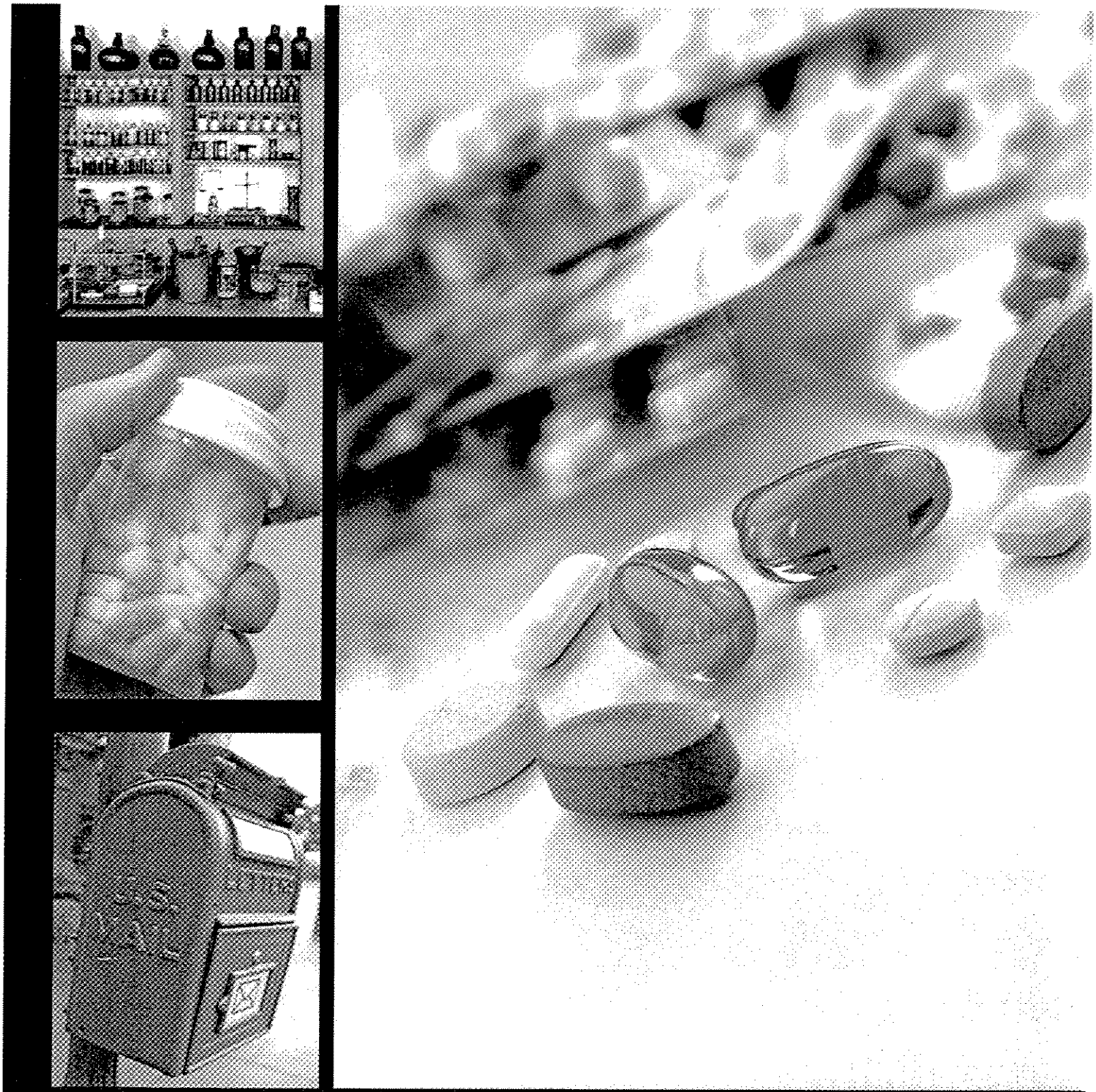

Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies

Federal Trade Commission
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EXECUTIVE SUMMARY

For millions of Americans, breakthroughs in medical research have allowed prescription drugs to save lives, reduce suffering, and enhance life. But these breakthroughs come with a price: increased usage and rising prices have pushed prescription drug expenditures to $179.2 billion in 2003, or 10.7% of national health expenditures. Prescription drugs are the most rapidly increasing component of U.S. health care costs.

Against this backdrop, Congress in 2003 added a new benefit to Medicare that provides senior citizens and other Medicare beneficiaries with a voluntary prescription drug benefit beginning in 2006. The new benefit relies heavily on private sector entities and competition to ensure that Medicare enrollees have a choice of prescription drug plans.

Private sector entities that offer medical insurance ("plan sponsors"), such as employers, labor unions, and managed care companies, also offer prescription drug insurance coverage. Plan sponsors often hire pharmacy benefit managers (PBMs) to manage these insurance benefits. This Study examines one facet of private sector competition – how PBMs' use of mail-order pharmacies that they own affects their clients' prescription drug costs.

PBMs engage in many activities to manage their clients' prescription drug insurance coverage. PBMs assemble networks of retail pharmacies so that a plan sponsor's members can fill prescriptions easily and in multiple locations by just paying a copayment amount. PBMs consult with plan sponsors to decide for which drugs a plan sponsor will provide insurance coverage to treat each medical condition (*e.g.*, hypertension, high cholesterol, etc.). The PBM manages this list of preferred drug products (the "formulary") for each of its plan sponsor clients. Consumers with insurance coverage are then provided incentives, such as low copayments, to use formulary drugs. Because formulary listing will affect a drug's sales, pharmaceutical manufacturers compete to ensure that their products are included on these formularies. They do so by paying PBMs "formulary payments" to obtain formulary status, and/or "market-share payments" to encourage PBMs to dispense their drugs. These payments are based on the quantity of drugs dispensed under the plans administered by the PBM.

PBMs use mail-order pharmacies to manage prescription drug costs. Many plan sponsors have encouraged patients with chronic conditions who require repeated refills to seek the discounts that 90-day prescriptions and high-volume mail-order pharmacies can offer. Many PBMs own their own mail-order pharmacies. These PBMs have suggested that they have greater control over the drugs dispensed through mail-order pharmacies and, therefore, can provide greater formulary compliance.

And this is where the controversy lies. If a plan sponsor's agreement with a PBM does not properly align the plan's interests with the PBM's incentives, there could be a conflict of interest. Although PBMs are tasked to manage and lower the costs of pharmacy benefits, in theory they could have incentives to increase costs and generate additional profits through their mail-order pharmacies. Congress requested that the Federal Trade Commission (FTC or Commission) determine whether a PBM that owns a mail-order pharmacy acts in a manner that

maximizes competition and results in lower prescription drug prices for its plan sponsor members.

At the request of Congress, the Commission collected aggregate data on prices, generic substitution and dispensing rates, savings due to therapeutic drug switches ("therapeutic interchange"), and repackaging practices. These data provide strong evidence that in 2002 and 2003, PBMs' ownership of mail-order pharmacies generally did not disadvantage plan sponsors. Because these data are aggregated, they do not answer whether each plan sponsor has negotiated the best deal possible or whether each PBM has fulfilled its contractual obligations due to each of its plan sponsor clients. The data also do not indicate whether, in individual instances, a PBM might have favored its mail-order pharmacy in ways contrary to a plan sponsor's interests. Nonetheless, these data suggest that competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests.

Congressional Request

Congress requested in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that the Federal Trade Commission 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 (Question 1).
>
> (2) Whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees (Question 2).[1]

As explained in the Conference Report for the MMA, Congress requested that the Commission determine whether the use of mail-order pharmacies owned by PBMs that administer the Medicare prescription drug benefit would adversely affect Medicare spending, as compared to the use of mail-order pharmacies not owned by a PBM. Accordingly, Congress asked the FTC to consider the following business practices:

> (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 that are not owned by PBMs (Question 3);
>
> (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

[1] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. I, § 110, 117 Stat. 2066, 2174 (2003) (codified at 42 U.S.C. § 1395w-101 (Historical and Statutory Note)).

absence of a clinical indication) more frequently than mail-order pharmacies that are not owned by PBMs (Question 4);

(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 (Question 5a);

(4) whether mail-order pharmacies owned by PBMs (or entities owned by PBMs) sell repackaged drugs at prices above the manufacturer's average wholesale price (Question 5b); and

(5) other factors deemed relevant by the FTC.[2]

Finally, Congress requested that the FTC "consider whether competition or drug pricing behavior by PBMs would be affected if PBMs were to bear financial risk for drug spending." (Question 6)[3]

The Commission's Approach to the Conflict of Interest Study

The Commission used a two-stage process to collect the company-specific information and data necessary to complete the study.[4] During the first stage, the Commission identified four groups of participants and issued Special Orders that subpoenaed data and documents. The Commission included PBMs that owned mail-order pharmacies and those that did not, so that it could assess the differences in prices for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to both mail-order pharmacies not owned by PBMs and community pharmacies. The Commission also obtained data from four large stand-alone retail pharmacies to assess the price differences for customers with insurance and those that paid cash for their prescriptions. The four groups of study participants included the following:

- *Large PBMs*: Medco Health Solutions, Inc., Express Scripts, Inc., and Caremark Rx, Inc.[5]

- *Small and Insurer-Owned PBMs*: Aetna Inc., Cigna Corporation, National Medical Health Card Systems, Inc., Prime Therapeutics, Inc., Restat LLC, and Wellpoint Health Networks, Inc.

- *Retailer-Owned PBMs*: Eckerd Health Systems (formerly a subsidiary of Eckerd Corp.), PharmaCare Management Services (a subsidiary of CVS Corp.), RxAmerica (a

[2] H.R. CONF. REP. NO. 108-391 at 519-520 (2003), *reprinted in* 2003 U.S.C.C.A.N. 1808, 1891.

[3] *Id.* at 520.

[4] See FTC, "Pharmacy Benefit Manager Conflict of Interest Study, Public Notice," (Mar. 26, 2004), *at* http://www.ftc.gov/os/2004/03/040326pnpbm.pdf.

[5] Caremark completed its acquisition of Advance PCS in 2004. For purposes of this report, the data from Caremark and Advance PCS were reported separately.

subsidiary of Longs Drug Stores Corp.), Walgreens Health Initiative (a subsidiary of Walgreen Co.).[6]

- *Stand-Alone Retail Pharmacies*: CVS Corp., Longs Drug Stores Corporation, Rite Aid Corporation, Wal-Mart Stores, Inc., Walgreen Co., and Argus Health Systems, Inc.[7]

The data and documents subpoenaed included high-level business documents and aggregate data for three business practices (generic substitution and dispensing, therapeutic interchange, and repackaging practices). The Commission obtained agreements between plan sponsors and PBMs to examine how PBMs price their services to their clients. In addition, the Commission obtained agreements between pharmaceutical manufacturers and PBMs to examine how pharmaceutical manufacturers compete in this area.

These data permitted the Commission to compare differences in business practices based on three factors: (1) PBM category (*i.e.*, large PBM, small or insurer-owned PBM, retailer-owned PBM); (2) dispensing channel (*i.e.*, mail vs. retail); and (3) ownership of the dispensing channel (*i.e.*, owned mail, not-owned mail, owned retail, not-owned retail).

In the second round of information collection, the Commission obtained individual claims data for December 2003 from a subset of the companies listed above. These companies included all large independent PBMs, one small or insurer-owned PBM, two retailer-owned PBMs, and two stand-alone retailers. These data permitted the Commission to examine PBMs' business practices in more depth.

Background on the PBM Business

As noted earlier, many health plan sponsors offer their members prescription drug insurance and hire PBMs to manage these pharmacy benefits on their behalf. As part of the management of these benefits, PBMs assemble networks of retail and mail-order pharmacies so that the plan sponsor's members can fill prescriptions easily and in multiple locations.

When a consumer fills a prescription at a local pharmacy, the pharmacist usually asks whether the consumer has insurance to cover the prescription's cost. If there is coverage, the consumer provides the insurance card to the pharmacist. While the pharmacist fills the prescription, sophisticated computer interactions between the pharmacy and the PBM ensure that the prescription is filled according to the insurance coverage provided by the plan sponsor. The consumer usually is unaware of these processing interactions, and the consumer's only additional responsibility is to pick up the filled prescription and pay the retail pharmacy the copayment that is due.

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[6] In 2004, CVS completed its acquisition of Eckerd. For purposes of this report, the data from PharmaCare and Eckerd Health Systems (EHS) were reported separately.

[7] Argus Health Systems processes third-party claims for PBMs. Unlike the stand-alone retailers in this group, Argus did not provide data for cash-paying customers.

Other services a PBM may perform as the pharmacist fills the prescription include, among other things, automatic checks on whether: (a) there will be interactions with other pharmaceutical products the consumer may be taking, (b) a generic version of the prescribed drug is available, and (c) enough days have passed before a prescription can be refilled. These claims adjudication and other more sophisticated services are often referred to as the management and design of pharmacy benefits that PBMs provide to their clients.

A PBM's clients include entities that provide prescription drug insurance to their enrollees or members. These entities generally include, for example, Health Maintenance Organizations (HMOs), self-insured employers, labor union plans, and other entities that have "carved out" the administration of pharmacy benefits from other health or medical benefits. Many large insurers, however, offer "in-house" PBM services to their plan sponsors. Throughout this report, a PBM's clients are referred to as "plan sponsors" or "plans" and a plan's enrollees are referred to as "members."

Approximately 40 to 50 PBMs operate in the United States today.[8] The relative size and ranking of PBMs vary according to the measure used, *i.e.*, annual prescription expenditures, prescriptions per year, or the number of enrollees covered by a plan (*i.e.*, "covered lives").[9] Approximately 12 PBMs have more than five million covered lives.[10] The market share figures, as well as the documents of almost all of the study participants, described an industry in which the three large PBMs (all of which are study participants) are the major players, and several insurer-owned PBMs and retailer-owned PBMs have a substantial market presence.

PBM Ownership of Mail-Order Pharmacies

A PBM that owns a pharmacy (whether retail or mail) is considered vertically integrated. A vertically integrated PBM may have a greater ability to influence which drugs are dispensed under the plans it administers than a non-vertically integrated PBM. If plan sponsor contracts with PBMs do not properly align the incentives of PBMs with those of the plans, this lack of alignment could create a conflict of interest. Potential conflicts of interest should be rare, however, if competition among PBMs provides plan sponsors with alternative choices.

The economic literature on vertical integration suggests that it can lower costs. First, integration can reduce transaction costs. In addition, it also avoids double markups (or what economists call "double marginalization") in which two independent, vertically related firms each have some ability to charge above marginal cost. A PBM that owns a mail-order pharmacy may have an incentive to charge a lower overall price for the product than two independent entities setting prices optimally.

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[8] Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, 2004 HEALTH AFFAIRS (Web Exclusive), W4-504, 506, *at* http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w4.504.

[9] Atlas, *supra* note 8, at 506.

[10] *Id.*

Nonetheless, some have alleged that a conflict of interest arises when PBMs both administer the pharmacy benefits for a client and sell drugs to a client's members via the PBM's owned mail-order pharmacy. These "self-dealing" arrangements purportedly would provide PBMs an opportunity to manipulate drug dispensing at their mail-order pharmacies to enhance their own profits at the expense of plans and members through the three business practices discussed above (lack of generic substitution and dispensing, interchange to more expensive brand products, and repackaging of drugs into more expensive units). One study concluded on the basis of high level data and theoretical calculations that self-dealing could cost the U.S. Government and Medicare beneficiaries up to $30 billion during the period 2004-2013.[11]

The actual data from the study participants on the business practices Congress requested the FTC to study revealed that these allegations are without merit. The following discussion provides a summary of the data and information produced by the study participants to answer the six questions in the MMA and its 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.

Background on How the Commission Collected Price Data: The Commission collected 2002 and 2003 price data for three types of drug products (single-source brand (SSB), multi-source brand (MSB), and generic (G) drugs) from each study participant.[12] The price data included the total amounts that members and plans paid, regardless of how various PBMs and plan sponsors labeled those outlays. Member prices included the sum of copayment, deductible, and any coinsurance amounts. Plan prices included the sum of ingredient costs (the portion of the dispensed drug for which the plan pays), dispensing fees, and any pharmaceutical payments shared with the plan that reduced the prices plan sponsors paid. For purposes of this report, "total price" equals the sum of "member price" and "plan price."

Answer -- Differences in average total 2002 and 2003 prices at owned mail-order pharmacies versus not-owned mail-order pharmacies for each drug type:

- For large PBMs, average total prices at owned mail-order pharmacies typically were lower than at mail-order pharmacies not owned by the large PBMs.

[11] *See* JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 30-31 (2003) [hereinafter SELF-DEALING STUDY], *at* http://www.mpaginc.com/news/pbmreport.pdf. This study, financed by several retail pharmacies, concluded on the basis of aggregate data and numerous simplifying assumptions that self-dealing would cost the U.S. Government and Medicare beneficiaries billions of dollars during the period 2004-2013. *See* Carol Ukens, *PBM Mail Order Would Up Medicare Rx Cost, Study Finds*, DRUG TOPICS, Oct. 6, 2003, at 34, *at* http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111109.

[12] The biggest difference between single-source and multi-source brand drugs is that single-source brand drugs do not have a generic alternative, whereas multi-source brand drugs do. For example, as of August 2005 among antidepressants, Zoloft is a single-source brand drug. Prozac is a multi-source brand drug, and fluoxetine (the active ingredient in Prozac) is a generic drug.

- Retailer-owned PBMs charged lower total average prices for generic and MSB drugs, but not for SSB drugs, at their owned mail-order pharmacies compared to not-owned mail-order pharmacies.

The data showed that mail prescriptions are typically three times as large as retail prescriptions (*e.g.*, 30 days at retail and 90 days at mail).[13] Moreover, the mix of drugs dispensed varies substantially across dispensing channels – mail-order pharmacies dispense a higher proportion of maintenance drugs for chronic conditions.

Answer -- Differences in average total prices at owned mail-order pharmacies versus not-owned retail pharmacies for each drug type:

- For a common basket of drugs dispensed in December 2003 with the same-sized prescriptions, retail prices typically were higher than mail prices at both large PBMs and retailer-owned PBMs.

- One reason for these differences can be seen in the contractual agreements that govern the relationship between the plan sponsor and the PBM. In the 26 PBM-plan sponsor contracts reviewed by the Commission staff, plan sponsors often secured more favorable pricing for mail dispensing than for retail dispensing. In other words, plan sponsors obtained larger discounts off the same reference drug price for prescriptions dispensed at mail than at retail.

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

Background on Prescription Drug Competition: One aspect of competition in the PBM industry is how pharmaceutical manufacturers' payments to PBMs affect the prices that plan sponsors and members pay for drugs dispensed under the plans administered by the PBMs. This inquiry often focuses on how much of these payments PBMs share with their plan sponsors to lower the plan sponsors' drug spending. A sole focus on the explicit contract terms governing sharing of manufacturer payments with plan sponsors, or the data showing the actual sharing of these payments, however, does not provide a basis for valid inferences regarding prescription drug competition or an alleged conflict of interest.

Answer: Manufacturer payments to PBMs can be passed on to plan sponsor clients through a complex array of adjustments in the prices for the services that PBMs provide to their plan sponsor clients. For example, plan sponsors and their members pay several types of fees for the services that PBMs render (*e.g.*, plan sponsors pay dispensing fees and ingredient costs for drugs dispensed and members pay copayments). Moreover, these fees are based on the full scope of services provided by the PBM, such as the broadness of the retail and mail-order pharmacy networks where members can fill their prescriptions at low prices, and the range of

[13] Retail dispensing includes all prescriptions dispensed at retail, regardless of whether the retail pharmacy is a chain pharmacy or an independent community pharmacy.

formulary drugs in each therapeutic class for which members pay lower copayments (*i.e.*, the formulary's "restrictiveness"). Thus, a high sharing level of pharmaceutical payments could be offset by high dispensing fees or high member copayments. Conversely, a low sharing level could be offset by low dispensing fees or low member copayments.

To shine further light on this aspect of competition, the Commission requested data from the study participants about their relationships with pharmaceutical manufacturers. The Commission also reviewed the contractual agreements between each PBM study participant and a common set of 11 pharmaceutical manufacturers. This report does not offer observations on or analysis of whether these agreements comply with federal and state anti-kickback laws, which generally prohibit an entity from knowingly and willingly offering, paying, soliciting, or receiving any remuneration to induce the referral of individuals or the purchase of items or services for which payment may be made under Medicare, Medicaid, or other federal or state health programs.

Importance of the Formulary: Pharmaceutical manufacturers recognize that having their drugs listed on the formulary or in a preferred spot on the formulary (as compared to competing drug products) will likely increase the drug products' sales. As noted earlier, pharmaceutical manufacturers use "formulary payments" to obtain formulary status, and/or they use "market-share payments" to encourage PBMs to dispense their drugs. Both payments are often specified as a percentage of the drug's wholesale price (*e.g.*, a percentage level of 10% means the manufacturer will pay the PBM 10% of a measure of the drug's wholesale price multiplied by the quantity dispensed).

Most industry members refer to these payments as "rebates," and they refer to the percentage level as the "rebate level." For purposes of this report, the term "pharmaceutical payments" will be used to describe these payments, and the term "allowance" will be used to describe the percentage level.

In addition to these two types of payments, pharmaceutical manufacturers pay PBMs fees to administer these formulary access programs on behalf of the manufacturer ("administrative fees") and to provide other services, including therapeutic interchange and compliance programs. This report uses the term "total payments" to refer to all four payments combined; otherwise, the report refers to each payment type individually to provide greater specificity and clarity rather than using the general term "rebates."

The data and information obtained by the Commission support the following findings about pharmaceutical manufacturer payments:

- On average, PBM study participants received total payments of $5.22 per normalized prescription of a brand drug dispensed in 2002.[14] The average increased 21.5% to $6.34 in 2003.

[14] Normalized prescriptions account for the differing size of mail and retail prescriptions – each mail prescription is counted three times when counting the number of normalized prescriptions.

- PBMs received the majority of their total payments for a limited number of single-source brand drugs. In 2003, each study participant's top 25 brand drugs (in terms of total payments received) accounted for approximately 71% of the participant's total payments received, on average. Single-source brand drugs were the most expensive drugs, and they generally accounted for over 50% of the drugs dispensed to plan members.

- The pharmaceutical manufacturer-PBM agreements showed that manufacturers readily raised and lowered allowance levels for each of their drug products as competition developed in the drug's therapeutic class.

- Allowance levels were higher for drugs on restrictive formularies and when there were several competing drugs in a therapeutic class.

- With few exceptions, the contracts did not provide higher allowance levels for drugs dispensed through PBM-owned mail-order pharmacies as compared to retail pharmacies.

- Most PBMs did not receive higher allowance levels for including a "bundle" of a manufacturer's drugs on their formularies. In the few cases in which a PBM did receive higher allowance levels, the bundle was a small subset of the manufacturer's drug products.

- Administrative fees that pharmaceutical manufacturers paid to PBMs to administer the formulary access programs on the manufacturers' behalf were approximately 3% of the wholesale price of the manufacturers' drugs.

- Plan sponsors often contract with PBMs for prescription compliance programs, preferred drug management programs, therapeutic interchange services, or similar activities to better control their prescription drug costs. A small number of the manufacturers paid PBMs in this study for these additional services and programs. Most of the drugs in these programs were in frequently prescribed therapeutic classes with competing drugs. In the few cases in which manufacturers paid PBMs for these specific programs, they paid separate fees for each communication with a patient or physician; total fees were capped between $100,000 to $1,000,000 per drug per year.

- The extent to which contracts between PBMs and their plan sponsor clients included explicit terms for the PBMs to share "formulary" and "market share" payments with plan sponsors varied among plans. The Commission staff examined 26 plan sponsor contracts with 3 large PBMs. Most of these contracts included provisions for the sharing of these payments between the PBM and the plan sponsor. Some of the contracts provided for the PBM to share varying percentages of the payments received from manufacturers. Other contracts provided for the PBM to share these payments by guaranteeing a certain dollar amount per eligible prescription. The data obtained from study participants did not reveal a consistent relationship between the type of PBM (*i.e.*, large PBM, small or insurer-owned PBM, and retailer-owned PBM) and the contractual sharing percentage. Plan sponsors generally have audit rights that allow them to verify whether they receive the

payments for which they contract. The extent of these audit rights varied among the study participants.

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

Background on Generic Drug Prices: Retail and mail-order pharmacies that dispense generic drugs lower overall prescription drug costs, because generic drugs are substantially less expensive than their brand drug counterparts. Generic drugs are bioequivalent to brand drugs, that is, they contain the same active ingredient(s) of the brand drugs and are, among other things, chemically identical in strength, concentration, dosage form, and route of administration. Pharmacists generally can substitute a generic drug for a multi-source brand drug without prior physician authorization when a consumer presents a prescription for a brand drug. The "generic substitution rate" (GSR) measures how often generic drugs are substituted for brand drugs when a generic drug is available.[15] The "generic dispensing rate" (GDR) measures the frequency of generic drug dispensing compared to the dispensing of *all* drugs (brand and generic), regardless of the extent to which generic drug substitutes are available for the brand drug dispensed.[16]

Answer – Generic Dispensing Rate (GDR) for Owned Mail v. Not-Owned Mail: For prescriptions dispensed in December 2003, the data showed that, for plans administered by large PBMs, mail-order pharmacies dispensed the same ratio of generic drugs compared to all drugs within the same therapeutic class regardless of the ownership of the mail-order pharmacy (owned mail weighted average GDR of 35% compared to not-owned mail GDR of 36%). For plans administered by retailer-owned PBMs in December 2003, owned mail-order pharmacies dispensed a slightly smaller ratio of generic drugs compared to all drugs within the same therapeutic class than did not-owned mail-order pharmacies (owned mail GDR of 37% compared to not-owned mail of 42%). These data do not suggest any significant differences in terms of generic dispensing rates between owned and not-owned mail-order pharmacies.

Answer – GDRs for Owned Mail v. Not-Owned Retail: For large PBMs, the weighted average GDR by therapeutic class was 39% at owned mail-order pharmacies and 44% at not-owned retail pharmacies. For retailer-owned PBMs, the weighted average GDR was 42% at owned mail-order pharmacies and 49% at not-owned retail pharmacies. Formulary status decisions (*i.e.*, which and how many brand drugs are preferred in each therapeutic class) and other aspects of plan designs (*e.g.*, copayment differentials for brand versus generic drugs or mail versus retail dispensing) may explain the differences in these rates.

[15] A generic substitution rate equals the number of generic prescriptions dispensed divided by the sum of the number of generic and multi-source brand prescriptions dispensed. Some PBMs refer to this calculation as generic utilization because the term "substitution" may imply that the PBM takes an affirmative action to substitute a generic version of a brand drug. This report does not use the term "substitution" to mean any particular action by the PBM and the report uses the term generic substitution throughout.

[16] A generic dispensing rate is the number of generic prescriptions dispensed divided by the total number of prescriptions dispensed for all drug types (single-source brand, multi-source brand, and generic).

Generic Substitution Rates Show High Generic Drug Dispensing at Owned Mail-Order Pharmacies -- Study findings concerning generic substitution rates include:

- Annual GSRs, by dispensing channel and ownership of the pharmacy, for each of the three PBM categories (large PBMs, small or insurer-owned PBMs, or retailer-owned PBMs) were above 80%, and above 90% for some owned mail-order pharmacies.

- GSRs increased from 2002 to 2003 in every dispensing channel, regardless of ownership, for each of the three PBM categories.

- Large PBM-owned mail GSRs were generally equal to not-owned retail or not-owned mail GSRs. For example, average annual GSRs for owned mail-order pharmacies were 92.5% and 93.3% (for 2002 and 2003, respectively) compared to 91.9% and 93.1% (for 2002 and 2003, respectively) for not-owned retail pharmacies used by these large PBMs.

- Small or insurer-owned PBMs and retailer-owned PBMs generally had higher GSRs at retail pharmacies than at the mail-order pharmacies they used – regardless of whether the PBM owned the mail-order pharmacy.

- For large PBMs and small or insurer-owned PBMs, generic drugs were more profitable at their owned mail-order pharmacies than were brand drugs – even when payments to the PBM from pharmaceutical manufacturers for brand drugs were included. The Commission obtained PBM strategy and planning documents that corroborated these data and explained how PBMs seek to increase generic substitution at both mail and retail. Many PBMs forecast the timing of new generic drug entry so that they can plan a smooth transition to the generic drug once it becomes available. Given these profit incentives for the PBM and lower prices to the plan sponsor and member, the PBM-owned mail-order pharmacies' incentives, on average, were consistent with those of their clients in 2002 and 2003.

- The data revealed two factors that may explain why mail GSRs for individual multi-source brand drugs, which are generally in the 80% to 90% range, are not closer to 100%. First, the data showed that prescriptions marked as "dispense as written" (DAW) occurred between 5% and 15% of the time, depending upon the dispensing channel and the reason for the DAW instruction. DAW prescriptions generally override state generic substitution laws and can reduce the GSR. Second, several PBMs continued to dispense the brand drug through their owned mail-order pharmacies, although a generic alternative was available, because they could obtain the brand drug at a price that was equal to or lower than the generic drug's price. In these situations, the PBM obtains volume-based payments or discounts from the pharmaceutical manufacturer that lowers the price of the brand drug so that it is competitive with the generic drug's price. The result is a lower GSR, but also a lower price to plan sponsors and their members. The data revealed that several PBMs have used this strategy, especially during the 180-day exclusivity period that generic drugs received when they entered prior to patent expiration.

- Review of 26 contracts between PBMs and plan sponsors showed that plan sponsors have several ways to contract with PBMs to obtain the savings that generic drugs provide. For example, some plans required PBMs to guarantee GSR and GDR rates. The contracts guaranteed different levels for mail-order and retail pharmacies and included penalties for not achieving these rates. Some plan sponsors and PBMs also designed plans that lower members' copayment amounts for generic drugs as an incentive for members to choose generic prescriptions.

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.

Background on Different Types of Therapeutic Interchange: Switching patients from one brand drug to another drug is termed "therapeutic interchange" (TI). TI typically involves switching a patient from a prescribed drug that is not on a plan sponsor's formulary to a therapeutically similar, but chemically distinct, drug that is listed on the formulary and is in the same therapeutic class as the prescribed drug. There are two types of interchanges. The first type involves brand-to-brand drug interchanges. For example, a patient presents a prescription for the cholesterol-lowering drug Crestor, but the PBM, after obtaining physician approval, fills the prescription with Lipitor instead. The second type involves brand-to-different generic drug interchanges in which the generic drug is therapeutically similar, but chemically distinct, from the prescribed brand drug (*e.g.*, generic Prozac is dispensed for a prescription of the brand-drug Zoloft).

Answer: PBMs' use of brand-to-brand therapeutic interchange is limited. For example, the data from two large PBMs showed TI involved in less than one-half of one percent (0.5%) of mail or retail prescriptions. In the 10 therapeutic categories the Commission examined, study participants' data showed that use of TI could reduce plan sponsors' costs in the majority of cases. The data showed that the financial impact on plan and member spending was generally the same across dispensing channels. With the exception of one PBM, the range of brand drugs in the study participants' TI programs was the same at the PBMs' owned mail-order pharmacies as through their retail pharmacy network.

The study data and other information support several additional findings concerning therapeutic interchange.

- If a generic version of a brand drug was available, only in rare cases did a PBM have a TI program that sought to interchange that brand drug with another brand drug.

- Some PBMs have brand-to-different generic TI programs in which they sought to use a generic version of a therapeutically similar, but chemically distinct, drug instead of a prescribed single-source brand drug. These types of interchanges would save money for plans because generic drugs are less expensive than single-source brand drugs. There were fewer brand drugs involved in these brand-to-different generic programs than in brand-to-brand TI programs.

- Plan sponsors have a variety of tools to ensure that TI programs benefit plan sponsors and their members. Plan sponsors' use of these tools varies by plan and PBM.[17]

Qeustion 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.

Background on Repackaged Drugs: Repackaged drugs are drugs manufactured by FDA-licensed manufacturers and purchased in bulk by FDA licensed repackaging companies. The repackaging companies then repackage the drugs, usually in quantities that correspond to individual prescription sizes. The repackaging company assigns a new national drug code (NDC) number to the repackaged drug, and reports an Average Wholesale Price (AWP) for the new NDC. Repackagers often report AWPs that differ substantially from the original manufacturer's AWP.

Answer: PBMs rarely dispensed repackaged drugs through their owned mail-order pharmacies. Repackaged drugs accounted for roughly one out of every one million prescriptions dispensed in December 2003 by the PBM study participants for the top ten drug products.

Question 5b: Whether Mail-Order Pharmacies Owned by PBMs (or Entities Owned by PBMs) Sell Repackaged Drugs at Prices Above the Manufacturer's Average Wholesale Price.

Answer: Because owned mail-order pharmacies dispensed so few repackaged drugs, the financial impact on plan sponsors' total drug spending was insignificant.

The study data support the following conclusions:

- Repackaged drugs accounted for *no more* than 0.024% of the prescriptions dispensed in December 2003 by the PBM study participants at *retail* for the top ten drugs.

- Prices for repackaged drugs dispensed through not-owned retail pharmacies varied considerably above and below each manufacturer's price.

- Only one of the PBM study participants had a FDA-regulated repackaging facility. This PBM billed its plan-sponsor clients for repackaged drugs based on the manufacturers' AWPs for the drugs dispensed, not based on new, higher AWPs. The clients of this PBM paid less, on average, for the repackaged drugs dispensed by mail pharmacies than they paid for the same drugs at retail pharmacies.

[17] Commission staff reviewed 26 plan sponsor contracts with three large PBMs and business documents from all study participants. Although the contracts suggested that some plan sponsors use the available tools to protect themselves financially, staff did not review all PBM/plan sponsor contracts, nor did staff review a statistically representative sampling of all PBM/plan sponsor contracts. Such a review was beyond the scope of this study.

Question 6: Whether Competition or Drug Pricing Behavior by PBMs Would Be Affected if PBMs Were to Bear Financial Risk for Drug Spending.

Background on Risk Sharing: In the mid-1990s, several PBMs assumed full risk for some of their large plan sponsor clients' drug spending. Observers have suggested that the PBMs found the assumption of full risk to be unprofitable and have avoided this type of contract since.[18]

Nonetheless, under current contracts PBMs do bear some of the risk of their plan clients' drug spending. There are two components of financial risk for drug spending by plan sponsors: (1) changing drug prices, and (2) changing utilization patterns by members of a plan. PBMs currently bear some of the drug price risk, because PBMs price their services indirectly on the drug pricing terms that they have with retail pharmacies and pharmaceutical manufacturers. The timing of these underlying arrangements is not synchronized with that of the agreements PBMs have with their plan sponsor clients and, thus, can cause the PBM to bear some price risk. For example, if retail pharmacies were substantially to reduce the discounts given to PBMs, PBMs would be at risk for the difference between the old discounts and the new discounts for the remaining terms of its plan sponsor contracts. PBMs are similarly at risk for decreases in payments from pharmaceutical manufacturers. Because of these many moving parts, each time a PBM enters into a contract to provide PBM services for a term longer than its existing contracts with its current inputs, PBMs bear some price risk.

PBMs also bear some of the financial risk associated with drug utilization patterns. For example, a PBM generally obtains the most profit per prescription, on average, when it fills a prescription for a generic drug through its owned mail-order pharmacy. If a member obtains a prescription for a brand drug filled at a retail pharmacy instead, both the PBM and the plan sponsor generally are worse off. Thus, to the extent that utilization is not geared toward the drugs most profitable to the PBMs – typically, generic drugs – PBMs bear some utilization risk.

Answer: The effects on competition and drug pricing if PBMs were to bear additional financial risk for drug spending would depend on a variety of factors relevant to a PBM's business model and likely profitability in those circumstances. Important factors would include the potential sources of a PBM's profitability, the extent of the additional financial risk, and the availability of methods by which the PBM could reduce or manage its financial risk. Because of this variety of factors, it is unclear to what extent, if any, drug prices might be lower or higher, or PBM competition might be reduced or enhanced, if PBMs bore greater financial risk. In 2002 and 2003, the status of generic drugs as typically the most profitable drugs for PBMs resulted in overall consistency in plan sponsors' interests in lower drug costs and PBMs' interests in profitable transactions.

[18] *See* THE HEALTH STRATEGIES CONSULTANCY LLC, HENRY J. KAISER FAMILY FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 21 (March 2005), *at* http://www.healthstrategies.net/research/docs/Follow_the_Pill.pdf.

CONGRESSIONAL REQUEST AND FTC APPROACH TO THE STUDY

In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[1] Congress requested that the Federal Trade Commission ("FTC" or "Commission") assess the differences in payment amounts incurred by plans and their members for prescription drugs dispensed by mail-order pharmacies owned by pharmacy benefit managers ("PBMs") compared to both not-owned mail-order pharmacies and community retail pharmacies. The central focus of this request is whether plan sponsors' contracts with PBMs properly align the incentives of the PBM with those of the plan sponsor, such that PBMs do not implement strategies that increase plan sponsors' prescription drug costs to levels higher than they would be otherwise. Stated another way, the request focuses on whether competition among PBMs constrains their ability to engage in conduct that could conflict with the objectives of their plan sponsor clients.

I. NATURE OF THE ALLEGED PROBLEM

Some have alleged that a conflict of interest arises when a PBM both administers the pharmacy benefits for a plan sponsor and sell drugs to a plan sponsor's members via the PBMs' owned mail-order pharmacy.[2] Such "self-dealing" arrangements could provide PBMs an opportunity to manipulate drug dispensing and enhance their own profits at the expense of plan sponsors and their members.[3]

A. PBMs That Own Retail or Mail-Order Pharmacies are "Vertically Integrated"

A PBM that owns a pharmacy (whether retail or mail) is considered vertically integrated. A vertically integrated PBM may have a greater ability to influence which drugs are dispensed under the plans it administers than a non-vertically integrated PBM. The concern is that a vertically integrated PBM will steer plan sponsors' members to drugs on which the PBM's mail-order pharmacy will make a greater profit, regardless of costs to the PBM's plan sponsor client. If plan sponsors' contracts with PBMs do not properly align the incentives of the PBM with those of the plan, this lack of alignment could create a conflict of interest that results in higher prices for plans and their members.[4] Potential conflicts of interest should be rare, however, if

[1] Pub. L.108-173.

[2] *See* JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 30-31 (2003) [hereinafter SELF-DEALING STUDY], *at* http://www.mpaginc.com/news/pbmreport.pdf. This study, financed by several retail pharmacies, concluded on the basis of aggregate data and numerous simplifying assumptions that self-dealing would cost the U.S. Government and Medicare beneficiaries billions of dollars during the period 2004-2013. *See* Carol Ukens, *PBM Mail Order Would Up Medicare Rx Cost, Study Finds*, DRUG TOPICS, Oct. 6, 2003, at 34, *at* http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=111109.

[3] In theory, the same alleged conflict of interest could arise if a PBM owned retail pharmacies.

[4] *See* JEAN-JACQUES LAFFONT & DAVID MORTIMORT, THE THEORY OF INCENTIVES 145-148 (2002).

competition among PBMs provides plan sponsors with alternative choices.[5]

The economic literature suggests that vertical integration can lower costs. First, integration can reduce transaction costs. When two separate firms enter into a supply relationship, they must negotiate the terms of that relationship. For example, the two firms must agree on and enforce prices, quantities, and other terms of trade. Such contract negotiations cost money in terms of personnel time, legal advice, and other matters. Vertical integration can reduce such transaction costs if it is easier to establish these terms through direct managerial control of two business units than through (1) long-term contracts or (2) repeated, arm's length transactions. If mutually beneficial terms of the trade between two vertically related business units are complex, and it is difficult to specify all future contingencies within a contract, direct managerial control is likely to reduce transaction costs below those associated with contractual relationships.

Second, vertical integration also avoids the double markups (or what economists call "double marginalization") in which two independent, vertically related firms each have some ability to charge above marginal cost. When a single entity owns both links in the supply chain, the entity generally will consider the impact that an increase in the markup at one link will have on the profits of both links. Depending on the contractual arrangement between the two entities, the single entity that owns both links in the supply chain may have an incentive to charge a lower overall price for the product than two independent entities setting price optimally.[6]

B. Specific Allegations Against PBMs Integrated with Mail-Order Pharmacies

Some have alleged that PBMs that own mail-order pharmacies have inherent conflicts of interest in four general areas: (1) pharmaceutical manufacturers' payments (*e.g.*, rebates) to sellers of their products – including PBMs – may create incentives for PBMs to dispense higher cost prescription drugs;[7] (2) PBMs may encourage plans to restrict the services retail pharmacies may provide to members, so that PBM-owned mail-order pharmacies can obtain a greater proportion of the business generated by plan members; (3) other PBM business practices also may favor a PBM-owned mail-order pharmacy; and (4) PBMs' repackaging practices may inflate mail-order pharmacy profits at the expense of plan sponsors. Each allegation is discussed briefly below.

First, some allege that pharmaceutical manufacturers' payments to PBMs may create incentives for the PBM to dispense a particular manufacturer's drug more frequently, regardless

[5] *See* Anthony G. Bower, *Procurement Policy and Contracting Efficiency*, 34 INT'L ECON. REV. 873 (1993).

[6] *See* LUIS CABRAL, INTRODUCTION TO INDUSTRIAL ORGANIZATION 190-192 (2000).

[7] Retail pharmacies viewed the dispensing of prescriptions by mail-order pharmacies owned by PBMs as an inherent conflict of interest analogous to that arising from prohibited self-referrals by physicians of patients to health services in which they have a financial interest. *See* 42 U.S.C. § 1395nn (2000). The difference in this situation is that plan sponsors, which have incentives to manage their prescription drug expenditures in the most cost-effective manner, have numerous ways to contract with vertically integrated PBMs to ensure that there is no conflict of interest.

of whether that drug costs more to the plan sponsor. Some allege that plan sponsors and members pay higher prices for mail prescriptions than for retail prescriptions because PBM-owned mail-order pharmacies allegedly dispense a larger portion of brand drugs for which the PBMs receive manufacturer payments.[8]

Related to this argument, PBMs allegedly encourage their owned mail-order pharmacies to dispense brand drugs that yield high pharmaceutical payments, rather than less expensive generic drugs. Similarly, PBM-owned mail-order pharmacies allegedly encourage therapeutic interchanges that enhance their payments from manufacturers, rather than improve the quality of care or provide savings for plan sponsors and their members.[9] Allegedly, adverse therapeutic interchanges (*i.e.*, switches to more expensive drugs) could occur at a PBM's mail-order pharmacy because the dispensing physician's permission for the interchange can be obtained during the time lag in dispensing that occurs at mail-order pharmacies.

These issues have gained the attention of some federal and state law enforcement agencies, which have sued PBMs based in part on allegations that PBMs retained rebates that should have been passed through to federal and state plan sponsors. In April 2004, the United States and 20 states announced a settlement with Medco Health Solutions, Inc., to resolve September 2003 complaint charges seeking injunctive relief and compensation for state unfair trade practices.[10] Among other things, the United States and the states alleged that Medco encouraged prescribers to switch patients to different prescription drugs but failed to pass on the resulting savings to patients or their federal or state plan sponsors. Medco, however, claimed that its actions saved money for plan sponsors and their members. The consent order requires Medco to pay $29 million to the states for damages, fees, and restitution.[11]

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[8] *See* NAT'L ASS'N OF CHAIN DRUG STORES, MAIL ORDER PHARMACY: IMPACT ON PATIENTS, PHARMACIES & STATE ECONOMY (Governmental Affairs Issue Brief, Oct. 2004), *at* http://www.nacds.org/user-assets/pdfs/gov_affairs/issuebriefs/MailOrderPharmacy%20December2004.pdf.

[9] *See* Letter from Lee L. Verstandig, Nat'l Ass'n of Chain Drug Stores, to Chairman Deborah Platt Majoras, Federal Trade Commission (FTC) 2 (May 26, 2005) [hereinafter NACDS Letter].

[10] *See* News Release, U.S. Dep't of Justice, The United States Settles Its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions (Apr. 26, 2004) (federal claims for damages, penalties, or restitution under federal statutes and common law were not resolved by the settlement and that portion of the case continues), *at* http://www.usdoj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf. *See also* News Release, U.S. Dep't of Justice, U.S. Files Complaint in Intervention in Two "Whistleblower" Actions Against Medco Health Solutions (Sept. 29, 2003), *at* http://www.usdoj.gov/usao/pae/News/Pr/2003/sep/medco.html.

[11] Similar allegations were made by the State of New York in a lawsuit alleging that a PBM, Express Scripts, Inc. (ESI), and its subsidiary, ESI Mail Pharmacy Service, Inc., engaged in fraudulent and deceptive schemes to increase ESI's revenues at the expense of the state employees' health plan and members. *See* Press Release, Office of N.Y. State Attorney Gen. Eliot Spitzer, Express Scripts Accused of Defrauding State and Consumers Out of Millions of Dollars: Lawsuit Alleges Pharmacy Benefit Manager Inflated Costs of Drugs and Diverted Rebates (Aug. 4, 2004), *at* http://www.oag.state.ny.us/press/2004/aug/aug4a_04.html.

Second, some allege that PBMs encourage plans to adopt copayment structures that "steer" consumers to a PBM's owned mail-order pharmacy and that this allows the PBM to manipulate the drugs dispensed in ways that are detrimental to the plan sponsor. For example, plan designs typically require a member copayment for a 90-day supply obtained through mail order that is only twice as much as the copayment for a 30-day supply dispensed by a retail store (rather than three times as much).[12] This copayment structure may allegedly provide financial incentives for members to use mail order in cases where the associated impact on plan costs does not justify such incentives. Moreover, some assert that the price of drugs obtained at retail is similar to the mail-order pharmacy price, but plan sponsors generally do not permit retail stores to dispense a 90-day supply to the plans' members.[13] In addition, some allege that the dispensing of 90-day supplies through mail-order pharmacies may result in expensive and wasteful over-dispensing of drugs.[14]

Third, some allege that various PBM business practices with retail pharmacies manipulate the prices plan sponsors pay for retail dispensing in order to inflate the PBM's profits.[15] For example, some object to PBMs retaining the difference between the amount plan sponsors pay the PBM for the dispensed drug product and the amount the PBM reimburses retail pharmacies to dispense the drug. Others allege that PBMs generate overpayments from their plans and underpayments to retail pharmacies by differentially timing the implementation of price increases to plans and retail pharmacies. PBMs allegedly have the opportunity to retain the difference and inflate their profits by rapidly initiating a price increase to the payer and delaying the higher reimbursement to the retailer. Others allege that PBMs also inflate their profits by reimbursing for generic drugs dispensed at their owned mail-order pharmacies at higher rates than for the same drugs dispensed at retail pharmacies.

Fourth, the SELF-DEALING STUDY has alleged that PBMs that own mail-order pharmacies inflate their profits by repackaging drugs and billing plans based on a higher per unit Average Wholesale Price (AWP). The SELF-DEALING STUDY asserted that, on the basis of actual AWPs and theoretical dispensing patterns, mail-order pharmacies increase their profits while appearing to offer larger discounts than retail stores offer.[16]

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[12] *See* GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 17-18 & tbl.3 (2003), *at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196 [hereinafter GAO]. NACDS Letter, *supra* note 9, at 2.

[13] *See* GAO, *supra* note 12, at 9, 23. NACDS Letter, *supra* note 9, at 2.

[14] NACDS Letter, *supra* note 9, at 2. At least two large retailers have decided to compete with PBMs by offering to fill 90-day prescriptions at the retail pharmacies for plans administered by PBMs owned by the retailers. *See* Matthew Boyle, *Drug Wars*, FORTUNE, June 13, 2005, 79-84.

[15] *See, e.g.*, Robert I. Garis & Bartholemew E. Clark, *The Spread: Pilot Study of an Undocumented Source of Pharmacy Benefit Manager Revenue?*, J. AM. PHARMACISTS ASS'N, Jan./Feb. 2004, at 15-21.

[16] SELF-DEALING STUDY, *supra* note 2, at 1, 5-6, 11-13 (2003).

II. CONGRESSIONAL REQUEST FOR THE CONFLICT OF INTEREST STUDY

Congress requested in the MMA that the Commission undertake this "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.[17]

As explained in the Conference Report on the legislation, Congress requested that the FTC undertake this study to determine whether the use of mail-order pharmacies owned by PBMs that administer the Medicare prescription drug benefit would adversely affect Medicare spending, as compared to the use of mail-order pharmacies not owned by a PBM. Accordingly, the FTC was asked to 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 that are 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 a clinical indication) more frequently than mail-order pharmacies that are not owned by PBMs;

(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 manufacturer's average wholesale price; and

(5) other factors deemed relevant by the FTC.[18]

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[17] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. I, § 110, 117 Stat. 2066, 2174 (2003) (codified at 42 U.S.C. § 1395w-101 (Historical and Statutory Note)). The Paperwork Reduction Act did not apply to the Commission's collection of information to complete the Study. *Id.*

[18] H.R. CONF. REP. NO. 108-391 at 519-520 (2003), *reprinted in* 2003 U.S.C.C.A.N. 1808, 1891.

Finally, Congress requested that the FTC "consider whether competition or drug pricing behavior by PBMs would be affected if PBMs were to bear financial risk for drug spending."[19]

III. THE COMMISSION'S APPROACH TO COMPLETE THE CONFLICT OF INTEREST STUDY

The Commission used a two-stage process to collect the company-specific information and data necessary to complete the study.[20] The Commission first obtained high-level business documents related to these issues and aggregate data for three business practices (generic substitution, therapeutic interchange, and repackaging of drugs) identified specifically in the Conference Report accompanying the MMA. The information obtained in the first stage enabled the Commission to seek specific claims information from several participants to engage in a more detailed empirical study.

During the first stage, the Commission identified four groups of participants and issued Special Orders that subpoenaed data and documents from them. The Commission included PBMs that owned mail-order pharmacies and those that did not so that it could assess the differences in costs incurred by plan sponsors and their members for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to both mail pharmacies not owned by PBMs and community pharmacies. For example, some PBMs use mail-order pharmacies they own as well as those they do not own to serve their plan sponsor clients. The Commission compared the prices of drugs at these various mail pharmacies to isolate the effect of PBM ownership of the mail pharmacy. Thus, the Commission was able to make "apples to apples" price comparisons for these PBMs. The Commission also obtained data from four large stand-alone retail pharmacies to assess the price differences for customers with insurance and those who paid cash for their prescriptions. The four groups of study participants included the following:

- Large PBMs: 5 participants.[21] All five participants owned a mail-order pharmacy during the study period, and three of these participants also provided data related to serving plan sponsors with mail-order pharmacies they did not own.

[19] *Id.* at 520.

[20] *See* FTC, Project No. P042111, Pharmacy Benefit Manager Conflict of Interest Study (public notice) (Mar. 26, 2004), *at* http://www.ftc.gov/os/2004/03/040326pnpbm.pdf. FTC staff obtained input on the design of the study from the study participants (identified below) and the following parties (in alphabetical order): James Langenfeld and Robert Maness (authors of the SELF-DEALING STUDY); Fred Mayer, Pharmacy Defense Fund; National Association of Chain Drug Stores; Pharmaceutical Care Management Association; and Marta Wosinska and Robert Huckman (authors of "Generic Dispensing and Substitution in Mail and Retail Pharmacies").

[21] Currently there are three large independent PBMs (Medco Health Solutions, Inc., Express Scripts, Inc., and Caremark Rx, Inc.). During 2002 and 2003 study period, there were four large independent PBMs, because Caremark had not yet completed its acquisition of AdvancePCS. *See In re* Caremark Rx, Inc./AdvancePCS, No. 031-0239, Statement of the Federal Trade Commission (announcing that the FTC had closed its investigation of Caremark Rx, Inc.'s proposed acquisition of AdvancePCS), *at* http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf. In addition, one of the four PBMs provided separate data files in response to the FTC Special Order because it maintained two separate data processing systems during the study period; thus, for purposes of this report, the Commission staff reported these as separate entities. As a result, there are five participants in the large PBM category for purposes of this report.

- Small or Insurer-Owned PBMs: 6 participants.[22] Five of these six participants used not-owned mail-order pharmacies because they did not own one during the study period (although one PBM acquired an interest in a mail-order pharmacy in 2003). The remaining participant owned a mail-order pharmacy during the study time period.

- Retailer-Owned PBMs: 4 participants.[23] All four participants were owned by chain retail drug stores and each participant owned a mail-order pharmacy during the study period. Three of the participants used the services of not-owned mail-order pharmacies as well.

- Stand-Alone Retail Pharmacies: 6 participants.[24] Five of the six participants were retail pharmacies that dispensed prescriptions that were paid by third-party payers (*e.g.*, PBMs) and by cash paying customers. The Commission included Argus Health Systems in this group because they processed third-party claims, as did retail pharmacies. Argus did not provide data for cash customers.

The Commission served Special Orders in May 2004 on each participant as authorized under Section 6(b) of the Federal Trade Commission Act (FTC Act, 15 U.S.C. § 46(b)). The Commission served two different Special Orders on participants – one Special Order for the three groups of PBMs and the other for Stand-Alone Retail Pharmacies. Copies of the Special Orders are contained in Appendices A and B.

The Special Orders required study participants to provide financial and volume data in a uniform format that summarized their 2002 and 2003 claims activity in response to questions about overall profitability, generic substitution, therapeutic interchange, and repackaging practices. The Special Orders also sought information on the most expensive and frequently dispensed brand and generic drugs.

The Special Orders required participants to segregate all of these data for three types of

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[22] Aetna Inc., Cigna Corporation, National Medical Health Card Systems, Inc. (NMHCRx), Prime Therapeutics, Inc., Restat LLC, and Wellpoint Health Networks, Inc. Aetna provided data on not-owned mail-order pharmacies for 2002 and 2003, and it provided owned mail-order pharmacy data for 2003. Cigna provided owned mail-order pharmacy data only. NMHCRx, Prime, and Restat provided not-owned mail-order pharmacy data only. Wellpoint provided both owned and not-owned mail-order pharmacy data.

[23] Eckerd Health Systems (EHS) (formerly a subsidiary of Eckerd Corp.), PharmaCare Management Services (a subsidiary of CVS Corp.), RxAmerica (a subsidiary of Longs Drug Stores Corp.), Walgreens Health Initiative (a subsidiary of Walgreen Co.). In 2004, CVS completed its acquisition of certain assets of Eckerd. For purposes of the Study, the data from PharmaCare and EHS were reported separately. EHS, RxAmerica, WHI provided data for owned and not-owned mail-order pharmacies. PharmaCare provided owned mail-order pharmacy data only.

[24] CVS Corp., Longs Drug Stores Corporation, Rite Aid Corporation, Wal-Mart Stores, Inc., Walgreen Co., and Argus Health Systems, Inc.

pharmacy benefit plans: (a) integrated plans in which the PBM managed both the mail-order and retail pharmacy benefit; (b) plans in which the PBM managed the retail benefit only; and (c) plans in which the PBM managed the mail benefit only.[25] The Special Orders also required participants to segregate all of these data by dispensing channel (*i.e.*, mail vs. retail) and by ownership interest (*i.e.*, whether the mail or retail pharmacy was owned by the study participant).[26] As a result, a study participant could have reported its data for "owned mail," "not-owned mail," "owned retail," and "not-owned retail" pharmacies. These four terms are used throughout this report to denote the type of pharmacy and PBM ownership of the pharmacy. The Commission used these segregated data to compare and analyze the differences, if any, between owned mail-order pharmacies and other types of pharmacies.

In addition to the financial data, the Special Orders subpoenaed high-level planning and strategy documents regarding company policies on mail-order distribution, generic substitution, therapeutic interchange, and repackaging practices.[27] The Orders required participants to produce a select set of contracts with pharmaceutical manufacturers. The Orders also required a subset of participants to submit contracts with a small number of plan sponsors, obtaining 26 PBM-plan sponsor contracts from three large PBMs.[28]

Two participants supplied specific claims data rather than the aggregate financial and volume data in the required format. After review of these data and of the aggregate data provided in response to the Special Orders, the Commission requested claims data for a one-month period (December 2003) from several additional participants to confirm patterns shown in the aggregate data.[29] As a result of this additional data request, the Commission obtained 166 million claims dispensed in December 2003 from five large independent PBMs, one small or insurer-owned PBM, two retailer-owned PBMs, and two stand-alone retailers.

To verify the data and to ensure comparability of the data among the participants, each respondent verified the accuracy of the methodologies staff used to analyze that respondent's data to determine PBM profitability, plan and member prices for pharmaceutical products, and generic substitution and dispensing rates. In addition, staff interviewed several of the PBMs to discuss, correct, and verify any data anomalies and to clarify the answers to any questions regarding the data and documents produced. These interviews were held in April and May 2005 (PBM Interviews).

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[25] Not all study participants managed plans in all three categories.

[26] Retail dispensing includes all prescriptions dispensed at retail, regardless of whether the retail pharmacy is a chain pharmacy or an independent community pharmacy.

[27] This report cites to these confidential high-level planning and strategy documents with the term "Company Document" (CD).

[28] This report cites to these two types of confidential contracts as "PBM contracts with plan sponsors" and "PBM contracts with pharmaceutical manufacturers."

[29] The format of the claims data requested is contained in Appendix C.

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