeriSourceBergen Corp.; Large Retail Chain Pharmacy: Rite Aid Corporation, CVS Corporation, Walgreen Company, and Longs Drug Stores Corp.; Health Plans: Aetna Inc, CIGNA Corporation, PacifiCare Health Systems, WellPoint Inc, Humana Inc., UnitedHealth Group Inc., and WellChoice Inc.
The FTC was correct in examining this question both in terms of performance and motivation. Unfortunately, the FTC ignored its own evidence on both issues and took positions that are not supported by the data it has collected, analyzed, and presented. Rather than use its unique access to PBM data to clarify the situation, the FTC has failed to structure and present the data in such a way that the reader and Congress can derive reasonable answers to the questions posed. Fortunately, the FTC provides some information to piece together a proper analysis.

The potential problem is not the incentives around the substitution of generic drugs for multi-source brand drugs since PBMs receive very little rebates from multi-source brand drugs. The problem is that, within a therapeutic class, pharmaceutical payments to a PBM for single-source brand drugs create differences in spreads whereby the PBM has greater incentive to dispense a preferred single-source brand drug than it does to dispense the alternative generic drug within the therapeutic class. The only way to test for performance on this basis is to use Generic Dispensing Rates.

A comparison of Generic Dispensing Rates clearly shows that PBM mail order pharmacies dispense significantly fewer generic drugs compared to single-source brand drugs than independent Retail (39% versus 44%). The FTC adjusts for differences in therapeutic class mix when developing these numbers. The FTC goes on to suggest that perhaps differences in plan structure could skew the numbers; however, the FTC provides no evidence of systematic skewing and indeed systematic skewing would be unlikely.

9 *The Study*, p. 63
The analysis of GSRs that the FTC subsequently espouses is irrelevant since it compares generic drug dispensing to dispensing of multi-source brand drugs on which PBMs receive little pharmaceutical manufacturer payments and it specifically ignores single-source brand drugs for which PBMs receive the vast majority of pharmaceutical manufacturer payments.

GSRs can offer only a limited comparison because they focus only on whether a generic drug is dispensed in place of its specific MSB. If a PBM chose to dispense a competing SSB in lieu of a MSB or its generic equivalent, this would not show up in the Generic Substitution Rate. Any conclusions based on the analysis are irrelevant since the analysis explicitly ignores the fundamental issue the FTC was asked to investigate. If there were any real potential issues in interpreting the GDR data then the FTC should have adjusted for any systematic skewing related to plan design not defaulted to a measure that has no meaning for the issue under question.

The FTC’s assessment of PBM spreads at mail-order is erroneous in that it looks at spreads on average rather than assessing specific transactions. Pharmaceutical manufacturers pay allowances for specific drugs in order to create incentives for the PBM to dispense that specific drug. By using averages rather than specific transactions, the FTC’s analysis applies these pharmaceutical payments to all brand drugs rather than the specific drugs for which the pharmaceutical manufacturer pays. By looking at example transactions we can identify multiple transactions where the PBM has greater incentive to dispense a single-source brand drug rather than a generic drug:

<table>
<thead>
<tr>
<th>Definition of GSR and GDR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GDR</strong> = ( \frac{\text{Generics} + \text{SSBs} + \text{MSBs}}{\text{within a therapeutic class}} )</td>
</tr>
<tr>
<td><strong>GSR</strong> = ( \frac{\text{Generics} + \text{MSBs}}{\text{within a set of bioequivalent drugs}} )</td>
</tr>
</tbody>
</table>
Indeed, when properly analyzed, it is apparent PBMs have a greater incentive to dispense single-source brand drugs on which they receive the bulk of their pharmaceutical payments than they do to dispense generics.

The only possible conclusion from the data presented is that PBMs are biased in their business practices to dispense the single-source brand drugs on which they receive the majority of their pharmaceutical company payments to the exclusion of alternative generic drugs within the same therapeutic class. This is supported by the performance data and is confirmed by our examination of the incentives PBMs face in light of the profitability of these two types of transactions on a prescription-by-prescription basis. Clearly these business practices are to the detriment of plan sponsors. The situation will become exacerbated in the Medicare Part D environment since the alignment of incentives is strongly related to the explicit rebate retention rate which will be 100% under Medicare Part D.

**Question 4: Whether Mail-Order Pharmacies that Are Owned by PBMs (or Entities that Own PBMs) Switch Patients from Lower Priced Drugs to Higher Priced Drugs (in the Absence of a Clinical Indication) More Frequently than Mail-Order Pharmacies that Are not Owned by PBMs**

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*The Study*, pp 63 & 66

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The FTC does not address this question in *The Study*. Instead the FTC suggests that it is not necessary to address the question since PBM’s use of brand-to-brand therapeutic interchange (TI) is limited. However, in their assessment of TI, the FTC failed to take into account refills and renewals. Although TI may appear limited when considering the number of individual prescriptions which are physically interchanged versus the total number of prescriptions dispensed, this is not the case when you take into account the effect of TI on future refills and renewals of chronic drugs. We estimate that when refills and renewals are taken into account TI would affect about 10% of brand prescriptions dispensed at mail order. Ten percent of total brand prescriptions dispensed through vertically integrated PBM mail is a high, rather than negligible, number that would have material impact on plan sponsor expenditures if the switch does not favor their total costs.

With respect to winners and losers from TI, it is difficult to draw conclusions from the data presented by the FTC because it addresses potential activity and not actual activity. However, in examining therapeutic interchange, the FTC identified that about 34% of approved TI programs would result in higher drug cost to the plan sponsor.

Table E-2: Share of Possible Therapeutic Interchanges that result in Higher Cost to Plans and Members in Ten Therapeutic Categories (Owned Mail, 2003)

<table>
<thead>
<tr>
<th>Company</th>
<th>% TI Beneficial*</th>
<th>% TI Detrimental**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large PBM A</td>
<td>49.4%</td>
<td>50.6%</td>
</tr>
<tr>
<td>Large PBM B</td>
<td>67.6%</td>
<td>32.4%</td>
</tr>
<tr>
<td>Large PBM C</td>
<td>71.4%</td>
<td>28.6%</td>
</tr>
<tr>
<td>Large PBM D</td>
<td>87.3%</td>
<td>12.7%</td>
</tr>
<tr>
<td>Large PBM E</td>
<td>52.2%</td>
<td>47.8%</td>
</tr>
<tr>
<td>AVERAGE</td>
<td>65.6%</td>
<td>34.4%</td>
</tr>
</tbody>
</table>

* % of TI programs resulting in a lower cost to plan sponsors (*The Study*, p. 87)
** % of TI programs resulting in higher cost to plan sponsors (1 minus % TI beneficial)

Beyond what the FTC did consider, it is also important to recognize that in assessing potential activity the FTC does not address potential avoidance of interchanges that would have been beneficial to the plan sponsor but not the PBM. The FTC analysis also indicated that TI was about ten times more prevalent at mail-order than at retail.

Across the ten therapeutic categories examined the FTC identified numerous cases of approved therapeutic interchange programs which switch prescriptions from multi-source brand drugs to single-source brand drugs rather than to the alternative cheaper generic drug available.
Table E-3: Comparison of # of Brand-to-brand TI programs to # of brand-to-brand TI programs when a generic equivalent was available (2003)

<table>
<thead>
<tr>
<th>Company</th>
<th># of Pref. Drugs*</th>
<th># of MSBs**</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large PBM A</td>
<td>8</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Large PBM B</td>
<td>28</td>
<td>5</td>
<td>18%</td>
</tr>
<tr>
<td>Large PBM C</td>
<td>28</td>
<td>5</td>
<td>18%</td>
</tr>
<tr>
<td>Large PBM D</td>
<td>12</td>
<td>1</td>
<td>8%</td>
</tr>
<tr>
<td>Large PBM E</td>
<td>60</td>
<td>3</td>
<td>5%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>161</strong></td>
<td><strong>20</strong></td>
<td><strong>10%</strong></td>
</tr>
</tbody>
</table>

* # of preferred drugs involved in active TI program (*The Study*, Appendix G, p. G-7)
** # of brand drugs with generic equivalent involved in active TI program (*The Study*, p. 88)

However, because the FTC methodology is not entirely clear and not necessarily consistent from analysis to analysis, it is difficult to draw conclusions about the prevalence of these programs or their potential impact on GDRs and/or drug costs. However, the existence of these programs is consistent with PBMs’ greater financial incentives to dispense preferred single-source brand drugs than generic drugs and is consistent with the lower GDRs observed at PBM-owned mail-order pharmacy versus not-owned retail pharmacy.

What one can conclude from the data is that therapeutic interchange is a prevalent practice at PBM mail-order pharmacy and a fundamental component of the PBM business model. One can also conclude that approximately one third of potential therapeutic interchange activity by PBMs may increase plan sponsor costs not decrease them. Finally, the FTC has established that most PBMs do, in fact, have programs in place to switch brand drugs to other brand drugs even after a generic equivalent for that drug is available. Since TI is much more prevalent at PBM-owned mail than at retail, this is consistent with the lower Generic Dispensing Rates at PBM-owned mail versus retail as discussed in Question 3 previously.

**Question 5a:** Whether Mail-Order Pharmacies Owned by PBMs (or Entities that Own PBMs) Sell a Higher Proportion of Repackaged Drugs than Mail-Order Pharmacies that are not Owned by PBMs. 5b: Whether Mail-Order Pharmacies Owned by PBMs (or Entities Owned by PBMs) Sell Repackaged Drugs at Prices Above Manufacturer’s Average Wholesale Price.

The FTC establishes that there is very little repackaging among the top ten selling drugs. It is unclear whether these are the drugs for which repackaging would logically occur. There may be other drugs for which repackaging are more prevalent. This is not addressed by *The Study* at all.
Question 6: Whether Competition or Drug Pricing Behavior by PBMs Would be Affected if PBMs Were to Bear Financial Risk for Drug Spending

Prior to Congress’ mandate to the FTC to examine risk sharing, economic studies had already suggested that a misalignment of interests existed between PBMs and payers and that risk sharing could decrease the degree of misalignment. Congress then specifically directed the FTC to study this issue. Despite these imperatives, the FTC failed to examine the issue in detail or respond to the prevailing view.

A thoughtful review of risk would have found that the government and seniors, as the ultimate payers of drug benefits under Medicare Part D bear risk of increased drug spend from price inflation, rising utilization, and shifts in product mix. With Medicare having largely adopted the PBM framework for administration of drug benefits, the standard misalignment of incentives exists in this relationship as was demonstrated in prior parts of this document. The misalignment is in fact worse under Medicare, as rebate retention is in effect 100%.

Some degree of risk for drug spend is shared under the basic benefit design in Medicare. A high level of risk sharing is present in the initial “pre-donut” spending increment, with PBMs responsible for 75% of total gross cost. But as spending grows through the “donut hole” and catastrophic levels of benefits, risk sharing drops (to 0% and 15% respectively) and is insufficient to align incentives in light of the PBM’s 100% retention of rebates. Beyond the average transaction, incentives only grow for PBMs to use their discretionary influence in a manner that suits them and harms seniors and the US Treasury.

Chart E-5: Net Economic Impact of Shift in Drug Mix from Generic to Preferred SSB under Catastrophic Coverage

In the mail channel, where PBMs are free to exercise their discretionary influence, PBMs are motivated to encourage higher utilization and a shift in product mix towards the expensive SSBs for which they receive rebates. The economic burden of this is borne by seniors and the Treasury. For seniors, however, at 5% or less, cost sharing is so minimal as to be of questionable influence on behavior. The result being that the payer, the U.S. Treasury and by default tax payers, hold responsibility for the cost differential. In the case of the average prescription, this equates to a benefit of $10.81 for the PBM ($29.44-$18.60), a $7.34 cost to the senior (5%*($52.41-$199.24)), and a liability of $117.46 to the government (80%*($52.41-$199.24)).
In short, rebate retention misaligns incentives and the risk sharing provisions of Medicare are insufficient to overcome this misalignment. Any move that tends to increase utilization of mail order increases the discretionary influence of PBMs, placing seniors and the government at risk of greater utilization and an economically unfavorable mix of pharmaceuticals. If PBMs pursue their interest in the mail channel it will have a substantial impact on the total national cost of drug benefits and the burden on the taxpayer.

**Overall Conclusions**

In summary we believe the FTC failed to properly examine the issues as requested by Congress. The FTC was ordered to use its privileged access to internal PBM information to provide a balanced assessment of conflicts of interests inherent in the traditional PBM business model, their effects on plan sponsor drug costs and the potential implications for Congressional legislation and/or government policies in implementing Medicare Part D. Instead, the FTC, either deliberately or through lack of understanding, has chosen to claim that the clear misalignment of incentives does not exist and have ignored the evidence of their effect. In light of the data presented by the FTC and further analyses in this document, it is apparent that PBMs promise savings on drug pricing while pursuing their own interests in drug mix and total utilization. Where these interests diverge at times from those of their clients, PBMs naturally choose to increase their own profits and are not subject to the corrective mechanism of fierce competition for plan sponsor business. Instead, PBMs operate in a relatively consolidated industry with significant vertical integration through a mail order channel that allows them to pursue their discretionary interests, while concealing information on their business practices.

We demonstrate in this assessment that the retention of pharmaceutical rebates by PBMs creates a misalignment between PBM profit incentives and plan sponsor interests in reducing drug costs. It is in PBM-owned mail-order pharmacies, where PBMs wield the greatest discretionary influence, that these issues have been and continue to be of greatest concern. PBMs have a fiduciary responsibility to increase profits to their shareholders and, when given the opportunity, will do so to the detriment of plan sponsor interests. In the Medicare Part D Benefit the incentives are particularly misaligned such that any move that increases utilization of mail within Medicare will potentially result in a substantial increase in the national cost of drugs and the burden on the taxpayer.