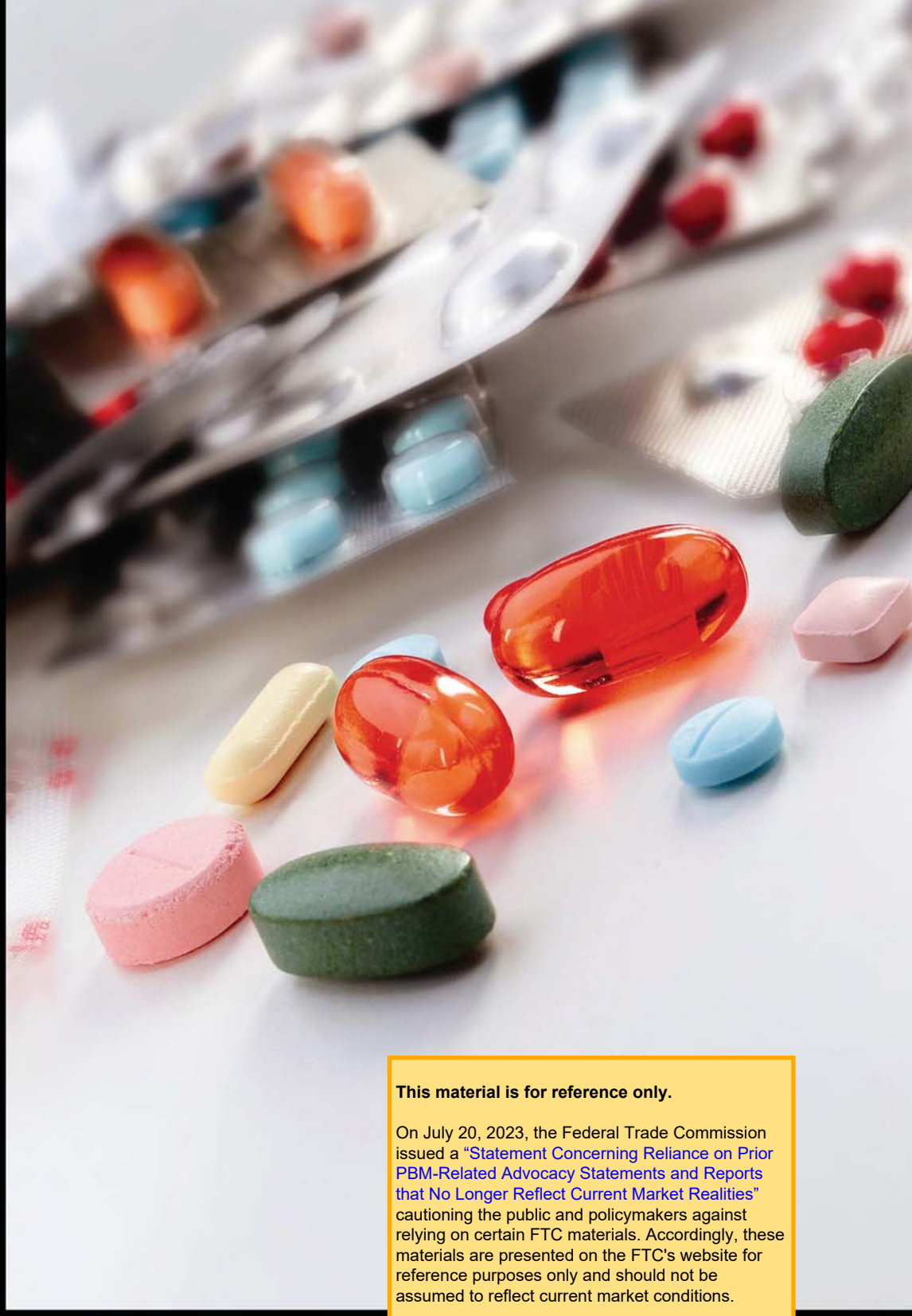

This material is for reference only.

On July 20, 2023, the Federal Trade Commission issued a "Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities" cautioning the public and policymakers against relying on certain FTC materials. Accordingly, these materials are presented on the FTC's website for reference purposes only and should not be assumed to reflect current market conditions.

Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies

Federal Trade Commission
August 2005

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.

[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.

[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]

[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]

[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).

[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.

TABLE OF CONTENTS

CHAPTER I INTRODUCTION AND BACKGROUND

Congress requested that the Commission assess whether a conflict of interest exists between a pharmacy benefit manager (PBM) and its plan sponsor clients when the PBM owns a mail-order pharmacy. 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, so that PBMs do not attempt to increase profits at their mail-order pharmacies by implementing strategies that increase plan sponsors' prescription drug costs to levels higher than they would be otherwise.

This Chapter describes the pharmacy benefits management business, the services PBMs offer, and how PBMs compete for plan sponsors' business. It also provides an overview of the growth of prescription drug expenditures and the increased use of mail-order pharmacies, and describes retail pharmacies' concerns about the possible threat that mail-order pharmacies pose. Finally, this chapter describes the Medicare Prescription Drug Benefit and the roles that PBMs may play to administer this benefit.

I. INDUSTRY BACKGROUND

A. PBMs Manage the Pharmacy Benefits Offered by Plan Sponsors

In addition to medical insurance, many health plan sponsors offer their members prescription drug insurance. Plan sponsors often 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 pharmacies so that the plan sponsor's members can fill prescriptions easily and in multiple locations. PBMs also negotiate with pharmaceutical manufacturers for payments that can lower the price that plans and members pay for prescription drugs.[1]

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.

During these computer interactions, the pharmacy transmits the insurance coverage information to a PBM, which verifies the insurance and determines if the consumer's insurance plan covers the prescribed drug. If so, the PBM determines three amounts: (a) the consumer's copayment; (b) how much the PBM will reimburse the pharmacy to dispense the drug; and (c) how much the PBM will bill the plan sponsor for the transaction. The PBM transmits the first two items (the consumer copayment and the pharmacy reimbursement amount) back to the pharmacy, logs the payment information on its computer system, and transmits the billing

[1] Plan sponsors also can use pharmacy benefit administrators (PBAs), which focus only on retail network administration and claims processing and do not represent their plan sponsors in financial negotiations with pharmaceutical manufacturers.

information to the plan sponsor. The plan sponsor then remits payment to the PBM, which then pays the local pharmacy. This process, known as claims adjudication, is handled electronically through the PBMs' sophisticated networks of databases.[2]

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.[3] 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.[4] 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").[5]

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[2] Small or Insurer-Owned PBM Company Document (CD); *see also* Retailer-Owned PBM CD (noting that claims processing is the most basic service provided by all PBMs and that PBMs charge between $0 and $.70 per claim); Large PBM CD; John Richardson, Director of Medicare, The Health Strategies Consultancy, Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy (June 26, 2003) at 8 [hereinafter Richardson 6/26 at relevant page(s)]. Transcripts of the Hearings are available at http://www.ftc.gov/ogc/healthcarehearings/index.htm#Materials.

[3] PBMs utilize electronic claims processing efficiently and cost-effectively to process claims. Small or Insurer-Owned PBM CD. As one study participant explained it:

> The electronic system allows the pharmacist to determine eligibility, copay information, and reimbursement amount at the point of sale. In addition, the electronic systems allow the PBM to perform hundreds of edits on the prescription to look for such things as drug interactions, duplicate therapies, overutilization, etc. If any of these edits brings up a flag, the claim can be denied. The systems will alert the dispensing pharmacist as to whether the drug is on formulary or whether there is a generic substitute, and prompt the pharmacist to contact the physician in order to solicit consent to effect a therapeutic switch.

Small or Insurer-Owned PBM CD.

[4] 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 [hereinafter Atlas]. *See also* Large PBM CD (in 2002 there were "approximately 70 PBMs [competing] to manage approximately $161 billion of drug spending"); Richardson 6/26 at 11 (approximately 60 PBMs).

[5] *See* Atlas, *supra* note 4, at 506; Large PBM CD; Small or Insurer-Owned PBM CD; Richardson 6/26 at 11.

Each measure has its own shortcomings, but the market share figures, as well as the documents of almost all of the study participants, describe an industry in which the three large national PBMs (all of which are study participants) are the major players. The documents of several study participants suggest a growth strategy aimed at competing with these three largest PBMs.[6]

Only about 12 PBMs have more than five million covered lives.[7] Three of these 12 PBMs are large, full-service independent PBMs that own and operate mail-order pharmacies (Caremark, Express Scripts, and Medco Health Services). These PBMs cover a combined 190 million lives and manage a combined $80 billion in drug spend.[8] These large PBMs tend to draw their clients from self-insured employers, health plans, HMOs, and labor unions.[9]

Six of the top twelve PBMs are owned by large health insurers, and provide benefits to approximately 40% of covered lives in the United States. Large health insurer-owned PBMs serve primarily members of their medical health plans. Three of these insurer-owned PBMs are study participants.

The final three of the top twelve PBMs are privately held. In addition, there are smaller PBMs owned by retail supermarket and pharmacy chains, as well as many smaller privately held PBMs.[10]

B. Relationships that a PBM Must Establish to Manage Pharmacy Benefits

A PBM must establish a network of retail pharmacies so that consumers with prescription drug insurance can fill their prescriptions without traveling long distances. Often, retail pharmacies compete to be part of the retail pharmacy network for a particular PBM.[11] In addition, PBMs may contract with pharmaceutical manufacturers to obtain various payments as compensation for managing the dispensing of the manufacturer's drug product. Pharmaceutical manufacturers compete to ensure that their products are included on the list of authorized drugs

[6] *See* Large PBM CD; Small or Insurer-Owned PBM CD; Retailer-Owned PBM CD (listed as a strategic goal that it wanted to grow its PBM into a Tier 1 player with 10 million lives by 2006); Small or Insurer-Owned PBM CD (one aspiration is to be "considered a first tier PBM among PBM competitive set" and one risk factor to achieving its strategic goals is that consultants are not promoting [this PBM] as a 1st tier PBM, which could interfere with its ability "to achieve being viewed as a 1st tier PBM"). *See also* Atlas, *supra* note 4, at 506; Richardson 6/26 at 13.

[7] Atlas, *supra* note 4, at 506.

[8] *Id.*

[9] *See* Small or Insurer-Owned PBM CD; Richardson 6/26 at 7.

[10] *See* Richardson 6/26 at 13; Large PBM CD; Small or Insurer-Owned PBM CD.

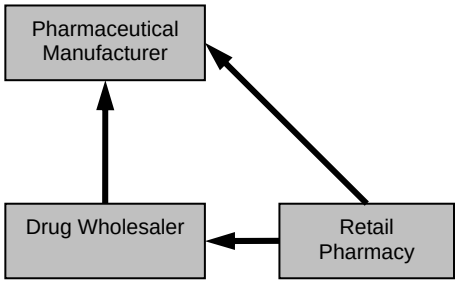
[11] Some PBMs offer their plan sponsor clients a choice of pharmacy networks. One network generally includes a high percentage of all retail pharmacies. The second network is sometimes called the "preferred" network. The preferred network offers a more limited selection of retail pharmacies at which plan members can fill their prescriptions, but the cost to the plan sponsor and/or member generally is lower than the cost for prescriptions filled at a PBM's more inclusive network.

managed by the PBM (the "formulary"). PBMs then package these services together to offer a pharmacy management product to their clients – plan sponsors. Indeed, some call PBMs the "middlemen" among plan sponsors, pharmaceutical manufacturers, and retail and mail-order pharmacies.[12]

1. PBM Relationships with Retail and Mail Pharmacies

Retail pharmacies are on the front line of providing health care services to consumers when the pharmacist fills the consumer's drug prescriptions. Because of the variety of drugs that consumers may request at any given time, retail pharmacies must stock a wide range of brand and generic drugs. They purchase these drug products directly from pharmaceutical manufacturers or from drug wholesalers. The arrows in Figure I-1 show the dollar flows between retail pharmacies and drug manufacturers/wholesalers.

Figure I-1



PBMs must establish networks of retail pharmacies that will fill prescriptions for the plan sponsors' members. Most PBMs contract with 90% to 95% of the retail pharmacies in the regions they serve.[13] Retail pharmacies receive revenue from two sources for filling PBM-administered prescriptions: (a) the consumer (copayment or coinsurance amount); and (b) the PBM (reimbursement of the dispensed drug's ingredient cost plus any dispensing fee associated with filling the prescription, less the copayment). To become part of a PBM's network, retail pharmacies often compete over the discounts they will offer to PBMs on the reimbursement amounts for ingredient costs and dispensing fees for prescriptions that they fill.[14]

The price at which the PBM will reimburse a retail pharmacy for a given drug is stated as a discount from a measure of list price plus a dispensing fee for the pharmacy.[15] For brand drugs, the "average wholesale price" (AWP) as stated by the wholesaler or manufacturer is used

[12] John E.Calfee, Resident Scholar, American Enterprise Institute, Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy (June 26, 2003) at page 46 [hereinafter Calfee 6/26 at relevant page(s)].

[13] Richardson 6/26 at 9.

[14] *See* Small or Insurer-Owned PBM CD.

[15] *See, e.g.*, Small or Insurer-Owned PBM CD (retail composite reimbursement rate is AWP-15% as an average across all pharmacies).

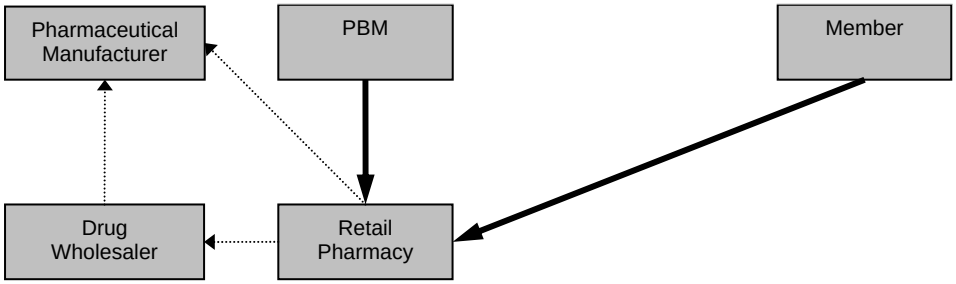
as a basis for the discount. AWP is not the actual price that wholesalers or pharmaceutical manufacturers charge or the amount retail pharmacies pay to acquire drugs; rather it is more like a sticker price in the automobile industry.[16] For example, the price formula might be "AWP minus 12% of AWP plus $2.00."

For generic drugs, the discount is even greater than for brand drugs, *e.g.*, "AWP minus 50% of AWP plus $2.00." Instead of using the AWP for generic drugs, some PBMs use a "maximum allowable cost" (MAC) to reimburse the retail pharmacy. MAC prices for generically equivalent drugs are based on the AWPs of competing generic drug manufacturers. The federal government issues a MAC price schedule (the "Federal Upper Limit" (FUL)) for generic products that have three or more manufacturers or distributors. Some PBMs utilize the FUL schedule, while others calculate a maximum allowable cost based on their own formulae, which utilize the AWPs of competing generic drug manufacturers.[17] Each PBM can have its own MAC list and some even maintain more than one MAC list.[18]

Retail pharmacies may compete over the discounts from the reference price (AWP or MAC) they will offer a PBM depending on the type of plan sponsors and the number of members covered by the PBM. Retail pharmacies generally will offer higher discounts to be in a more exclusive network, because each retail pharmacy will fill a larger percentage of prescriptions if fewer retail pharmacies are in the PBM's network. A PBM may have several networks, which differ in their exclusivity, that it offers its clients.

The bold arrows in Figure I-2 show the dollar flows between the PBM, the retail pharmacy, and a plan member. The lighter arrows show the relationships between the retail pharmacy, drug wholesaler, and pharmaceutical manufacturers already shown in Figure I-1.

Figure I-2



In addition to including retail pharmacies in their pharmacy networks, most PBMs also offer mail-order pharmacy services. The three large independent PBMs (Caremark, Express

[16] CONG. BUDGET OFFICE, PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS: A CBO PAPER 3 (June 2005) *available at* http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf.

[17] DAWN M. GENCARELLI, NAT'L HEALTH POLICY FORUM, AVERAGE WHOLESALE PRICE FOR PRESCRIPTION DRUGS: IS THERE A MORE APPROPRIATE PRICING MECHANISM? 7, 15 (Issue Brief No. 775, 2002) *available at* http://www.nhpf.org/index.cfm?fuseaction=Details&key=412.

[18] *See, e.g.*, Small or Insurer-Owned PBM CD (MAC list contains over 1,200 products and maintains an average discount equal to AWP minus 62%); PBM Interviews.

Scripts, and Medco Health) own the mail pharmacies they use to serve their plan sponsor clients. Small or insurer-owned PBMs and retailer-owned PBMs either own mail pharmacies or contract with other mail-order pharmacies owned by another PBM or retail pharmacy. Some PBMs have used a competitive bidding process to choose the mail-order pharmacy they will use to serve their clients. The bold arrows in Figure I-3 show the dollar flows between PBMs, members, and mail-order pharmacies not owned by the PBM, as well as dollar flows between mail pharmacies and drug wholesalers/pharmaceutical manufacturers.

Figure I-3

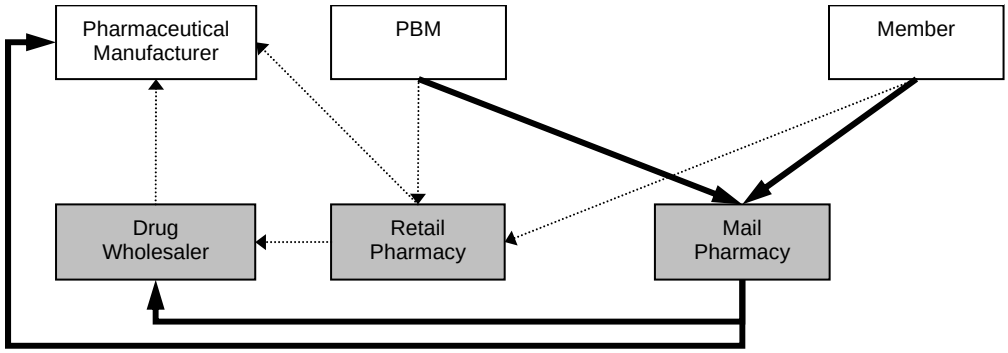


Figure I-3 shows that retail and mail-order pharmacies are often competitors, because both seek to fill the prescriptions of plan sponsors' members.

2. PBM Relationships with Pharmaceutical Manufacturers

PBMs also establish relationships with pharmaceutical manufacturers, who compete to have their drugs placed on a PBM's formulary.[19] A formulary is a list of approved or preferred drugs for the plan.[20] Prescription drugs that are "on formulary" often have lower member copayment amounts, thereby providing incentives to members to seek prescription drugs that are "on formulary" to lower their out-of-pocket costs. Thus, formulary status can drive the sales of a manufacturer's drug products.

Formulary compliance is the extent to which members use drugs on the formulary. The level of formulary compliance demonstrates the ability of the PBM to steer enrollees to drugs on the formulary. PBMs strive for high formulary compliance, because high compliance enables a

[19] Formularies are one way to overcome the fact that consumers with insurance coverage have a low sensitivity to the prices of prescription drugs. *See, e.g.*, CONG. BUDGET OFFICE, HOW THE MEDICAID REBATE ON PRESCRIPTION DRUGS AFFECTS PRICING IN THE PHARMACEUTICAL INDUSTRY 1 (1996) (quoting F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, J. ECON. PERSPEC. (1993)).

[20] Richardson 6/26 at 16. Many plans reimburse members for both formulary and non-formulary drugs, but the formulary informs members, physicians, and pharmacists about the preferred drugs, which are then more likely to be prescribed and dispensed. In addition, some plans also have different copayments for formulary and non-formulary drugs. Other plans only reimburse members for drugs that are on the formulary. *See* PBM Interview.

PBM to show the manufacturers that the PBM can induce use of formulary products and increase their products' market shares.[21]

Most PBMs contract with pharmaceutical manufacturers for payments that are based on inclusion on the formulary or on the particular drug's share of the drug products sold to a plan's members.[22] Pharmaceutical manufacturers use "formulary payments" to obtain formulary status, and/or they use "market-share payments" to encourage PBMs to dispense their drugs, especially in crowded therapeutic classes in which there are many similar 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). PBMs receive payments from pharmaceutical manufacturers even though PBMs do not take physical possession of drug products that are dispensed through retail pharmacies.[23] Industry participants generally refer to these payments as "rebates." This report will use the term "pharmaceutical payment," rather than the term "rebate," because pharmaceutical manufacturers make these payments to PBMs and not to the entity that actually purchased the drug.

PBMs' contracts with pharmaceutical manufacturers also may provide for administration fees, data sharing fees, and promotional programs under which the PBM can earn additional revenues.[24] PBMs are often the central repository of claims data that can be used for studies of utilization trends, prescribing patterns, and outcomes. Some PBMs sell this aggregated, non-identifiable data, or studies based on the data, to pharmaceutical manufacturers.[25] The bold arrow in Figure I-4 shows the dollar flows between the manufacturer and the PBM.

[21] *See* PBM Interview (the ability to drive market share, even if done infrequently, puts pressure on all manufacturers to offer higher payments to prevent the PBM from shifting market share away from them); Anthony Barreuta, Senior Counsel, Kaiser Foundation Health Plan, Inc., Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy (June 26, 2003) at 91 [hereinafter Barreuta 6/26 at relevant page(s)].

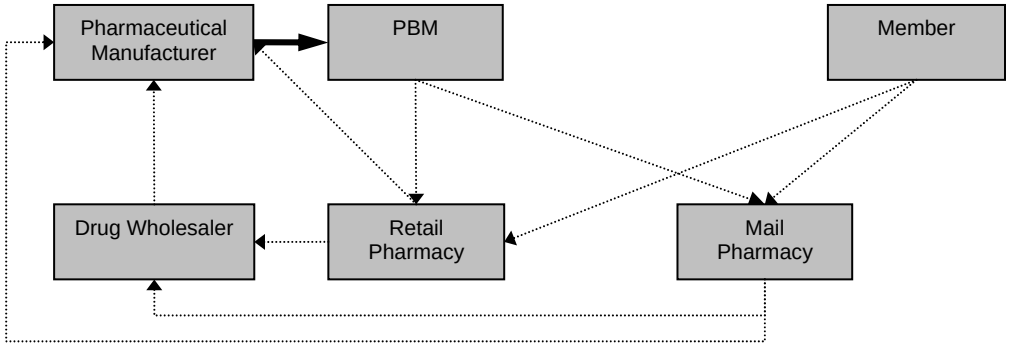
[22] *See* discussion of manufacturer payments, *infra* at Ch. III. *See also* CENTERS FOR MEDICARE & MEDICAID SERVICES, DRAFT INSTRUCTIONS FOR COMPLETING THE MEDICARE PRESCRIPTION DRUG PLAN BID FORM FOR CONTRACT YEAR 2006 33 (Feb. 11, 2005) *at* http://www.cms.hhs.gov/pdps/draftrxbidinstructions.pdf (CMS, in its draft prescription drug bid form instructions, defines a "rebate" as "any price concessions that are provided after sale, as opposed to any price concessions that may have contributed to a lower negotiated ingredient cost at point of sale and that we would expect to be included in the price paid at the point of sale.").

[23] A PBM may take physical possession of drug products if it owns a mail-order pharmacy.

[24] *See* discussion of the various types of contracts that PBMs may have with pharmaceutical manufacturers, *infra* at Ch. III. According to some PBMs, they no longer accept any fees other than formulary and market-share payments, and administrative fees. *See, e.g.*, PBM Interview; Large PBM CD (stated it would no longer take pharmaceutical manufacturers' "ancillary" money).

[25] Small or Insurer-Owned PBM CD (also noting that some PBMs may provide this information to plan sponsors as a "value-added" service).

Figure I-4



3. PBM Relationships with Plan Sponsors

PBMs contract with plan sponsors to provide pharmacy benefit management services to their members. Plans, often with the help of consultants, issue requests for proposals (RFPs) to several PBMs and then evaluate the proposals based on costs and the package of services offered by each bidder. Insurer-owned PBMs often compete for these contracts in addition to offering PBM services to their health plan members.

The RFPs vary depending upon the attributes of the prescription drug insurance coverage that the plans want to provide to their members. For example, some plans may not require members to make copayments for drugs dispensed by network pharmacies, while others may require varying copayments depending on whether the drug is a generic, a brand, or an off-formulary drug and whether it is purchased at a network retail pharmacy, mail-order pharmacy, or out-of-network pharmacy. Plans also consider other factors, including generic dispensing rates, the range of prescription drug choices available to their members, and the price of dispensing fees, drug ingredient costs, and member copayments.[26] In all, plans seek to match PBM services to best meet their objectives in offering pharmacy benefit insurance coverage.[27]

PBMs compete on price and non-price dimensions to serve these varying client needs. One survey of plan sponsors using PBM services showed that the financial terms of the bid (such as the reimbursement rate and dispensing fee paid to pharmacies, the manufacturers' payments to plan sponsors based on formulary drugs utilized, mail-order pricing, and administrative fees) often were the key determinants in the selection of the winning bid.[28] This survey also found

[26] Because of the varied range of client plans, no two PBMs will have the same mix of dispensed drugs.

[27] Thomas M. Boudreau, Senior Vice President, General Counsel, and Corporate Secretary, Express Scripts, Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy (June 26, 2003) at page 65 [hereinafter Boudreau 6/26 at relevant page(s)]; *see also* Barrueta 6/26 at 105.

[28] *See* PRICEWATERHOUSECOOPERS LLP, HEALTH CARE FINANCING ADMINISTRATION, STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT 103-14 (2001), *available at* http://www.cms.gov/researchers/reports/2001/cms.pdf.

that plan sponsors were concerned about non-price dimensions of service, such as benefit design, the extent of the retail network, and the quality of mail-order service.

The Commission collected data on the amounts that PBMs pay to the plan sponsor to help defray the costs of switching to the PBM at the start of a new contract or bonus amounts to obtain or retain the plan sponsor as a customer.[29] The data revealed that large PBMs and retailer-owned PBMs often make these payments, but they usually do not total more than $100,000 per client. There were exceptions. In 2002 and 2003, some PBMs made payments to plan sponsors that ranged between $1.5 and $20 million per client.

The Commission staff's review of PBM contracts with plan sponsors suggested that member satisfaction, dispensing accuracy rates, turn-around time at mail pharmacies, wait time for customer service calls, distance to a network retail pharmacy, and timeliness of management reports are also key factors in any contract.[30] Most PBM-plan sponsor contracts included performance guarantees (*e.g.*, prescription fill time, call center response time, and generic substitution rates) that required the PBM to make specified dollar payments to the plan sponsor if the PBM failed to meet the guarantees.[31]

PBMs often work with plan sponsors to create plan designs with copayments, co-insurance, or deductibles that provide members with incentives to comply with a plan's formulary.[32] Those incentives range from differential copayments to complete denial of coverage for out-of-network or off-formulary purchases. Plan sponsors and PBMs also may negotiate over incentives for enrollees to use mail-order pharmacies for maintenance medications.[33]

The PBM's contract with a plan sponsor covers the amount that the plan sponsor will pay to the PBM for each prescription dispensed at a network retail pharmacy. The PBM's charge to the plan sponsor per prescription is similar in form to the retail pharmacy contract. For brand drugs, it is a discount off AWP plus a dispensing fee and an administrative charge per script, *e.g.*, "AWP minus 10% plus $1.50 plus $0.10." For generic drugs, the charge is similarly calculated, but the discount is usually off of the price specified on the PBM's MAC list.[34] Some PBMs earn revenues and profits through the "spread" between the amount charged to a plan sponsor and the amount paid for the drug product, including a dispensing fee if any, to the retail or mail-order

[29] *See* Special Orders, Item 10, Appendix A.

[30] *See, e.g.*, PBM contracts with plan sponsors.

[31] *See, e.g.*, PBM contracts with plan sponsors. *See also* discussion of the types of generic substitution rate and generic dispensing rate guarantees that a PBM makes with its clients, *infra* at Ch. IV

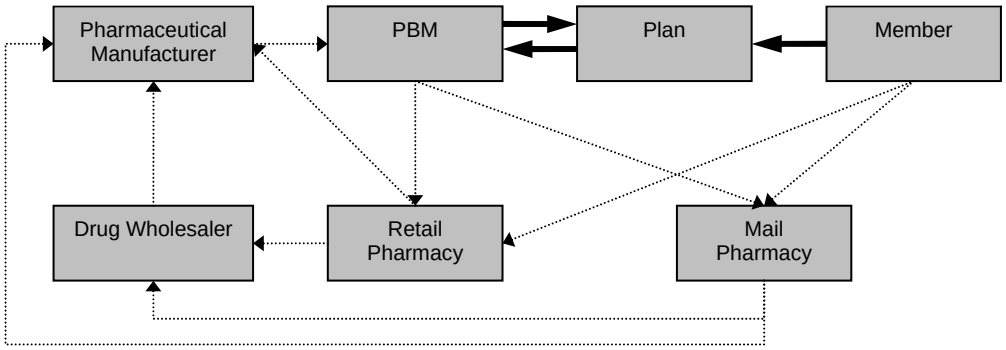
[32] Barrueta 6/26 at 87.

[33] Maintenance drugs are those used for treatment of chronic conditions, *e.g.*, hypertension, diabetes, etc. *See* Retailer-Owned PBM CD (PBMs offer clients greater discounts to use mail).

[34] *See generally* Small or Insurer-Owned PBM CD; Small or Insurer-Owned PBM CD (MAC list contains over 1,200 products and maintains an average discount equal to AWP minus 62%).

pharmacy that dispenses the drug product to the plan member.[35] The bold arrows in Figure I-5 show the dollar flows between plan sponsors, PBMs, and members.

Figure I-5



Plans may contract for other PBM services. Retrospective drug utilization reviews (DURs) analyze physician prescribing patterns to identify physicians who prescribe high cost drugs when lower cost alternatives are available.[36] Concurrent DURs check for drug interactions to minimize adverse reactions, early or late refills, or duplicate therapies.[37] Clinical pharmacy management or disease management offers treatment information to, and monitoring of, patients with certain chronic diseases. One insurer-owned PBM noted that it charges a plan sponsor approximately $1.00 per member per month for such programs and guarantees the plan sponsor $2.00 in drug-spend savings per member per month. The actual savings are averaging $3.00 per member per month. This PBM believes clinical pharmacy management programs will be a significant revenue source for PBMs in the future.[38]

C. The PBM's Tools for Managing Prescription Drug Benefits

PBMs use a variety of tools to manage pharmacy benefits, but the formulary is the centerpiece around which the other tools work. To design formularies, PBMs use an independent pharmacy and therapeutics (P&T) committee comprised of pharmacists and physicians from different specialties. Most P&T committees evaluate the drugs in particular therapeutic categories for clinical effectiveness and safety. In addition to evaluating all drugs currently on a PBM's national formulary, most P&T committees evaluate therapeutic class reviews and new drug monographs compiled from various public and private sources. According to one PBM, its "P&T Committee also considers utilization data, financial

[35] *See* Retailer-Owned PBM CD (*i.e.*, the spread may be the PBM paying a retail pharmacy AWP minus 15% and charging the plan sponsor AWP minus 14% and the spread may differ from client to client and from retail to mail); Small or Insurer-Owned PBM CD ("spreads much higher for generics than branded drugs; For generics, ingredient spread is higher than reimbursement spread").

[36] *See* Richardson 6/26 at 21-22; Retailer-Owned PBM CD.

[37] *See* Richardson 6/26 at 21-22; Retailer-Owned PBM CD.

[38] Small or Insurer-Owned PBM CD.

information such as pricing and rebates, and results from 'net' drug cost modeling to estimate the potential economic impact of formulary changes relative to the current formulary status. Decisions are based, first and foremost, on appropriate care for the member and result from stepwise consideration of the following criteria: safety, efficacy, uniqueness, and net drug cost."[39]

Some P&T committees classify each drug for formulary purposes as "include on the formulary," "exclude from the formulary," or "optional."[40] The P&T committee then ranks the drugs classified as "optional" on clinical effectiveness. Some PBMs claim that the P&T committee does not consider financial information, whereas others may consider the market share of the "optional" drugs and the likely customer reaction if the PBM excludes the drug(s) or prefers certain drugs. P&T committees consider the availability of both generic substitutes and therapeutic alternatives when deciding which drugs should be included in the formulary and where they should be placed within various tiers on the formulary. After the rankings are complete, the PBM decides which drugs to include on its preferred formularies.

A "tiered" formulary is one in which a member's copayment varies by the tier on which the drug is listed. On a typical 3-tier formulary the member's copayment would be the lowest for the first-tier, which includes generic drugs; somewhat higher for the second-tier, which usually includes preferred brand drugs with no generic equivalent; and highest for the third-tier, which includes non-preferred brand drugs or those brand drugs with a generic equivalent.[41] Some plan designs include a fourth tier for drugs not included on the PBM formulary and for so-called lifestyle drugs, *e.g.*, drugs to combat hair loss.[42] The member would pay the entire cost of the fourth-tier drug, but it might be at a discounted price negotiated by the PBM for its members.[43] The ascending rates of the copayments are designed to create an incentive for the enrollee to choose the lowest cost, yet clinically effective, alternative. Similarly, a plan design may include copayment differentials depending on whether the prescription is filled at the mail-order or retail pharmacy.[44] Tiered formularies increased from 29% of covered workers in 2000 to 57% of covered workers in 2002, with three-tier formulary designs dominating.[45]

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[39] Small or Insurer-Owned PBM CD.

[40] *See, e.g.*, Large PBM CD (P&T committee determines "formulary status of drugs, *i.e.*, drugs that must be on, must not be on, or may be on [PBM] formularies; safety and efficacy are primary factors; decisions rest on clinical considerations").

[41] Richardson 6/26 at 19. *See also* Large PBM CDs (discussing scenarios for copayment and coinsurance differentials for various formulary designs and tiers, as well as recommended copayments between generics, brand-name drugs, and non-preferred brand-name drugs); Small or Insurer-Owned PBM CD (discussing various options for tiered formulary designs); PBM contract with plan sponsor.

[42] *See* Richardson 6/26 at 19; Small or Insurer-Owned PBM CDs ("develop and implement 'Exclusions/Lifestyle' drug benefit product – discounts on oral contraceptives, weight loss products, cosmetic drugs, etc." and "Create/support new benefit designs – 4-Tier copays, reference pricing, etc.").

[43] *See, e.g.*, Small or Insurer-Owned PBM CD; Large PBM CD.

[44] *See, e.g.*, Large PBM CD.

[45] Large PBM CD. *See also* Small or Insurer-Owned PBM CD (three-tier formularies are used in

Substantial public information is available about the efficacy of various prescription drugs in each therapeutic class.[46] Based on this and other information, a plan sponsor can decide whether to accept a PBM's national or preferred formulary or to negotiate a custom formulary for its members. The documents of several PBMs indicate that plans can customize certain aspects of a PBM's formulary.[47] The starting point for these formularies, however, is the PBM's national or preferred formulary list developed by the PBM's P&T committee.[48]

PBMs utilize various techniques to ensure formulary compliance, including generic substitution, therapeutic interchange, step-therapy and prior authorization protocols, and reference-based pricing. The latter two are more recent techniques used by PBMs.[49]

1. Generic Substitution

Generic substitution is the dispensing of a bioequivalent generic drug product that contains the same active ingredient(s) as the brand drug and is, among other things, chemically identical to the brand product in strength, concentration, dosage form, and route of administration. Generic substitution generally occurs without prior physician authorization when a consumer presents a prescription for a brand drug and the pharmacist fills the prescription with a generic version of the drug product. Indeed, many states legally require generic substitution when a generic drug is available. In contrast, dispense as written (DAW) orders on prescriptions for brand drugs require the pharmacist to dispense the brand drug for which the prescription is written rather than a generic substitute. With DAW orders, neither pharmacists nor PBMs have the discretion to substitute a generic drug for a brand drug unless they contact, and persuade, the physician and/or patient to allow generic substitution.

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approximately 80% of PBM's business); THE KAISER FAMILY FOUND. & HEWITT ASSOC., CURRENT TRENDS AND FUTURE OUTLOOK FOR RETIREE HEALTH BENEFITS: FINDINGS FROM THE KAISER-HEWITT 2004 SURVEY ON RETIREE HEALTH BENEFITS 27 (Dec. 2004) (58% now have three-tiered plan designs for retirees), *available at* http://www.kff.org/medicare/7194/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=49752.

[46] *See, e.g.*, STRATEGIC HEALTHCARE GROUP, U.S. DEP'T OF VETERANS AFFAIRS, NATIONAL FORMULARY, *at* http://www.vapbm.org/PBM/natform.htm (last updated Aug. 10, 2005); AARP, EFFECTIVE AND SAFE PRESCRIPTION DRUGS, *at* http://www.aarp.org/health/comparedrugs/ (last visited July 18, 2005).

[47] *See, e.g.*, PBM contract with plan sponsor (explicitly acknowledges that customers may use the PBM's National Formulary or a custom formulary); PBM contract with plan sponsor ("Client has the sole discretion and authority to determine the formulary for the plan").

[48] Large PBM CD (P&T Committee is responsible for reviewing the formulary and the rules and guidelines for clinical programs, including: for which condition is the drug safe or effective; should one drug be taken before another; for how long should a particular drug be taken; and how many doses should be dispensed per prescription). *See also* Boudreau 6/26 at 60-64; Barreuta 6/26 at 92.

[49] *See, e.g.*, Small or Insurer-Owned PBM CD (discussing drug protocol management and step therapy); Large PBM CDs; Jesse D. Malkin et al., *The Changing Face of Pharmacy Benefit Design*, 23 HEALTH AFFAIRS 194 (Jan./Feb. 2004).

Because generic drugs are substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs.[50] There are approximately 10,000 brand drugs currently on the market, and approximately 8,000 have generic equivalents.[51] Generic drugs account for nearly 50% of all prescriptions dispensed.

2. Therapeutic Interchange

Therapeutic interchange is the substitution of one drug in a therapeutic class for another drug in the same class.[52] Therapeutic interchange occurs when a pharmacist substitutes a therapeutically equivalent, but chemically distinct, drug product for the drug product specified on the member's prescription. There are two types of interchanges. The first type involves brand drug-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 of therapeutic interchange refers to interchange of a generic version of a therapeutically similar brand drug for the prescribed brand drug (*e.g.*, generic Prozac is dispensed for a prescription for Zoloft).

Prior physician authorization is required before a pharmacist is allowed to interchange one brand-name drug for another.[53] PBMs institute therapeutic interchange programs to encourage plan members to use formulary products or preferred formulary products.[54]

3. Step-Therapy and Prior Authorization

Large PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance.[55] Step-therapy refers to plan designs that will pay for certain more expensive drugs only if a

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[50] *See* John Dicken, Assistant Director for Health Care Issues, U.S. Gen. Accounting Office, Remarks at the Federal Trade Commission and Department of Justice Hearings on Health Care and Competition Law and Policy (June 26, 2003) at page 32 [hereinafter Dicken 6/26 at relevant page(s)]. *See* discussion of generic substitution and dispensing rates, *infra* Ch. IV.

[51] *See* FOOD AND DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (25th ed. 2005), *available at*, http://www.fda.gov/cder/orange/obannual.pdf (commonly known as the "Orange Book").

[52] *See* Large PBM CD (defines therapeutic alternatives as "drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses").

[53] *See, e.g.*, Large PBM CD; PBM Interview; Large PBM CD ("in the case of therapeutic interchange (in which the pharmacist seeks to change the actual drug prescribed), a pharmacist first must contact the prescribing physician to receive permission to switch drugs; only after that permission is secured, may the drug interchange be made").

[54] *See generally* PBM Interview; discussion of therapeutic interchange, *infra* at Ch. V.

[55] *See, e.g.*, Small or Insurer-Owned PBM CD; Large PBM CD (discussing drug protocol management and step-therapy); Malkin et al., *supra* note 49, at 194.

physician first prescribes one or two less expensive prescription or over-the-counter drugs prior to prescribing a more expensive single-source drug from the same therapeutic category. Prior authorization refers to the requirement that the physician or patient receive prior approval from the PBM before certain non-preferred drugs will be reimbursed by insurance.[56] Prior authorization often involves a clinical justification for the use of drugs that are prone to misuse or are especially costly.

If a plan allowed the PBM to institute step-therapy programs, the PBM could require that a physician try two different generic non-steroidal anti-inflammatory drugs prior to prescribing a more expensive branded product such as a Cox-II Inhibitor used for inflammation and associated pain.[57] The PBM could implement a step-therapy program by issuing point-of-service messages that tell the pharmacist that insurance coverage is blocked for certain National Drug Codes (NDCs) or that certain NDCs require prior authorization before the plan will pay for the prescription.[58] Some PBMs are considering step-therapy programs for other therapeutic categories and drugs, including ACE Inhibitors, Proton Pump Inhibitors, Hypnotics, SSRIs, Enbrel (antirheumatic),[59] and non-sedating antihistamines.[60]

4. Reference-Based Pricing

Some PBMs are exploring the use of reference-based pricing, which would cap the amount they will pay for a drug within a specific therapeutic class.[61] According to one PBM, approximately a dozen therapeutic classes, representing 40% of the total amount spent on drugs, are composed of several drugs that are similar in terms of safety and effectiveness, but vary significantly in price. This PBM is developing a reference-based drug formulary that will establish a reimbursement level for each therapeutic class. For example, a member could pay a small copayment for products that are priced at or below the reference price. If a product is more

[56] *See generally* Small or Insurer-Owned PBM CD; Large PBM CD (discussing drug protocol management and step-therapy); Malkin et al., *supra* note 49, at 194 (also noted that private insurers seem to prefer the use of tiered copayments or coinsurance to receive the same result with less irritation to providers and consumers, but, because of certain restrictions in the Medicaid program, Medicaid programs will likely increase their use of step-therapy and prior authorization). The new Medicare drug benefit, however, allows plans to use tiered copayments for different categories of drugs on the formulary. *See* discussion of Medicare drug benefit, *infra* at Sec. IV.

[57] Thus, the plan design would require physicians first to prescribe ibuprofen or naproxen for a patient prior to prescribing Celebrex.

[58] *See, e.g.*, Large PBM CD; Small or Insurer-Owned PBM CD.

[59] *See* Large PBM CD.

[60] Small or Insurer-Owned PBM CD (noted that the business plan assumed the maintenance of $8.8 million in pharmaceutical payments on bundled products, but acknowledged that the probability of losing this $8.8 million in pharmaceutical payments was 80% if the particular drug was not kept on the formulary without prior authorization and 20% if the particular drug was kept on the formulary subject to prior authorization).

[61] *See, e.g.*, Small or Insurer-Owned PBM CD; Small or Insurer-Owned PBM CDs; Small or Insurer-Owned PBM CD; Malkin et al., *supra* note 49, at 194-96 (article also noted, however, that few, if any, major U.S. employers have adopted reference pricing to date).

expensive than the reference price, the member pays the difference between the product and reference prices.[62]

II. PRESCRIPTION DRUGS: INCREASED USAGE AND COSTS

The role of prescription pharmaceutical drugs has changed significantly in the last several decades. Medicines now exist to treat conditions that previously had no treatment or required lengthy hospital stays and/or surgery. These medical breakthroughs have allowed health care providers to employ much less invasive treatments.[63] Advances in science and technology have given researchers more sophisticated knowledge of the root causes of diseases. Scientists can more effectively design medicines to attack specific diseases, resulting in the invention of new medicines.[64]

United States spending on prescription drugs mirrors this changing role. Prescription drug expenditures, which were once a relatively minor component of overall health care, have become a substantial expense to millions of Americans. In 1997, national prescription drug expenditures totaled $75.7 billion, or 6.9% of all national health expenditures. In 2003, prescription drug expenditures had more than doubled to $179.2 billion, or 10.7% of all national health expenditures. These figures reflect an annual increase in prescription drug expenditures of more than 15% for every year from 1998 to 2002,[65] making prescription drugs the most rapidly increasing component of U.S. health care costs.[66] Although the growth in spending for prescription drugs declined to 10.7% in 2003, prescription drug spending continues to increase

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[62] Small or Insurer-Owned PBM CD; *see also* Small or Insurer-Owned PBM CD; Small or Insurer-Owned PBM CD.

[63] PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA (PHRMA), PHARMACEUTICAL INDUSTRY PROFILE 2004: FOCUS ON INNOVATION 10-12 (2004), *available at* http://www.phrma.org/publications/publications//2004-03-31.937.pdf (also noted that "for each additional dollar spent on new medicines, the savings on hospital spending is $4.44", citing to F.R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data From 52 Countries, 1982–2001* (Nat'l Bureau of Econ. Res., Working Paper No. 9754, 2003). *See also* PHRMA, ANNUAL REPORT 2004-2005, *available at* http://www.phrma.org/publications/publications//2004-10-06.1085.pdf; PHRMA, INSIGHTS 2003: HIGHLIGHTS FROM THE PHARMACEUTICAL INDUSTRY PROFILE 3 (2003), *available at* http://www.phrma.org/publications/publications//2003-10-07.892.pdf.

[64] For example, "[p]rotease inhibitors can commute the death sentence that HIV infection once conferred; antipsychotic medications allow many mentally ill persons to live full, productive lives in their communities; and beta blockers can help prevent repeated heart attacks." CHRISTIE PROVOST PETERS, NAT'L HEALTH POLICY FORUM, FUNDAMENTALS OF THE PRESCRIPTION DRUG MARKET 3 (Background Paper, Aug. 24, 2004), *available at* http://www.nhpf.org/index.cfm?fuseaction=Details&key=521.

[65] *See* NAT'L HEALTH STATISTICS GROUP, CENTERS FOR MEDICARE & MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURES TABLES *(Table 2: National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1980-2003), at* http://www.cms.hhs.gov/statistics/nhe/historical/tables.pdf (last modified Jan. 18, 2005).

[66] *See* NAT'L HEALTH STATISTICS GROUP, *supra* note 65; *see also* CONG. BUDGET OFFICE, ISSUES IN DESIGNING A PRESCRIPTION DRUG BENEFIT FOR MEDICARE 3 (2002), *available at* http://www.cbo.gov/ftpdocs/39xx/doc3960/10-30-PrescriptionDrug.pdf.

more rapidly than other components of health care costs.[67]

Substantial increases in drug costs and utilization, as well as population growth, underlie the growth in aggregate prescription drug expenditures. From 2000 to 2004, the average usual and customary retail prices for frequently used drugs rose by about 22%.[68] Drug utilization also rose significantly. For all ages, those who reported using at least one prescription drug during the past month rose from 39% during the 1988-94 time period to 44% during 1999-2000. The increase in multiple drug use among older persons was even greater, from about one-third to one-half over the same period.[69] Indeed, typical seniors now obtain "more than 20 prescriptions a year to improve their health or manage their diseases."[70] Thus, for those people over 65, prescription drug spending was estimated to be about $2,439 per person in 2003.[71]

III. GROWTH OF MAIL-ORDER PHARMACY BUSINESS

Mail-order distribution of prescription drugs has grown dramatically, from 12.7% of all pharmacy sales in 1997 to 17.2% in 2003.[72] In 2003, retail chain drug stores accounted for 42.1% of total pharmacy sales and independent retail pharmacies accounted for 18.8%.[73] In

[67] *See* NAT'L HEALTH STATISTICS GROUP, *supra* note 65; NAT'L HEALTH STATISTICS GROUP, CENTERS FOR MEDICARE & MEDICAID SERVICES, HIGHLIGHTS – NATIONAL HEALTH EXPENDITURES (2003), *at* http://www.cms.hhs.gov/statistics/nhe/historical/highlights.asp (last modified Jan. 11, 2005); Cynthia Smith et al., *Health Spending Growth Slows in 2003*, 24 HEALTH AFFAIRS 185 (Jan./Feb. 2005).

[68] *See* GOV'T. ACCOUNTABILITY OFFICE (GAO), PRESCRIPTION DRUGS: TRENDS IN USUAL AND CUSTOMARY PRICES FOR DRUGS FREQUENTLY USED BY MEDICARE AND NON-MEDICARE ENROLLEES 2 (2004), *available at* http://www.gao.gov/new.items/d05104r.pdf. *See also* John F. Moeller et al., *Looking Inside the Nation's Medicine Cabinet: Trends in Outpatient Drug Spending by Medicare Beneficiaries, 1997 and 2001*, 23 HEALTH AFFAIRS 217, 219 (Sept./Oct. 2004) (reporting an increase in the price per prescription from $42 in 1997 to $53 in 2001, a 26% increase).

[69] *See* NAT'L CENTER FOR HEALTH STATISTICS, U.S. DEP'T HEALTH & HUMAN SERVICES, HEALTH, UNITED STATES 50 (2004), *available at* http://www.cdc.gov/nchs/data/hus/hus04.pdf.

[70] H.R. CONF. REP. NO. 108-391 at 427 (2003), *reprinted in* 2003 U.S.C.C.A.N. 1808, 1810. *See also* Moeller et al., *supra* note 68, at 219 (reporting that among non-institutionalized Medicare beneficiaries prescriptions per user increased from 23 per beneficiary in 1997 to 29 prescriptions per beneficiary in 2001).

[71] *See* CONG. BUDGET OFFICE, ISSUES IN DESIGNING A PRESCRIPTION DRUG BENEFIT FOR MEDICARE 4 (2002). This estimate was based on data from prior years, and includes the total spending per Medicare beneficiary on outpatient prescription drugs not covered under Medicare, regardless of payer. *Id. See also* Fadia T. Shaya et al., *Prescription Drug Spending Trends for the Privately Insured in Maryland, 2000-2001*, 23 HEALTH AFFAIRS 226, 228 (Sept./Oct. 2004) (total spending, including payments from the insurer as well as the patient, on prescription drugs for privately insured persons less than 65 years of age averaged $783/person in one state in 2001).

[72] *Pharmacy: Retail Chains Seek Competitive Advantage*, AMERICAN HEALTH LINE (Dec. 11, 2003). *See also* Retailer-Owned PBM CD (discussing similar trends, but citing to NACDS projections that estimate somewhat higher mail-order share and growth rate projections).

[73] *Drug Chains Make the Most of Opportunities in Retail Pharmacy*, 26 CHAIN DRUG REV. 69 (Aug. 30, 2004). In addition, pharmacies within discount stores accounted for 9.6% of prescription drug sales and pharmacies in supermarkets accounted for 12.3%.

recent years, independent, privately-owned retail pharmacies have experienced a decline in their market share, as retail chain drug stores, food stores, and mass merchandisers have filled an increasing share of all prescriptions.[74]

The mail-order pharmacy channel is growing more rapidly than other pharmacy channels. For example, from 2002 to 2003, mail-order pharmacy sales in dollars increased by 15.5%, while sales in dollars at chain drug stores grew 12.5%.[75] The difference in unit sales growth (as compared to dollar growth) is even more marked – mail-order unit sales were up 8.4%, while unit sales at chain drug stores increased only 1.4%.[76] The retail drug store industry believes that mail-order growth is likely to be even greater in the future.[77]

A. Drug Usage by Members with Chronic Conditions Drives Mail Order Growth

Mail-order pharmacies can be used to obtain prescription drugs that treat chronic illnesses and conditions ("maintenance medications"), but they generally are not suitable for acute illnesses because it usually takes several days for members to receive their drugs.[78] A large PBM noted that one-third of its plan sponsors' members who take maintenance medications used its mail-order pharmacy during the first five months of 2003.[79] This information suggests that even without a large increase in maintenance medication usage, there is a large pool of people who, given the right incentives, may start filling their prescriptions at a mail-order pharmacy. In fact, a "growing trend among employer-based plans is to mandate mail service for long-term prescriptions or to strongly encourage its use through cost-sharing incentives."[80] Although the trend is toward increased use of mail-order pharmacies, some plans administered by PBMs do

[74] PETERS, *supra* note 64, at 17.

[75] CHAIN DRUG REV., *supra* note 73. *See also* Large PBM CD (discussing fact that mail order is the fastest growing channel).

[76] CHAIN DRUG REV., *supra* note 73.

[77] *See, e.g.*, Retailer-Owned PBM CD (noted mail-order sales are outpacing retail prescription drug sales and mail order is gaining 2% of the prescription dollar market share per year and is expected to have a 26% share in 2006. Also noted that mail-order growth is driven by mandatory mail programs, convenience, and low cost; maintenance medications represent 50% to 60% of total U.S. prescriptions and represent a high potential for conversion to mail order).

[78] PRICEWATERHOUSECOOPERS LLP, *supra* note 28 at 8-9, 74, 81. Mail-order drugs are generally shipped by overnight delivery. *Id. See also* Marta Wosinska & Robert S. Huckman, *Generic Dispensing and Substitution in Mail and Retail Pharmacies*, 2004 HEALTH AFFAIRS (Web Exclusive) W409, 411 *at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.409v1.

[79] Large PBM CD.

[80] Atlas, *supra* note 4, at 506; *see also* Retailer-Owned PBM CD (according to a recent Hewitt study, 15% of employers currently use a mandatory mail-order plan, 6% planned to adopt such a plan in 2004, and 48% of employers are considering using a mandatory mail order plan in the future). In this same Retailer-Owned PBM CD, the PBM noted that many retail pharmacies have taken a stand against mandatory mail plans and some are refusing to accept companies and plans that force mandatory mail for chronic medications.

not offer incentives to use mail-order pharmacies. One retailer-owned PBM promoted choice by offering savings for 90-day supplies regardless of whether the prescription was dispensed by a mail-order or retail pharmacy.[81]

B. PBM Services that Plans May Purchase to Increase Mail Pharmacy Usage

Plan designs may include a variety of provisions intended to increase mail-order pharmacy usage, because of the increased convenience and lower prices of many mail-order pharmacies. Those plans that want the greatest control could opt for a design that requires members to refill maintenance medications through a mail-order pharmacy.[82] Conversely, plans could choose to promote mail order but still give members the greatest choice by opting for a design that has a flat dollar copayment that is lower for mail than retail. Those plans that want more balance between choice and cost could opt for a design that provides greater disincentives for retail, such as coinsurance (usually a percentage of the prescription price) at retail and a flat dollar copayment at mail (regardless of the prescription price).

Examples of incentives and disincentives include:

(1) The copayment for a 90-day supply of drugs obtained by mail may be the same or only twice as much as for a 30-day supply from a retail pharmacy, although the 90-day supply provides three times as many doses.[83] Alternatively, a plan could impose a deductible for retail prescriptions only.[84]

(2) A plan could impose different limits on the number of days supply of medication (*e.g.*, 30 at retail and 90 at mail).

(3) A plan could set various multiples of the retail copayment to be applied to mail prescriptions. For example, if the plan sponsor opted for a two-tier formulary, the mail copayment for a 90-day supply (versus 30 days at retail) could be 1.5 and 2.5 times the retail copayment, and for a three-tier formulary, the mail copayment would be 1.5, 2.0, or 2.5 times the retail copayment, depending on the formulary tier under which the medication was covered.[85]

(4) A plan could limit the number of retail fills and require that the member switch to mail order or could designate specific pharmaceuticals that must be refilled at a

[81] *See, e.g.*, Retailer-Owned PBM CDs.

[82] Large PBM CD (discussing effective retail and mail plan designs).

[83] PRICEWATERHOUSECOOPERS LLP, *supra* note 28, at 56. *See also* GEN. ACCOUNTING OFFICE, EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 18 & tbl.3 (2003), *available at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196 (health plans vary in the design of their copayments, but mail order generally has a lower copayment).

[84] Large PBM CD.

[85] Large PBM CD (discussing effective retail and mail plan designs).

mail-order pharmacy after the first retail fill.[86]

Some health plans will reimburse their members for maintenance medications only if the members fill their prescriptions through a mail-order pharmacy. The United Auto Workers (UAW) plan is one such plan.[87] One source estimated that approximately 20% of large employers have implemented a mandatory mail-order program for employees.[88]

IV. MEDICARE PRESCRIPTION DRUG BENEFIT

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a new voluntary prescription drug benefit.[89] The Centers for Medicare and Medicaid Services (CMS) explained the significance of adding voluntary prescription drug coverage to Medicare in its final regulations to implement this law:

> The addition of outpatient prescription drugs to the Medicare program reflects the Congress' recognition of the fundamental change in recent years in how medical care is delivered in the U.S. It recognizes the vital role of prescription drugs in our health care delivery system, and the need to modernize Medicare to assure their availability to Medicare beneficiaries. . . . All organizations offering drug plans will have flexibility in terms of benefit design, including the authority to establish a formulary to designate specific drugs that will be available, and the ability to have a cost-sharing structure other than the statutorily-defined structure, subject to certain actuarial tests.[90]

Congress required that the Medicare prescription drug benefit be implemented by private

[86] Small or Insurer-Owned PBM CD.

[87] *See* James Frederick, *Drug retailers reeling in Michigan as employers elsewhere eye mail*, 25 DRUG STORE NEWS 3 (Nov. 17, 2003); *Pharmacies seek changes in UAW contract provisions; United Auto Workers*, 25 CHAIN DRUG REV. 45 (Nov. 24, 2003); Barbara Martinez, *Generic Drugs By Mail Can Be a Raw Deal*, Wall Street Journal Online (Feb. 15, 2005), *at* http://online.wsj.com/article_print/0,,SB110843502061854868,00.html (Noting that IBM, Southwest Airlines, and Citigroup, as well as "numerous states and municipalities, have started mandatory-mail programs in recent years" and that a "survey by consultant Hewitt Associates found that 22% of employers will have mandatory mail plans in place this year, with another 51% considering such programs." This article also reported the prices of several individual generic drugs available to GM workers at mail, and suggested that the health plan pays more at mail than it would at retail. GM and Medco both responded that it was not fair to look at individual drugs for price comparisons and that GM was getting a good deal in the aggregate.) *See also* Atlas, *supra* note 4, at 506. *See also* Appendix D for an analysis of cash prices to owned mail-order prices.

[88] Retailer-Owned PBM CD (discussing the mail-order pharmacy business, an analysis of the industry, and possible opportunities for this Retailer-Owned PBM and citing to a June 2003 Citigroup Smith Barney Healthcare Distribution & Technology Report and a Dec. 2002 Kaiser-Hewitt Study on Retiree Benefits). According to the most recent Kaiser-Hewitt Report, "94 percent of plans offer both retail and mail-order coverage . . . [and a]mong employers that offer drug benefits, 21 percent require enrollees to use mail-order." KAISER FAMILY FOUND., *supra* note 45, at 27.

[89] Pub. L. No. 108-173, tit. XI, 117 Stat. 2066 (2003).

[90] 70 Fed. Reg. 4194, 4197 (Jan. 28, 2005).

sector health care insurers[91] so that competition could ensure that enrollees receive low prices for prescription drugs.[92] Congress, as well as CMS, anticipates that PBMs will help administer the benefit and that they will use established commercial practices and techniques, such as the ones discussed above, to manage the drug benefit.[93]

A. Selection of PDP Providers

The MMA authorized CMS to develop a bidding system in which potential prescription drug plan (PDP) sponsors would seek to offer prescription drug insurance to Medicare enrollees. To ensure all senior citizens are covered, CMS divided the United States into 34 geographic areas, in each of which it seeks to have at least two different PDP sponsors offer full risk plans to Medicare enrollees.[94] If this process does not result in two entities offering "full risk" plans to eligible enrollees in the geographic area, the MMA contains backup provisions to ensure that at least two PDPs are offered to senior citizens.[95]

The MMA requires potential PDP sponsors to submit bids that "reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a … eligible individual with a national average risk profile …."[96] The bid must include all costs the plan estimates it will incur in each PDP region to provide basic and supplemental benefits, including administrative costs and return on investment.

The MMA authorized CMS to review, negotiate, and approve PDP sponsors for each region based on an applicant's qualifications and bid submission.[97] CMS must consider various factors, including whether the bid reasonably and equitably reflects the plan's revenue

[91] *See* 42 U.S.C. § 1395w-112 (2004).

[92] 70 Fed. Reg. 4194, 4244 (Jan. 28, 2005). *See also* Small or Insurer-Owned PBM CD (summarizing the Medicare prescription drug benefit and noting that the drug benefit utilizes "a more market-based approach that is consistent with the way plans do business in the commercial sector").

[93] *See, e.g.*, 70 Fed. Reg. 4509-10 (Jan. 28, 2005) (Regulatory Impact Statement)); Atlas, *supra* note 4, at 504.

[94] A PDP plan sponsor is a full risk plan if it accepts the level of financial risk specified in the MMA. Even in that case, the PDP would not bear all of the risk for cost over-runs or under-runs, but rather it would share some of that risk with the government through reinsurance and other mechanisms specified in the MMA.

[95] There are three possible types of plans – full risk, limited risk, and fallback plans – that can offer services in each of the 34 geographic areas. *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,544-46, 4,575-77 (Jan. 28, 2005) (to be codified at 42 C.F.R. pt. 423, subpt. F (full and limited risk plans), subpt. Q (fallback plans)).

[96] Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,544 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.265 (c)).

[97] *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,544-45 (Jan. 28, 2005) (to be codified at 42 C.F.R. §§ 423.265 (c) and 423.272).

requirements and has actuarial support, and whether the plan design (such as the formulary and utilization management tools, including drug exclusions and tiered copayments) is fair and does not discourage enrollment by certain eligible enrollees.[98] Congress authorized CMS to approve as many PDP providers in an area as meet these qualifications.[99]

B. MMA Requirements for Pharmaceutical Payments

Because the MMA anticipates that competition among PDP providers will ensure competitive pricing, CMS does not specify the amounts or percentages of pharmaceutical payments that should be passed through to Medicare enrollees.[100] CMS anticipates that each PDP's bid will provide for a significant percentage of pharmaceutical payments passed through to Medicare beneficiaries, so that the overall bid is competitive. CMS does specify, however, the types of payments that must be passed through to Medicare for fallback plans (which assume no risk and are not part of the regular bidding process).[101] Regardless of the pass-through for purposes of determining price to the enrollee or Medicare, all PDP sponsors must provide CMS with information concerning all price concessions they receive from manufacturers, including a confidential accounting of how they are used.[102]

C. MMA Plan Design Requirements

The MMA also required that each PDP contain certain features regarding, for example, formulary development, formulary drugs, and the scope of the retail pharmacy network. CMS regulations require that a PDP's P&T committee[103] develop the formulary and include within each therapeutic category at least two drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs. CMS

[98] *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,545 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.272).

[99] *See id.* (to be codified at 42 C.F.R. § 423.272(c)).

[100] 70 Fed. Reg. 4244-45; 4393 (Jan. 28, 2005). Moreover, the MMA prohibited prices charged to Medicare from affecting Medicaid "best price" rules. *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,536 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.104(g)(2) ("Prices negotiated with a pharmaceutical manufacturer, including discounts, subsidies, rebates, and other price concessions, for covered Part D drugs . . . are not taken into account in establishing Medicaid's best price . . . .")).

[101] *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,575-77 (Jan. 28, 2005) (to be codified at 42 C.F.R. pt. 423, subpt. Q).

[102] *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,536 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.104(g)(3) ("A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers . . . .").

[103] The majority of members on the P&T committee must be practicing physicians and/or practicing pharmacists, and at least one physician and one pharmacist must be independent of the PDP sponsor, plans, and pharmaceutical manufacturers. The P&T committee also must include a practicing physician and practicing pharmacist who are experts in the care of elderly or disabled individuals. *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,537 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.120(b)(1)).

explained that not all drugs must be on a PDP sponsor's formulary.[104] If a category or class includes only one drug, then only that one must be on the formulary.[105] The formulary must also "include adequate coverage of the types of drugs most commonly needed by Medicare enrollees, as recognized in national treatment guidelines."[106]

The final regulations set forth the acceptable distances within which all plan beneficiaries must live to a network pharmacy, adjusted for urban, suburban, and rural areas. For example, at least 90% of Medicare beneficiaries, on average, must live within 2 miles of a retail network pharmacy in urban areas served by the PDP and within 5 miles in a suburban area; 70% of beneficiaries must live within 15 miles in a rural area.[107] In addition, the MMA allows Medicare beneficiaries to fill prescriptions at a retail pharmacy rather than through a mail-order pharmacy, but they could be charged more for doing so.[108]

[104] 70 Fed. Reg. at 4228-29 (Jan. 28, 2005).

[105] A PDP plan also may include only one drug in a particular category or class if it demonstrates, and CMS approves, "that only two drugs are available in that category or class" and "that one drug is clinically superior to the other drug in that category or class . . . ." Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,538 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.120 (b)(2)(ii)).

[106] *See id.* (to be codified at 42 C.F.R. § 423.120 (b)(2)(iii)). CMS requested that the U.S. Pharmacopoeia (USP) develop a model set of guidelines that consists of a list of drug categories and classes that may be used by PDP sponsors to develop formularies for their prescription drug coverage. The USP model guidelines are available at: http://www.usp.org/drugInformation/mmg/. If a PDP sponsor's formulary is consistent with this formulary, then the categories are presumed acceptable. In the bidding process, CMS also will review an applicant's formulary structure, including: tiered cost-sharing structures, utilization management processes, P&T committee utilization and structure, and the exceptions and appeals processes to ensure a comprehensive benefit. *See* 70 Fed. Reg. at 4258-59.

[107] *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,537 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.120(a)(1)).

[108] 70 Fed. Reg. at 4253. CMS's final regulations also require sponsors to permit plan enrollees to receive benefits, which may include a 90-day supply of covered drugs, at any of its network pharmacies that are retail pharmacies. *See* Voluntary Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,525, 4,537 (Jan. 28, 2005) (to be codified at 42 C.F.R. § 423.120(a)(10)).

CHAPTER II RETAIL AND MAIL-ORDER PHARMACY PRICING OVERVIEW

Congress requested that the Commission assess the differences in payment amounts incurred by plans and their members for prescription drugs dispensed by mail-order pharmacies owned by PBMs compared to both not-owned mail-order pharmacies and retail pharmacies. This chapter provides an overview of average prices that PBMs charge their plan sponsor clients for prescription drugs dispensed through retail and mail-order pharmacies.[1]

The data obtained by the Commission showed that:

- For large PBMs, average total 2002 and 2003 prices (paid by plan sponsors and their members) at owned mail-order pharmacies typically were lower than at mail-order pharmacies not owned by the large PBMs. Retailer-owned PBMs charged lower total average prices for generic and multi-source brand drugs, but not for single-source brand drugs, at their owned mail-order pharmacies compared to not-owned mail-order pharmacies in 2002 and 2003.

- 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.

Background

The Commission collected 2002 and 2003 price information for three categories of drug products (single-source brand (SSB), multi-source brand (MSB), and generic (G) drugs) from each study participant. 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.[2]

This chapter discusses the differences in 2002 and 2003 average member and plan drug prices 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.[3] The chapter also compares the prices that stand-alone retailers charge customers with insurance versus customers without insurance that pay cash for the entire prescription.

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

[2] *See* FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS xii, xvi (25th ed. 2005), *available at* http://www.fda.gov/cder/orange/obannual.pdf.

[3] All of the PBM data in this chapter relate to plans in which the PBM manages the plan sponsor's mail and retail pharmacy benefit ("integrated benefit plans").

One complexity in any comparison of pharmaceutical prices is that PBMs do not necessarily use the same set of reference prices to charge their plan sponsor clients. The price provisions in the PBM-plan sponsor contracts that the Commission obtained generally state the plan sponsor's price for the drug as a discount from a measure of the drug's wholesale price plus a dispensing fee for the pharmacy. For example, the price formula for a brand drug might be "AWP - 10% of AWP + $2.00." For brand drugs, the "average wholesale price" (AWP) as stated by the wholesaler or manufacturer is used as a basis for the discount. AWP is not the actual price that wholesalers or pharmaceutical manufacturers charge or the amount retail pharmacies pay to acquire drugs; rather it is more like a sticker price in the automobile industry.[4]

For generic drugs, the discount is much larger than for brand drugs, *e.g.*, "AWP - 50% of AWP + $2.00." Some PBMs use a "maximum allowable cost" (MAC), instead of discounted AWP, to reimburse the retail pharmacy. MAC prices are a schedule of pricing for generically equivalent drugs based on the AWPs of competing generic drug manufacturers. The federal government issues a MAC price schedule for generic products that have three or more manufacturers or distributors. PBMs sometimes use this MAC price schedule, and sometimes calculate a maximum allowable cost based on their own formulae, which also use the list AWPs of competing generic drug manufacturers.[5] Each PBM can have its own MAC list, and some PBMs maintain more than one MAC list.[6]

As a result of these differences in the referenced prices to which discounts are applied among plan sponsor contracts, it is difficult to know which prices are actually lower than others. For example, a large discount off a high reference price for one plan sponsor may not result in a lower total price than a small discount off a lower reference price for another plan sponsor. To avoid this problem, the Commission collected data that showed the actual prices paid by plan sponsors and members and compared those prices across different dispensing channels within a PBM category. The price data used by the Commission include 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 example, some plan sponsors may forgo pharmaceutical payments in exchange for a larger discount on the drug ingredient costs and lower or no

[4] CONG. BUDGET OFFICE, PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS, A CBO PAPER 3 (June 2005). In addition, manufacturers can assign different AWPs for each drug based on the package size in which they sell the drug to a pharmacy. Sales of drugs with large package sizes often have lower AWPs than the AWP of the same drug with a smaller package size, just as products in large package sizes may have lower prices per unit at a grocery store.

[5] DAWN M. GENCARELLI, NAT'L HEALTH POLICY FORUM, AVERAGE WHOLESALE PRICE FOR PRESCRIPTION DRUGS: IS THERE A MORE APPROPRIATE PRICING MECHANISM? 15 (Issue Brief No. 775, 2002), *available at* http://www.nhpf.org/index.cfm?fuseaction=Details&key=412.

[6] Some PBM contracts with plan sponsors explicitly state that the PBM has multiple MAC lists used for generic pricing and that the PBM can choose which list it will use with a particular plan sponsor.

dispensing fees.[7] Other plan sponsors may obtain a high percentage of pharmaceutical payments related to drugs dispensed to their members, but also pay higher dispensing fees and receive lower discounts on the drug ingredient costs.[8] For purposes of this report, the phrase "total price" equals the sum of "member price" and "plan price." Analysis of 2002 and 2003 total price data showed that plans and their members paid substantially less for generic drugs than for brand drugs – at both mail-order and retail pharmacies, regardless of ownership.

This aggregate data is not well suited for price comparisons between mail and retail prices because the prescription size and drug mix differ substantially between the two dispensing channels. 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). Moreover, the mix of drugs dispensed varies substantially across dispensing channels. Thus, the Commission collected claims data to account for these factors.

After controlling for prescription size and drug mix differences, mail prices are typically lower than retail prices. 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.

* * * * *

This chapter first examines the different size prescriptions that are dispensed at retail and mail through plans administered by PBMs, and by stand-alone retail pharmacies generally. Second, the chapter assesses differences in average retail and mail prescription prices for three drug types (SSB, MSB, and G) and compares these prices at mail-owned pharmacies and mail-not-owned pharmacies. The chapter then compares differences in retail and mail prices for a common basket of drugs and prescription sizes. Finally, the chapter reviews the variation in contractual terms that plan sponsors have used to obtain favorable mail pricing for themselves and their members.

I. PRESCRIPTION SIZES DIFFER AT RETAIL AND MAIL-ORDER PHARMACIES

The average prescription size differs substantially between the retail and mail dispensing channels. Several factors may account for this difference. First, drugs for the treatment of acute

[7] *See* PBM contract with plan sponsor (in this contract, the PBM keeps all pharmaceutical payments but charges the plan sponsor no administrative fees). *See also* PBM contract with plan sponsor (this contract did not address the sharing of pharmaceutical payments, but the discounts off of AWP at both mail and retail were among the largest of any plan sponsor contract reviewed).

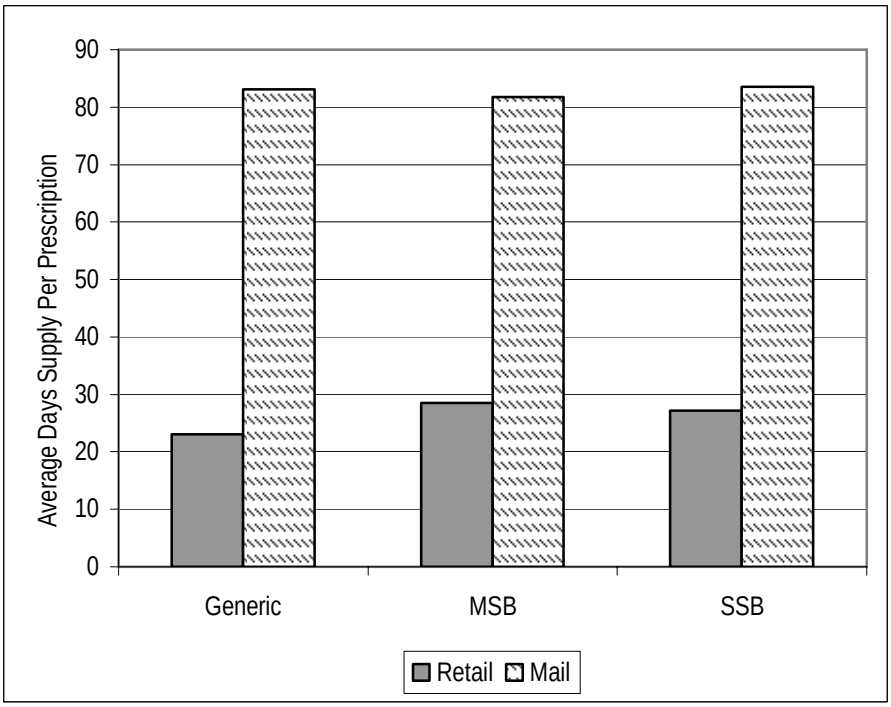
[8] *See, e.g.*, PBM contract with plan sponsor (client obtains 100% of pharmaceutical payments, but there is a $0.10 fee per eligible claim and a $2.00 dispensing fee and lower discounts at mail – 16% for brand and 40% for generic drugs).

medical conditions generally are taken for a limited period of time. For example, a prescription for antibiotics to treat an infection usually will be for 7 to 14 days. Such prescriptions generally are dispensed by retail pharmacies, not by mail-order pharmacies. Second, plan sponsors often allow a larger quantity of a drug to be dispensed through mail-order pharmacies than through retail pharmacies.

A. Mail Prescriptions Are Typically Three Times as Large as Retail Prescriptions

Figure II-1 shows the weighted average number of days supply per retail and mail prescription for each drug type for all of the study participants in 2002 and 2003.[9] The data show days supply dispensed were approximately three times as large for mail prescriptions as for retail prescriptions.

Figure II-1. Average Days Supply per Prescription – Retail vs. Mail Prescriptions



In addition, Figure II-1 highlights that retail prescriptions for generic drugs were, on average, 22 or 23 days, and prescriptions for brand drugs were, on average, 26 or 27 days. Thus, the number of days dispensed in retail prescriptions was approximately 15 percent smaller for generic drugs than for brand drugs. Average prescription size through mail-order pharmacies

[9] "Days supply dispensed" is not a precise measure of quantity. One individual may take two pills of a particular drug per day and another person may take only one pill of the same drug per day. Thus, the same 60 pill bottle could be either a 30-day supply or a 60-day supply. Nonetheless, days supply represents the most workable measure of the size of a prescription when aggregating across various drug forms (*e.g.*, pills, eye drops, transdermal patches, etc.).

was roughly the same for all types of drugs (G, MSB, SSB). Average prescription size through retail and mail-order pharmacies did not vary on other dimensions – *e.g.*, between different types of PBMs, between pharmacies that are owned or not owned by the PBM, or between 2002 and 2003.

Retail and mail-order prescription size differences are likely relevant to cost differences between mail and retail. Some costs to dispense prescriptions vary with the size of the prescription, and some do not. Obviously, it costs a pharmacy more to acquire 90 pills from a manufacturer or wholesaler than it does to acquire 30 of the same pills. Dispensing a bottle of 90 pills, however, likely requires not much more of a pharmacist's or cashier's time, and uses the same infrastructure; all 90 pills may be placed in the same bottle. Thus, a prescription for 90 pills may not cost a pharmacy three times as much to dispense as one for 30 pills. In other words, there are economies of scale in dispensing large prescription sizes. For the same reason, the price per tablet for aspirin and other over-the-counter (OTC) drugs often decreases dramatically as the quantity purchased increases.

B. Length of Mail Prescriptions Dispensed by Stand-Alone Retailers

Table II-1 presents average days supply per prescription for the three drug types dispensed for customers with insurance coverage provided by plan sponsors and for customers without insurance that paid cash for the entire prescription for 2002 and 2003 at stand-alone retail pharmacies. Because some of these stand-alone retailers also own and operate mail pharmacies, Table II-1 also includes mail-order pharmacy data.

Table II-1. Stand-Alone Retailer Data: Average Days Supply per Prescription

Channel	Payer Type	G	MSB	SSB
Retail	Insurance	23	26	27
Retail	Cash	24	29	26
Mail	Insurance	86	87	87
Mail	Cash	78	74	67

Two observations stand out from Table II-1. First, *retail* prescription sizes were similar for customers with insurance and those who paid cash. These prescription sizes mirrored the results presented in Figure II-1. Second, *mail* prescription sizes for all three drug types were larger if the customer had insurance coverage than if the customer paid cash for the entire prescription.

II. COMPARISON OF PLAN AND MEMBER PRICES FOR MAIL AND RETAIL DISPENSING

To assess differences in payments by plans and their members for prescription drugs dispensed through mail-order and retail pharmacies, the Commission collected information on actual payments made by plans and their members for three drug types (SSB, MSB, and G).[10]

[10] *See* Item 8 in the PBM and Stand-Alone Retailer Special Orders, Appendices A and B.

These data enabled the Commission staff to calculate each study participant's average price per prescription, by drug type, dispensing channel, and ownership of that channel for the years 2002 and 2003. The following three sections discuss how in 2002 and 2003 (a) overall generic drug prices were substantially lower than brand drug prices, regardless of whether the generic drugs were dispensed through mail-order or retail pharmacies; (b) large PBMs charged lower total average prices at their owned mail-order pharmacies compared to total average prices at not-owned mail-order pharmacies; and (c) retailer-owned PBMs charged lower total average prices for generic and MSB drugs, but not SSB drugs, at their owned mail-order pharmacies compared to not-owned mail-order pharmacies.

A. Generic Drug Prices at Mail and Retail Were Significantly Lower than Brand Drug Prices in 2002 and 2003

Figure II-2 presents the average total prices that plan sponsors and members paid to PBMs in this study for retail and mail prescriptions (without adjusting for prescription size differences), by drug type, for 2002 and 2003. Generic drugs were substantially less expensive than brand drugs. The data in Figure II-2 show that the average total price for generic drug prescriptions was less than half the price of multi-source brand drugs (which generally have generic equivalents) and approximately one-fourth the price of single-source brand drugs.

Figure II-2. PBM Data: Average Total Retail and Mail Prescription Prices
(No Adjustments for Different Retail and Mail Prescription Sizes)

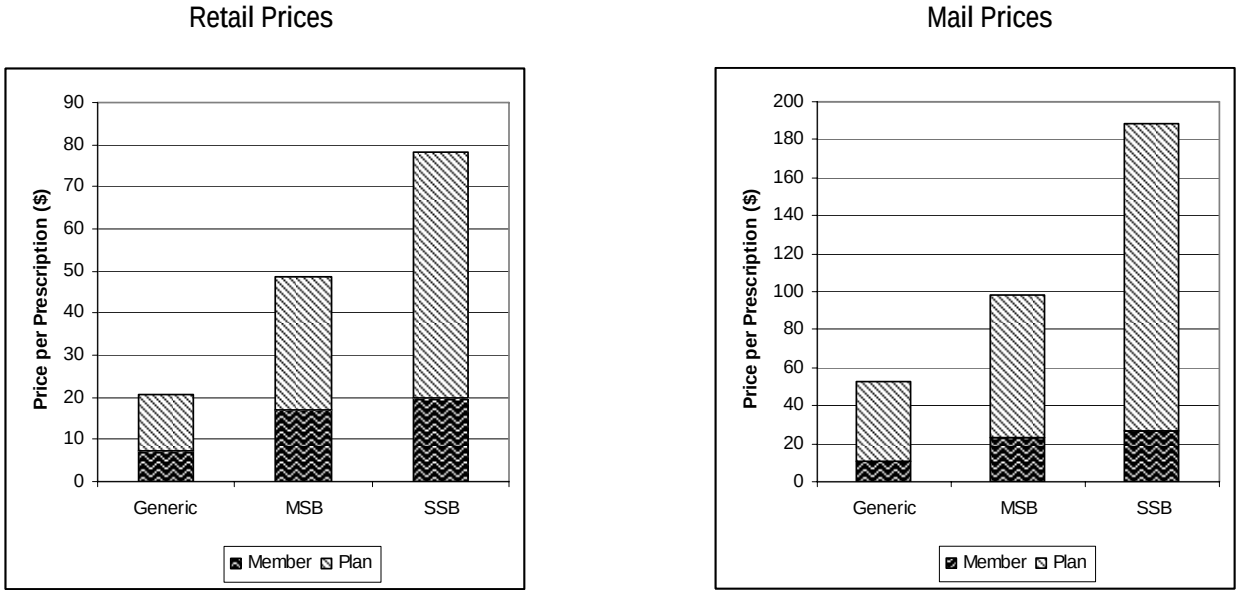


Table II-2 breaks out the data shown in Figure II-2 to show average plan and member prices for retail and mail prescriptions (*without* adjusting for the fact that mail prescriptions are generally *three* times the size of retail prescriptions) in the three different drug categories. The plan sponsor and the PBM typically decide how to divide the price of a prescription between the

plan and its members, based upon the benefit coverage the plan sponsor wishes to provide. Thus, differences in average *member* prices between retail and mail may reflect decisions that plan sponsors make about the purchasing incentives they wish to give their members. Although the decision of a plan sponsor about how to divide the cost of pharmacy benefits between itself and its members is not a concern of this study, member prices are of interest because they provide an understanding of the incentives that influence members' decisions.

Differences in member prices for different drug types may provide members with incentives to purchase the drug with the lower price. Table II-2 suggests that plan designs, on average, maintain a member price differential between generic and brand drugs of at least $10 at retail and $12 at mail.

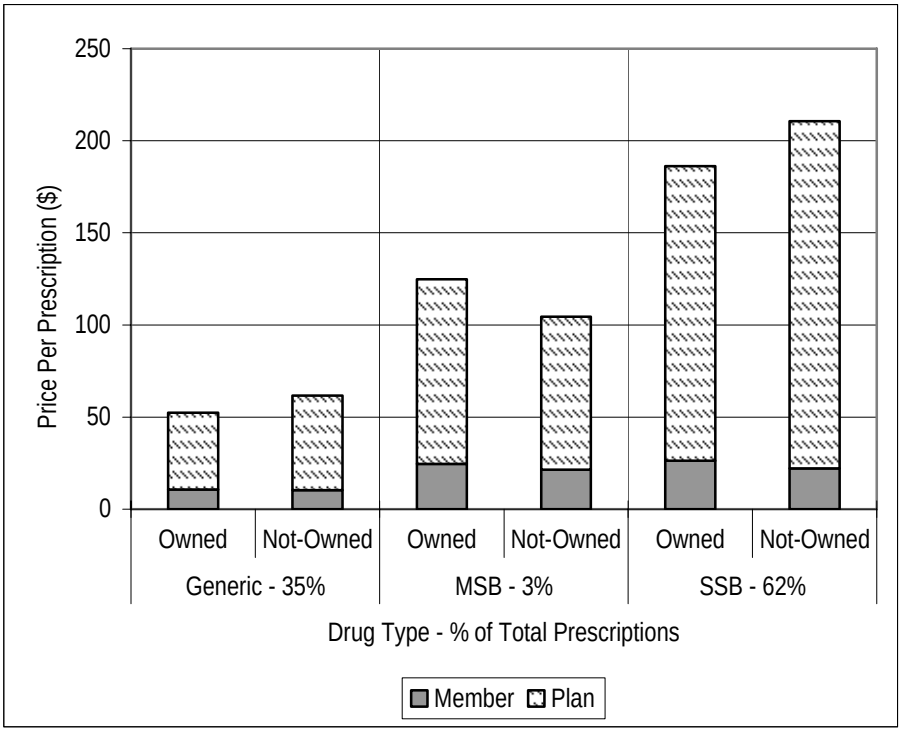
Table II-2. PBM Data: Average Plan and Member Prices for Retail and Mail Prescriptions for 2002 and 2003 (No Adjustments for Different Retail and Mail Prescription Sizes)

Drug Type	Retail Prices			Mail Prices		
	Plan	Member	Total	Plan	Member	Total
G	$13.30	$7.40	$20.71	$41.49	$10.92	$52.41
MSB	$31.31	$17.14	$48.45	$75.86	$22.77	$98.63
SSB	$58.57	$19.69	$78.26	$161.34	$26.96	$188.30

B. Prescription Prices that Large PBMs Charged Plan Sponsors and Members Typically Were Lower at Their Owned Mail-Order Pharmacies than at Not-Owned Mail-Order Pharmacies in 2002 and 2003

Figure II-3 presents the large PBM study participants' average total price for mail prescriptions by drug type and by ownership of the mail-order pharmacy for 2002 and 2003. All five large PBMs own mail-order pharmacies, and three of these five large PBMs also reported data from mail-order pharmacies they did not own. Some plan sponsors require that the PBM use an unaffiliated mail-order pharmacy instead of one they own. Comparing the prices of the same drug type attempts to isolate the relationship between PBM ownership and the price of mail prescriptions. Moreover, because the comparisons in Figure II-3 (and Figure II-4) are between owned mail and not-owned mail drug prices, the data did not have to be adjusted for differences in prescription size or drug mix because all the data is from the mail channel.

Figure II-3. Total Average Price per Mail Order Prescription for Large PBMs



The data showed that average 2002 and 2003 total prices for G and SSB drugs at PBM-owned mail-order pharmacies were lower than prices paid at mail-order pharmacies not owned by the large PBMs (*i.e.*, $53.65 vs. $61.69 (G); $190.50 vs. $210.70 (SSB)). These two drug types accounted for 97% of the prescriptions dispensed.[11] At not-owned mail-order pharmacies, plan sponsors paid higher prescription prices on average – members did not.

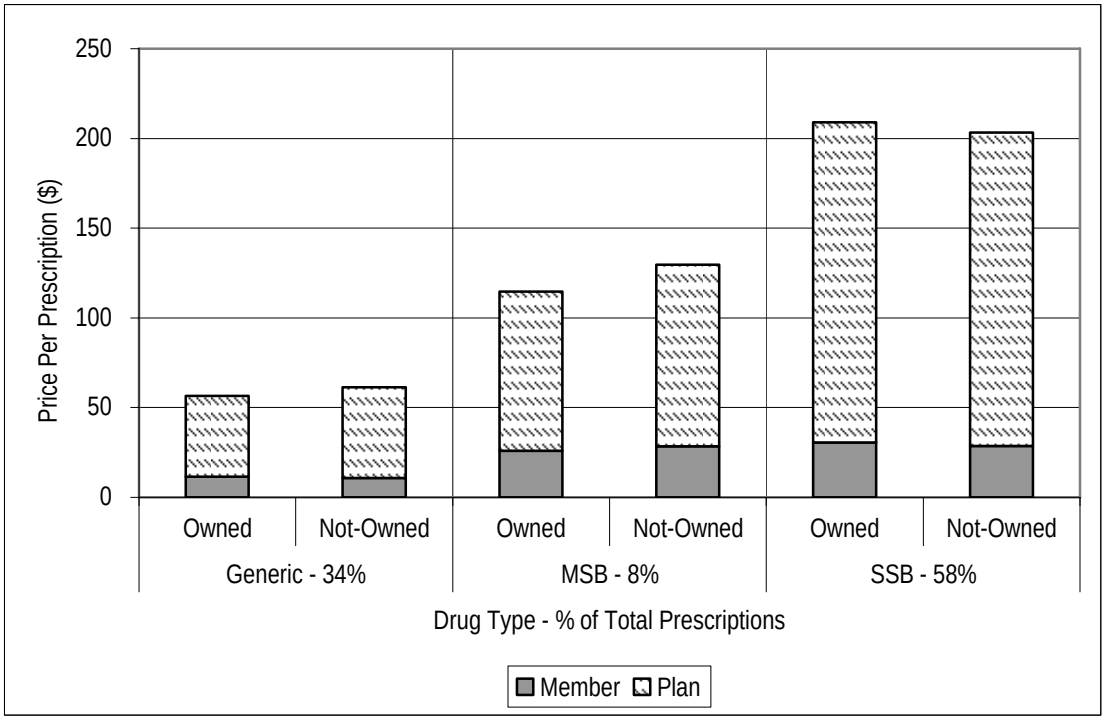
C. Prescription Prices that Retailer-Owned PBMs Charged Plan Sponsors and Members Typically Were Lower for Generic and MSB Drugs, but not SSB Drugs, at Their Owned Mail-Order Pharmacies than at Not-Owned Mail-Order Pharmacies in 2002 and 2003

Figure II-4 shows total 2002 and 2003 mail-order pharmacy average prices for retailer-owned PBMs. Four retailer-owned PBMs reported data for owned mail-order pharmacies, and three of these retailer-owned PBMs reported information for those mail-order pharmacies that they did not own. Average total prices for G and MSB drugs were lower by approximately $5 and $15 per prescription, respectively, at owned mail-order pharmacies than at not-owned mail pharmacies. However, average total prices for SSB drugs were higher by approximately $6 per prescription at owned mail-order pharmacies than at not-owned mail-order pharmacies. Generic,

[11] The relative comparisons between owned and not-owned mail-order pharmacies did not change substantially when the Commission staff recalculated the large PBM average prices in Figure II-3 based only on the three large PBMs that reported data from both types of mail-order pharmacies.

MSB, and SSB drugs accounted for 34%, 8%, and 58% of drugs dispensed in 2002 and 2003, respectively.[12]

Figure II-4. Total Average Price per Mail Order Prescription for Retailer-Owned PBMs



III. COMPARISON OF DECEMBER 2003 MAIL AND RETAIL PRESCRIPTION PRICES WITH CONTROLS FOR DRUG MIX AND PRESCRIPTION SIZE

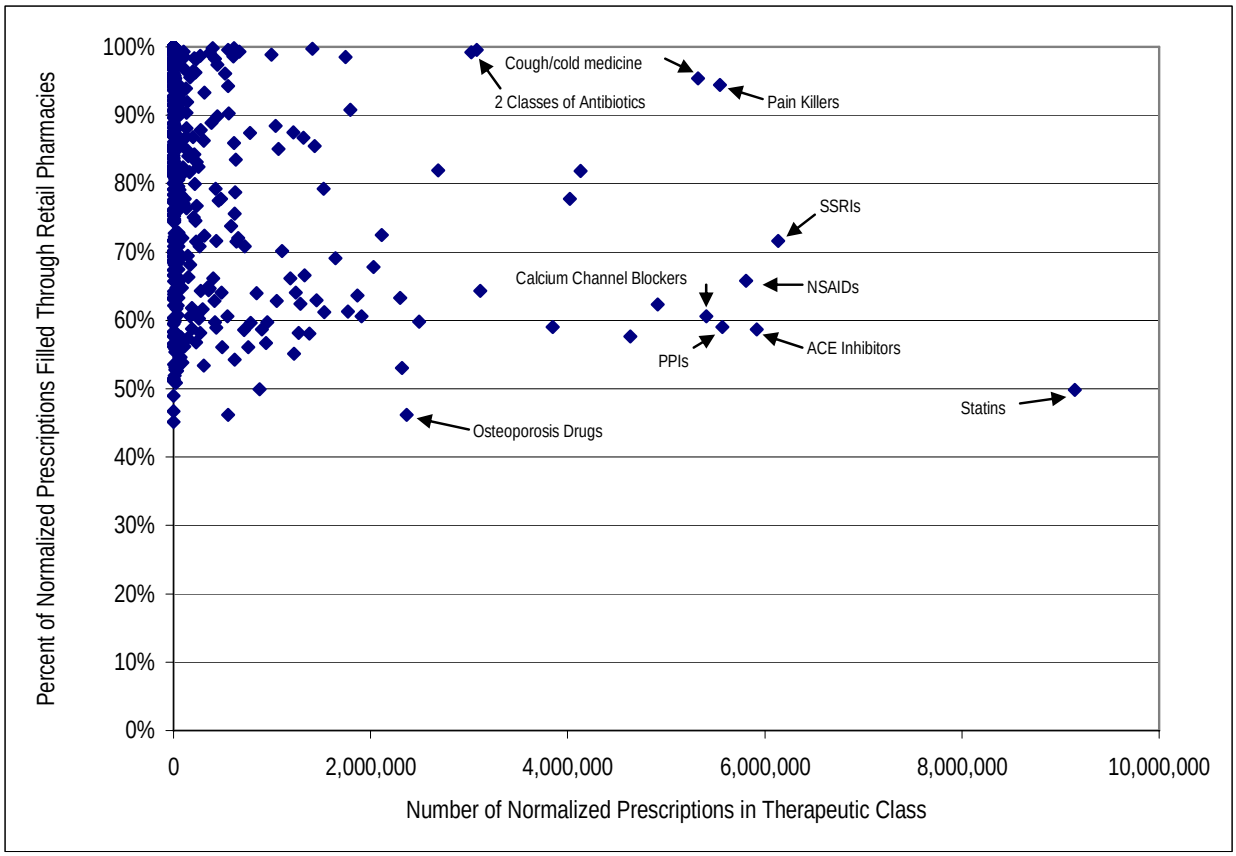
Two factors complicate any comparison of retail and mail prescription prices for the three drug types (SSB, MSB, and G). First, mail prescriptions are approximately three times the size of retail prescriptions. Second, mail and retail price comparisons at the drug type level do not control for the mix of drugs within each drug type dispensed through each channel.

Figure II-5 shows how the mix of drugs varies between dispensing channels by showing the mail dispensing rate of drugs within each therapeutic class. Each point represents the number of normalized prescriptions dispensed within a unique therapeutic class during December 2003 for 8 PBMs that provided claims data to the Commission. This analysis normalized the number of prescriptions to account for the differing size of mail and retail prescriptions – each mail prescription is counted three times when counting the number of normalized prescriptions.

[12] As with the large PBM data, the relative comparisons between owned and not-owned mail-order pharmacies did not change substantially when the Commission staff recalculated average prices based on only the three retailer-owned PBMs that reported data from both type of mail pharmacies.

The therapeutic classes with drugs used to provide acute treatment (*e.g.*, pain killers, cough/cold drugs) have high retail dispensing rates, while drugs used to treat chronic diseases (*e.g.*, osteoporosis and cholesterol-lowering drugs) have lower retail dispensing rates. This wide differential suggested that the three drug type classifications (SSB, MSB, and G) were not sufficient to control for the different mixes of drugs dispensed at mail and retail.[13]

Figure II-5. Retail Dispensing Rate by Therapeutic Class – December 2003 Claims for 8 PBMs



[13] The mix of drugs dispensed at mail and retail is affected by plan sponsor decisions on formulary design, generic substitution policies, therapeutic interchange programs, patient demographics and preferences, etc. Several of these factors will be the focus of chapters to follow this one.

In light of these two difficulties, the Commission staff compared the weighted average of mail and retail prices for all prescriptions of common sizes[14] of the same drug products[15] based on all prescriptions dispensed in December 2003. In other words, Commission staff included in the analysis all drugs for which a prescription of the same size was dispensed in both channels. For example, it is possible to calculate the average mail and retail prices for a 30-capsule prescription of 200 mg Celebrex based only on prescriptions for the exact drug and prescription size. For reporting purposes, Commission staff grouped these drugs into G, MSB, and SSB pools based on drug type. The analysis below summarizes by drug type the comparisons of mail and retail prices of 30-unit and 90-unit prescriptions for (1) large PBMs, (2) retailer-owned PBMs, and (3) stand-alone retail pharmacies.

A. Large PBM Average Mail Prices Were Lower Than Retail Prices for the Same Drug Products and Same-Sized Prescriptions in December 2003

The Commission used December 2003 claims data to compare the mail and retail prices of the same drug products for (a) 30-unit and (b) 90-unit prescriptions. None of the retail prescriptions were filled at pharmacies owned by the PBMs, and all of the mail prescriptions were filled at pharmacies owned by the PBMs.

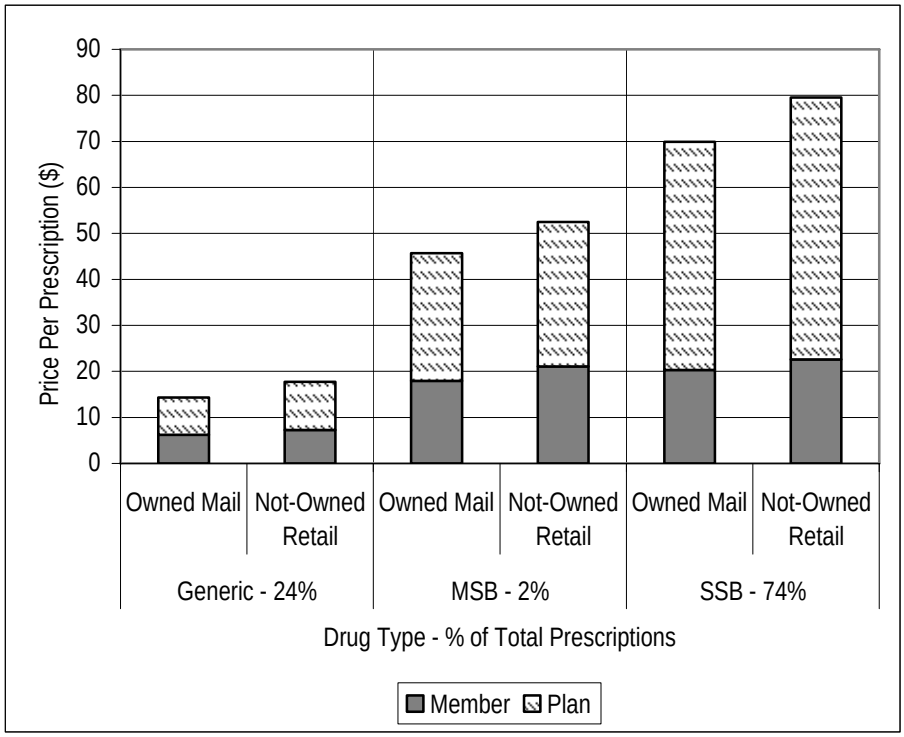
Figure II-6 presents average plan and member prices for 30-unit prescriptions under plans administered by large PBMs, stated separately for each drug type.[16] These averages are based on approximately 147,000 mail prescriptions and 14,873,000 retail prescriptions.

[14] The number of units dispensed (number of capsules, for instance) was used rather than prescription duration because it describes the physical product that was dispensed. Days supply dispensed can vary depending on how pharmacists report that field when processing the prescription.

[15] All of the study participants stated that they were unable to track pharmaceutical payment disbursements to plan sponsors at the transaction level. Thus, the average prices presented in Figures II-6 and II-7 do not reflect any pharmaceutical payments the plan sponsors may have received. As a result, total average prices may be overstated. Moreover, if a plan sponsor's contract with a PBM required the PBM to share more pharmaceutical payments for prescriptions dispensed at mail than at retail (as reported in the discussion of PBM-plan sponsor contracts in Ch. III, Section VI.A, *infra*), the average total prices for mail would be overstated as compared to retail.

[16] The claims data showed the precise drug dispensed (identified by a 9-digit NDC) for each claim along with the dispensing channel and pricing information, so it was possible to identify all products that were dispensed in both channels in the same prescription size for each respondent. For a given prescription size, 30 units or 90 units, the Commission staff calculated the average price for each drug in each channel. Then, the cost of a common market basket of drugs based on the total amount of each drug dispensed through both of the channels combined was calculated using these average prices.

Figure II-6. Large PBMs: Average Prices for 30-Unit Prescriptions

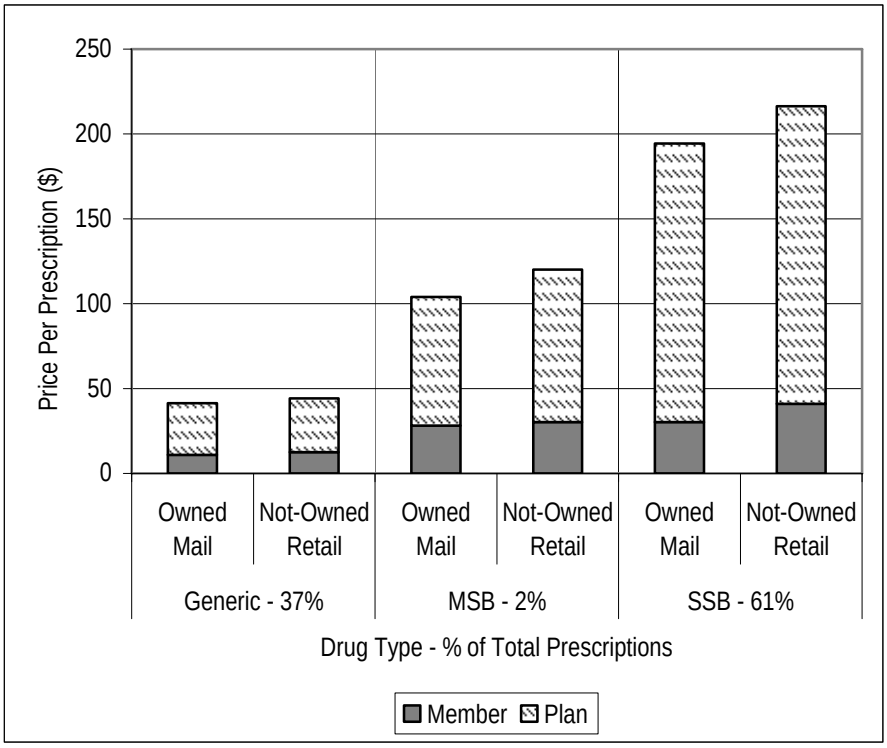


For 30-unit prescriptions dispensed by large PBMs, both members and plans paid lower average prices at mail than at retail for each of the three drug types. For G, MSB, and SSB drugs, the total average not-owned retail price was higher than the owned mail price by 23.9%, 14.9%, and 13.9%, respectively.

Figure II-7 presents the same information for 90-unit prescriptions. This analysis is based on approximately 3,463,000 mail prescriptions and 1,745,000 retail prescriptions. Similar to 30-unit prescriptions, both members and plans paid lower average prices for 90-unit prescriptions dispensed by large PBMs at owned mail-order pharmacies than at not-owned retail pharmacies. For G, MSB, and SSB drugs, the total average not-owned retail price was higher than the owned mail price by 6.8%, 15.6%, and 11.3%, respectively.[17]

[17] The prices in Figrues II-6 and II-7 should not be compared to try to determine the discount from buying a larger prescription size (90 units instead of 30 units) because the mix of drug products is not necessarily the same in the underlying data.

Figure II-7. Large PBMs: Average Prices for 90-Unit Prescriptions



Some plan sponsors insisted that large PBMs not use their owned mail-order pharmacy when they filled mail-order prescriptions. The claims data from three of these large PBMs included a relatively small number of prescriptions filled at mail-order pharmacies that were not owned by the PBM. The Commission staff conducted an analysis to compare prices at these pharmacies to prices at PBM-owned mail pharmacies for the same three PBMs. The data showed that, on average, the total prices at the PBM-owned mail pharmacies were three percent lower than the total prices at other mail-order pharmacies for both 30-unit and 90-unit prescriptions.[18]

B. Retailer-Owned PBM Average Mail Prices Were Lower Than Retail Prices for the Same Drug Products and Same-Sized Prescriptions in December 2003

Because a primary focus of this analysis is to examine whether ownership of the pharmacy affects prices paid, the Commission staff compared the prices at the mail-order pharmacy owned by the retailer-owned PBM to prices at retail pharmacies not owned by the retailer-owned PBM.

[18] The analysis of 30-unit prescriptions included 2,200 not-owned mail prescriptions and 46,000 owned mail-order prescriptions. Average owned mail prices (compared to not-owned mail prices) were 13% lower for members, and 2% higher for plan sponsors, for a combined total of 3% lower overall. The analysis of 90-unit prescriptions included 98,000 not-owned mail prescriptions and 1.8 million owned mail prescriptions. Average owned mail prices (compared to not-owned mail prices) were 5% lower for members, and 2% lower for plans, for a combined total of 3% lower overall.

For 30-unit prescriptions dispensed by retailer-owned PBMs, both members and plans paid lower average prices at mail than at retail for each of the three drug types.[19] For G, MSB, and SSB drugs, the total average not-owned retail price was higher than the owned mail price by 27.6%, 14.4%, and 10.6%, respectively. The substantial majority of prescriptions dispensed were for SSB drugs.

For 90-unit prescriptions dispensed by retailer-owned PBMs, both members and plans paid lower average prices at mail than at retail for each of the three drug types, except that plan prices for SSB drugs dispensed through owned mail-order pharmacies were $0.64 higher on average than not-owned retail pharmacies. For G, MSB, and SSB drugs, the total (plan plus member) average not-owned retail price was higher than the owned mail price by 12.1%, 10.0%, and 7.5%, respectively.

C. Cash-Paying Customers Paid More than Customers with Insurance at Stand-Alone Retailers in December 2003

Using December 2003 data, the Commission staff calculated average prices paid to the pharmacy by members with insurance, as well as the average prices paid by cash customers, after controlling for product mix and prescription size.[20] For both 30-unit and 90-unit prescriptions, generic drugs were the least expensive, on average, and single-source brand drugs were the most expensive.[21]

For example, customers without insurance (*i.e.*, cash-paying customers) paid an average of over 15% more for each 30-unit prescription of an SSB drug than customers with insurance. The differences in 30-unit prices were even larger when looking at MSB drugs (cash price greater than 25% more) and generic drugs (cash price greater than 50% more). For 90-unit prescriptions, cash customers paid over 15% more for SSB drugs, over 25% more for MSB drugs, and over 50% more for generic drugs than customers with insurance coverage.

The types of drugs that stand-alone retailers dispensed shifted between 30-unit prescriptions and 90-unit prescriptions. The majority of 30-unit prescriptions dispensed were for SSB drugs whereas the majority of 90-unit prescriptions dispensed were for generic drugs.

[19] Most of the mail prescriptions that retailer-owned PBMs reported were dispensed through mail-order pharmacies owned by the PBM.

[20] The price listed for the insurer is generally not the amount paid by the plan sponsor; instead, it is the amount of money typically paid to the pharmacy by the PBM. *See* Ch. I *supra*.

[21] Appendix D compares December 2003 cash prices at stand-alone retailers to PBM-owned mail-order prices. The analysis shows that PBM-owned mail-order prices, after adjusting for drug mix and prescription size, were lower than cash prices.

IV. PRICING TERMS IN PBM CONTRACTS CAN PROVIDE FINANCIAL INCENTIVES FOR MEMBERS TO USE MAIL PHARMACIES

Commission staff's review of 26 PBM-plan sponsor contracts showed that plan sponsors negotiated different prices for the same drugs dispensed through mail-order and retail pharmacies, which may have contributed to the price differences shown above.[22] As explained above, the portion of the total prescription price that plan sponsors paid was typically based on a measure of the cost (or AWP) of the drug dispensed, less a discount (plus a dispensing fee). In contracts with differential mail and retail pricing, mail prescriptions often received a higher discount than retail prescriptions.

In contracts with less restrictive or open formularies, mail discounts for brand drugs ranged from a low of 16% of AWP to a high of 27.9% of AWP, with the majority in the 20.5% to 23% range.[23] Dispensing fees at mail-order pharmacies ranged from no dispensing or shipping charges to $2.00 per prescription. By contrast, discounts on brand drugs in the same contracts were not as high for retail as they were for mail. For example, retail prescription discounts for brand drugs generally ranged from a low of 13.5% of AWP to a high of 15% of AWP plus a dispensing fee that ranged between $1.75 and $2.50.[24]

Plans obtained larger retail discounts for brand drugs if they used more restrictive formularies. For example, one plan obtained retail discounts of approximately 21% of AWP, with a dispensing fee of $1.85.[25]

Generic drug pricing also differed at mail and retail. Generic prescriptions dispensed at mail were often priced at AWP minus a percentage, which varied from AWP - 45% of AWP to AWP - 60% of AWP; AWP - 50% of AWP was the most common discount. The dispensing fee, if any, ranged from $1.00 to $1.95, but plan sponsors most commonly paid no dispensing and shipping fees. MAC pricing, although used at mail, does not appear to be as widespread a measure of the cost of generic drugs dispensed through mail-order pharmacies. By contrast, generic prescriptions dispensed at retail were most often priced at the MAC price. For non-MAC drugs, however, the most common price was AWP - 15% of AWP. The retail dispensing fee for generic drugs ranged from $1.75 to $2.50, and was either the same as the fee for brand drugs or slightly higher (*e.g.*, usually $0.25 more).

[22] These contracts were not a representative sample of all contracts, but provide valuable information concerning the pricing terms for which different plan sponsors contracted.

[23] The amount of the member's copayment, among other charges, also may have affected the level of the discount a plan sponsor obtained.

[24] PBM contracts with plan sponsors.

[25] PBM contract with a plan sponsor (the dispensing fee decreased by $0.10 in each of Years 2 and 3 of the contract).

V. PLAN SPONSOR ALSO CAN SPECIFY THE PACKAGE SIZE USED TO DETERMINE THE AWP

An additional explanation for mail and retail pricing differentials is that a drug product can have multiple AWPs based on different package sizes. For example, if a retail or mail-order pharmacy buys a large quantity of a drug from a manufacturer, the AWP per unit on that package size may be lower than if the pharmacy had purchased the drug in a smaller package size from the manufacturer. Thus, the same drug product can have a different AWP based on the package size in which the dispensing pharmacy purchased the drug product. Because of these differences, a PBM may bill its plan sponsors based on AWPs for the smaller package size (which would be a higher AWP) even though the pharmacy purchased the drug in a larger package size (and thus paid a lower AWP).

Contracts between PBMs and plan sponsors sometimes specify the package size that will be used to determine the drug's AWP for both mail and retail prices. Most contracts the Commission staff reviewed defined AWP, some with more specificity than others. For example, one PBM's contract with a plan sponsor defined AWP as:

> the average wholesale price of the Covered Drug dispensed, determined as of the date the Prescription is dispensed, as set forth in (i) the First Databank's National Drug Data File; or (ii) the direct cost of the Covered Drug in those instances in which only the direct cost of the Covered Drug is listed in First Databank's National Drug Data File; or (iii) the Medi-Span Prescription Pricing Guide. Under the Retail Pharmacy Program, AWP is based on the pharmacy's package size as submitted to PBM. Under the Mail Service Program, AWP is based on package sizes of 100 units or 16 oz. Quantities, or smaller quantities if such sizes are not available. All other Covered Drugs will be priced as individual units or smallest package size available (*e.g.*, per vial, per suppository, etc.). If Medi-Span or other applicable pricing source changes the methodology for calculating AWP in a way that materially changes the economics of the Program, the parties agree to modify the Program Pricing Terms to preserve the parties' relative economics before such changed methodology. [26]

Other plan sponsor contracts were less specific, defining the AWP of a drug as that set forth in one of the official pricing guides (Medi-Span or First Databank), but not stating the package size.[27] Some plan sponsor contracts defined AWP "for a standard package size of a Prescription drug as established by First Data Bank or other nationally available reporting service of pharmaceutical prices, and is the "list price" as reported by drug wholesalers."[28]

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[26] PBM contract with a plan sponsor. Most of another PBM's contracts with plan sponsors defined AWP with very similar language and specificity.

[27] *See, e.g.*, PBM contract with a plan sponsor; same PBM's contract with another plan sponsor ("AWP means the average wholesale price of the drug dispensed as set forth in the latest edition of the First DataBank Blue Book (with supplements) or any other similar nationally recognized reference … . The applicable AWP for Claims submitted by retail Network Providers is based on the average AWP for each drug.").

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[28] PBM contract with plan sponsor. Most of this large PBM's contracts with plan sponsors contained a similar definition.

Although the PBM contracts with plan sponsors varied with respect to the specificity with which they defined AWP, it appears that the contracting process provided plan sponsors with an opportunity to specify the package size upon which a drug's AWP would be based.

CHAPTER III THE ROLE OF PHARMACEUTICAL PAYMENTS TO PBMS

I. INTRODUCTION

Congress requested that the Commission examine "differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers," including an assessment of "[w]hether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees."[1] One facet of this inquiry concerns whether pharmaceutical manufacturers' payments to PBMs create incentives for PBMs to dispense those manufacturers' drugs more frequently through their owned mail-order pharmacies, regardless of whether those drugs cost more to the plan sponsor.

The Commission requested data from the study participants about their relationships with pharmaceutical manufacturers. This chapter examines these data and provides an analysis of the contractual agreements between the PBM study participants and a common set of 11 pharmaceutical manufacturers. This chapter 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.

The analysis in this chapter highlights the central role the formulary plays in determining which drugs are dispensed to a plan sponsor's members. The starting point for a plan sponsor's formulary is the PBM's national or preferred formulary developed by the PBM's pharmacy and therapeutics (P&T) committee. Most P&T committees evaluate the drugs in particular therapeutic categories for clinical effectiveness and safety and then decide which drugs to include on their national formularies. Most PBMs suggested that only after a PBM decides which drugs to include on the formulary are costs of the drugs considered.

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. Pharmaceutical manufacturers use "formulary payments" to obtain formulary status, and/or they use "market-share payments" to encourage PBMs to dispense their drugs, especially in crowded therapeutic classes in which there are many similar 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.

[1] 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)).

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 chapter uses the term "total payments" to refer to all four payments combined; otherwise, the chapter 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:

- On average, PBM study participants received total payments of $5.22 per normalized prescription[2] of a brand drug dispensed in 2002. The average increased 21.5% to $6.34 in 2003.

- 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

[2] Analysis presented in Chapter II showed that mail prescriptions were typically three times larger than retail prescriptions. Thus, when combining mail and retail prescriptions to calculate a total number of prescriptions, each mail prescription is counted as three. This calculation will be referred to as "normalized" prescriptions.

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 usually 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 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.

- 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. 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 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.

* * * * *

The chapter first discusses the importance of the PBM formulary in determining the drugs dispensed to plan sponsor members. The central role of the formulary explains why manufacturers pay PBMs rather than offer similar payments to the direct purchasers of their drug products – that is, retail and mail-order pharmacies. The chapter then presents information on average manufacturer payment amounts per prescription and the number of drugs that account for the majority of these payments.

The chapter also analyzes in depth the contracts between a set of 11 pharmaceutical manufacturers and each of the PBM study participants. The chapter reports the four general

types of manufacturer payments and the factors that affect the allowance levels manufacturers specify in their contracts with PBMs. The chapter also analyzes a set of PBM contracts with plan sponsors and explains how pharmaceutical payments were shared with plan sponsors and plan sponsors' audit rights. Finally, the chapter discusses 2003 data that shows the percentage of total payments PBMs retained versus the percentage they passed through to their plan sponsors.

II. PHARMACEUTICAL MANUFACTURERS PAY PBMS TO ENCOURAGE DISPENSING OF THEIR PHARMACEUTICAL PRODUCTS

When a health plan sponsor pays the bulk of a drug's cost, consumers have little incentive to select the most cost effective alternative; indeed, consumers often do not know the full cost of a drug.[3] In addition, physicians, not patients, have the expertise and authority to select the particular drugs their patients take. Physicians may not consider the price of a drug or whether it is covered by a patient's insurance when deciding what to prescribe. This combination of factors results in a low price sensitivity among consumers for prescription drugs.[4]

One way to overcome this low retail price-sensitivity and to control prescription drug costs is through use of a formulary.[5] The formulary is a list of approved drugs for which the plan sponsor will pay some portion of the prescription price. Typically, members pay a lower copayment when they purchase a drug that is listed on the formulary than they pay if they purchase a drug not on the formulary. Among drugs on the formulary, there may be different tiers with different copayment levels.

A. PBM Formularies Control Dispensing of Brand Drugs

When a therapeutic class contains a number of competing drug products that have similar therapeutic effects, PBMs can use the formulary to promote the sales of particular brand drugs within the class. [6] Manufacturers recognize the importance of the formulary in influencing their sales and offer PBMs payments for formulary access or as an incentive to increase or maintain

[3] *See, e.g.*, F.M. Scherer, *The Pharmaceutical Industry — Prices and Progress*, 351 NEW ENGL. J. MED. 927, 928-29 (2004). Insurance also results in increased usage of covered products or services, because if consumers do not have to pay the cost, they typically are not as sensitive to price as if they paid the entire cost; this phenomenon is known as moral hazard. *See, e.g.*, JUDITH AREEN ET AL., LAW, SCIENCE AND MEDICINE 792-93 (2nd ed. 1996).

[4] *See, e.g.*, CONG. BUDGET OFFICE (CBO), HOW THE MEDICAID REBATE ON PRESCRIPTION DRUGS AFFECTS PRICING IN THE PHARMACEUTICAL INDUSTRY 1 (1996) (quoting F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, J. ECON. PERSPEC. (1993)).

[5] *See, e.g.*, *id.* at 1.

[6] *See* JACK HOADLEY, COST CONTAINMENT STRATEGIES FOR PRESCRIPTION DRUGS: ASSESSING THE EVIDENCE IN THE LITERATURE 25 (Kaiser Family Found., Pub. No. 7295, 2005); WILLIAM M. MERCER INC., PRESCRIPTION DRUG COVERAGE AND FORMULARY USE IN CALIFORNIA (Cal. HealthCare Found., Report No. 2, 2001), *available at* http://www.chcf.org/topics/view.cfm?itemID=12658.

sales of their drugs relative to similar drugs.[7] The formulary, therefore, can enhance sales of a particular drug product regardless of which pharmacy a consumer purchases from, as long as the pharmacy is part of the PBM's network and is subject to the PBM's formulary controls. *See* Box III-1 for a discussion of the brand and generic drugs four PBMs placed on their national formularies in one therapeutic class.

Box III-1: The Availability of Statins on the National Formularies of Four PBMs

The statins are a therapeutic class of drugs that lower cholesterol.[1] Currently, there are six FDA-approved statins, of which five are brand drugs (Crestor, Lescol (and its extended release form, Lescol XL), Lipitor, Pravachol, and Zocor) and one is a generic drug (lovastatin, which is the generic version of Mevacor). The table indicates whether a particular statin is included on the national formularies of four PBMs.[2] The table shows that all four PBMs include the generic version of Mevacor (lovastatin) on their national formularies, but none includes all of the brand statins on their national formulary.

PBM	Crestor	Lescol/XL	Lipitor	Pravachol	Zocor	lovastatin
Aetna		X			X	X
Caremark	X		X	X		X
Express Scripts	X		X		X	X
Medco			X		X	X

[1] The statins work by blocking the enzyme HMG CoA Reductase. They are one subclass of a broader pharmacological class of cholesterol-lowering drugs known as Dyslipidemics. The Dyslipidemics, in turn, are a subclass of the broad therapeutic category of cardiovascular drugs. *See, e.g.*, VHA PHARMACY BENEFITS MGMT. STRATEGIC HEALTHCARE GROUP & THE MEDICAL ADVISORY PANEL, DRUG CLASS REVIEW: HYDROXYMETHYLGLUTARYL-COENZYME A REDUCTASE INHIBITORS (STATINS), *at* http://www.vapbm.org/reviews/HMGStatins04-09-03.pdf; U.S. PHARMACOPEIAL CONVENTION, INC., COMPREHENSIVE LISTING OF DRUGS IN THE USP MODEL GUIDELINES FOR DRUGS APPROVED THROUGH OCTOBER 2004, *at* http://www.usp.org/pdf/EN/mmg/comprehensiveDrugListing2004-12-31.pdf.

[2] AETNA, AETNA PREFERRED DRUG (FORMULARY) GUIDE (Jan. 2005), *at* http://www.aetna.com/formulary/2005_formulary_provider.pdf; CAREMARK, PRIMARY/PREFERRED DRUG LIST (July 2005), *at* http://www.caremark.com/portal/asset/Primary_Preferred_DL.pdf; EXPRESS SCRIPTS, 2005 EXPRESS SCRIPTS NATIONAL PREFERRED FORMULARY, *available at* http://member.express-scripts.com/web/formulary/OpenFormulary.do?portal=member&formularyId=393 (last updated May 1, 2005); MEDCO HEALTH, MEDCO HEALTH 2004 FORMULARIES (July 2004), *at* http://www.medco.com/art/corporate/medco_formularies_2004.pdf.

Pharmaceutical manufacturers do not make these payments to actual purchasers (wholesalers and retail pharmacies), because retail pharmacies dispense prescription drugs to members of many plans, each of which may have different preferred drugs and formulary arrangements with PBMs. Thus, these purchasers do not have as much ability as PBMs to influence what is dispensed.

[7] *See* Richard Frank, *Prescription Drug Prices: Why Do Some Pay More Than Others Do?*, 20 HEALTH AFFAIRS 115, 125 (Mar./Apr. 2001). In addition, the PBM contracts with pharmaceutical manufacturers assert this view. *See, e.g.*, "Competitive Circumstances — [PBM] represents and warrants that the Rebates provided by [Pharmaceutical Manufacturer] hereunder have been negotiated under circumstances which render the net prices of Products resulting from such rebates competitive with net prices of competitive products. This Agreement has been offered by [Pharmacueutcal Manufacturer] in good faith to meet competition." PBM contract with pharmaceutical manufacturer.

B. Generic Manufacturers Do Not Use Payments to PBMs in the Same Way as Brand Manufacturers

Generic manufacturers generally cannot use payments to PBMs to enhance the use of their particular drugs in the same way that brand manufacturers do. Generic drugs are chemically identical and bioequivalent to the reference-listed brand or innovator drug,[8] and retail pharmacies that receive a prescription for a generic drug can dispense the generic product of any manufacturer. Thus, although formularies endorse the use of a particular drug, once a drug is available as a generic, any manufacturer's product may be used. In fact, state generic substitution laws often encourage or require pharmacists to substitute a generic drug for the brand drug.[9] Retail pharmacies may stock only a single manufacturer's generic product, which makes it almost impossible for a PBM to use its formulary to move market share for a particular manufacturer of a generic drug.[10] Thus, pharmaceutical manufacturers offer payments to PBMs for formulary placement of brand, but not generic, drugs.[11]

In the case of generic drugs, retail pharmacies generally obtain discounts on purchases of generic drugs. Retail pharmacies obtain discounts on generic products because they can purchase a drug from one of many manufacturers of the drug, thus enhancing a particular manufacturer's sales.[12]

III. AVERAGE ALLOWANCE LEVELS AND AMOUNTS

The data revealed that pharmaceutical manufacturers' total payments per prescription varied depending upon the type of PBM.[13] Figure III-1 presents the weighted average amount per brand prescription of all PBMs within the three PBM categories.[14]

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[8] *See* FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS ix-xiv (25th ed. 2005), *available at* http://www.fda.gov/cder/orange/obannual.pdf.

[9] *See, e.g.*, HOADLEY, *supra* note 6, at 32.

[10] It is possible that a PBM-owned mail-order pharmacy could agree to purchase only one manufacturer's available generic products in exchange for deeper discounts. One PBM did consider the possibility of strategic financial relationships with certain generic manufacturers in order to obtain favorable pricing and preferential treatment to purchase products that faced supply constraints. *See, e.g.*, Large PBM Company Document (CD).

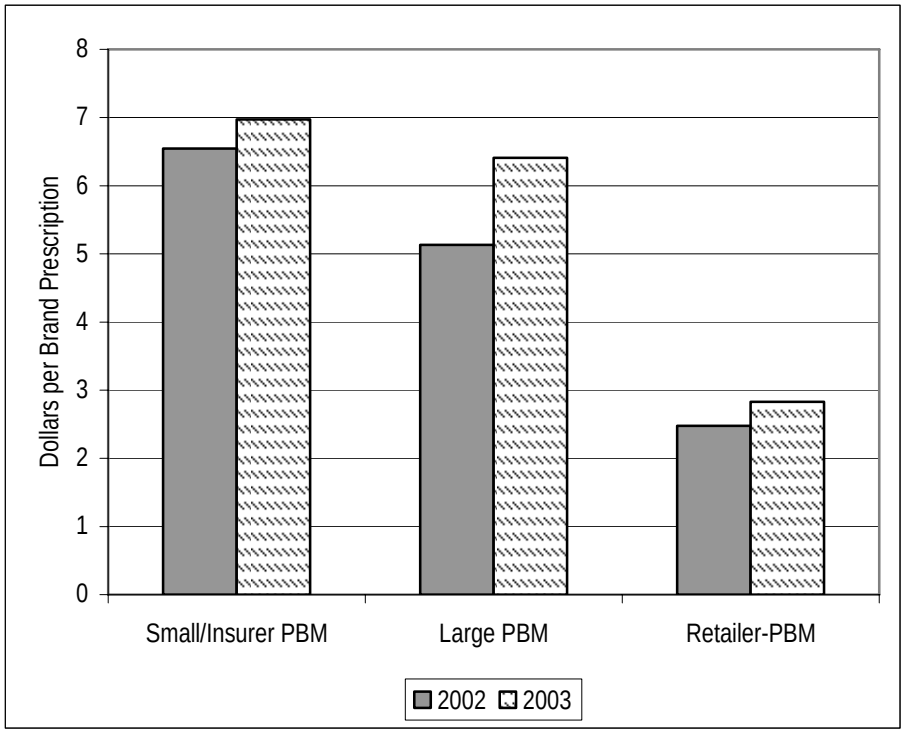
[11] *See, e.g.*, PRICEWATERHOUSECOOPERS LLP, HEALTH CARE FIN. ADMIN., STUDY OF PHARMACEUTICAL BENEFIT MANAGEMENT 9 (2001), *available at* http://www.cms.gov/researchers/reports/2001/cms.pdf; PATRICK J. HOLJO & MATTHEW KAMM, BANC OF AM. SEC., PHARMACY BENEFIT MANAGERS: KEEPING A LID ON DRUG COSTS 21 (Feb. 20, 2002); HOADLEY, *supra* note 6, at 83-84.

[12] Mail-order pharmacies also can obtain similar discounts on generic drugs from manufacturers, regardless of whether they are integrated with a PBM.

[13] The Special Order required study participants to provide annual total payment data as well as financial and usage information for each drug for which they received a pharmaceutical payment in 2003. *See* Appendix A, Items 8 and 11 of the PBM Special Order.

[14] Dollar per prescription equals the sum of all payments received by all companies in the category divided by the number of normalized prescriptions dispensed by PBMs in that category. This analysis normalized the

Figure III-1: Total Payments per Brand Drug Prescription



The data revealed that, on average, the PBM study participants received $5.22 per normalized prescription of a brand drug dispensed in 2002. The average increased 21.5% to $6.34 in 2003.

Small or insurer-owned PBMs received slightly above the overall averages. They received, on average, $6.13 per script in 2002 and $6.67 in 2003. There was considerable variation across companies, however, with the average ranging from $3.47 to $9.27. Large PBMs were very close to the overall averages, with relatively little variation across companies. Retailer-owned PBMs averaged considerably smaller payments per prescription than the other types of PBMs, receiving $3.19 in 2002 and $3.95 in 2003.

The differences between companies, and thus across types of PBMs, may reflect differences in the plan designs selected by each PBM's clients. For example, if plans administered by small or insurer-owned PBMs tend to have more restrictive formularies, this could explain their relatively higher amounts presented in Figure III-1.

Regardless of the PBM category, a majority of these payments were derived from a limited number of brand drugs. The data showed that, in 2003, each PBM's top 25 brand drugs

number of prescriptions to account for the differing size of mail and retail prescriptions. Based on data presented in Chapter II, mail-order prescriptions are typically three times larger than retail prescriptions. Thus, each mail-order prescription is counted three times when counting the number of normalized prescriptions.

(in terms of total payments received) accounted for approximately 71% of its total pharmaceutical payments, on average.

IV. OVERVIEW OF PHARMACEUTICAL MANUFACTURER – PBM AGREEMENTS

The Special Orders required PBM study participants to produce any pharmaceutical manufacturer contract for which it received a "pharmaceutical rebate" for calendar year 2003.[15] The Commission staff examined the agreements each PBM had with the same 11 pharmaceutical manufacturers.[16] These 11 manufacturers accounted for between 61.1% and 83.3% of each PBM's 2003 total payments received, with a weighted average of 72.0%. Other manufacturers may use different provisions not discussed here to drive sales of their drug products.

A. Conditions to Obtain Pharmaceutical Manufacturer Payments

Pharmaceutical manufacturers required PBMs (and their plan sponsors clients) to fulfill a number of conditions before the manufacturers made any payments to the PBM. Generally, manufacturers required that their drugs be available on a plan's formulary without restriction (*e.g.*, no prior authorization by the PBM is required before the drug can be dispensed). In addition, PBMs agreed not to disadvantage the manufacturer's drug relative to other brand drugs (*e.g.*, with regard to copayment or coinsurance levels, treatment guidelines such as step-therapy protocols, or promotion of a competing product).[17] Most manufacturers also required PBMs to provide formulary-management services that demonstrate the PBM's ability to influence drug dispensing.[18] Formulary-management services may include controls at the time the prescription is filled (*e.g.*, point of sale edits), controls on reimbursement amounts, formulary design, drug

[15] To ensure that the Commission obtained all contracts providing for payments from pharmaceutical manufacturers to PBMs, the Special Orders defined "pharmaceutical rebates" broadly to include the dollar amounts received from pharmaceutical manufacturers for items including, but not limited to, rebates, administrative fees, volume discounts, patient conversion payments, market share movement payments, formulary placement fees, disease management program payments, and promotional allowances.

[16] Four PBM study participants had agreements with other PBMs to administer payments from pharmaceutical manufacturers for which their plan sponsors' prescriptions were eligible. Appendix E discusses these agreements.

[17] To assist physicians in prescribing drugs for their patients, PBMs and plan sponsors typically provide physicians with formulary information, which may include relative indicators of the costs of different drugs to the health plan. Although a high cost ranking may discourage prescribing, most contracts between PBMs and pharmaceutical manufacturers provide that factual cost rankings are acceptable. A few such contracts, however, specify that the manufacturer's product must not be disadvantaged by any cost indicators, except in regard to generic drugs. Step therapy protocols and certain other eligibility criteria may be relevant to the definitions of certain types of formularies, and thus factor into the determination of formulary or access pharmaceutical payment levels as discussed below. Promotion of a competing product ("counter-detailing") includes interventions such as physician counseling, electronic messages or blocking, and other efforts that encourage use of a competing product. *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[18] *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

utilization review, patient and physician education, and the development of step therapy protocols.[19]

Few manufacturer agreements conditioned one drug's allowance level on inclusion of another drug on the PBM's formulary, a practice known as "bundling." Two manufacturers accounted for the vast majority of bundling provisions in the contracts reviewed.[20] These two manufacturers routinely provided bonuses for inclusion of a group of products on formularies and often included provisions requiring all products to be on the formulary.[21] A few other manufacturers included "bonus" payments for inclusion of particular bundles of products on the formularies of certain PBMs.[22]

B. Manufacturers Typically Did Not Provide Different Allowance Levels for Mail and Retail Dispensing

Allowance levels generally were the same regardless of whether a drug was dispensed through mail-order or retail pharmacies. Manufacturers defined "Participating Pharmacy" in their agreements with PBMs as a pharmacy that adheres to the PBM's dispensing and formulary controls, as a result of either a contractual or ownership relationship with the PBM. Although some PBMs suggested that they had greater control over drugs dispensed through their owned mail-order pharmacies, they acknowledged that few manufacturers recognized this ability by providing higher allowance levels for drugs dispensed through a PBM-owned mail-order pharmacy.[23]

Nonetheless, one manufacturer occasionally specified higher allowance levels for certain drugs when dispensed through the PBM-owned mail-order pharmacy.[24] The mail/retail

[19] *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[20] This analysis reviews only the final agreements between the 11 manufacturers and the PBM study participants. It does not consider any bundling offers that the parties may have discussed but not adopted in the agreements. Interviews with study participants did not indicate widespread pharmaceutical manufacturer bundling beyond the extent discussed here.

[21] *E.g.*, PBM contract with pharmaceutical manufacturer (portfolio allowances are each 1%; maximum allowances are 3-9%, but most are 7%)); PBM contract with pharmaceutical manufacturer (formulary inclusion allowances (.025%-3%)); PBM contract with pharmaceutical manufacturer (lists of drug products that have to be on formulary); PBM contract with pharmaceutical manufacturer (lists core and additional products: requires core products be in formulary and provides for higher formulary access allowance depending on number of products beyond the core products).

[22] PBM contract with pharmaceutical manufacturer (incremental tiered allowances: additional percentage added if all strategic products are on formulary and there are no disadvantaging requirements (*e.g.*, prior authorization, NDC block, etc.)); PBM contract with pharmaceutical manufacturer (larger allowance levels on specified drug products). *See also* PBM contract with pharmaceutical manufacturer (pharmaceutical payment and allowance depends on drug product remaining on formulary).

[23] PBM Interviews.

[24] Mail/retail differences were observed primarily for one manufacturer, and were not present in contracts with all PBMs. *See* PBM contracts with pharmaceutical manufacturers.

differentials were associated with drug products in crowded therapeutic classes, which often included generic equivalents of products within the class.[25]

C. Pharmaceutical Manufacturers Used Two Types of Payments: Formulary and Market Share

The contracts between manufacturers and PBMs generally specified two types of payments to the PBMs: formulary and market share. Regardless of which type (or both) a manufacturer used, the key negotiation appeared to be over the allowance level or percentage, which depends both on the drug's competitiveness with similar drugs, and on the PBM's ability to drive the drug's sales. The allowance level is important because formulary and market-share payment amounts generally were calculated by multiplying: (a) a plan sponsor's sales volume (*e.g.*, units dispensed) for the specific drug by (b) a measure of the drug's wholesale price[26] by (c) the allowance level. These calculations were frequently made on a quarterly basis.

The various contracts between PBMs and pharmaceutical manufacturers specified many ways to determine the allowance level. PBM and manufacturer preferences and their evaluations of market conditions result in different arrangements.[27] The different structures provide flexibility for plan sponsors to use formularies with different degrees of restrictiveness or with different choices of drugs to meet the needs of their members.

When a manufacturer provided for both formulary and market-share payments, a higher allowance level for one of these types of payments was typically associated with a lower allowance level for the other, other things being equal.[28] Thus, when a manufacturer provided for both types of allowances, formulary allowance levels were higher and market-share allowance levels were lower for restrictive formularies than for open formularies. Such an arrangement apparently anticipated that a drug's placement on a closed formulary leads to a high market share for the drug without further intervention by a PBM.[29]

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[25] *See, e.g.*, PBM contract with pharmaceutical manufacturer (market definitions for Angiotensin Receptor Blockers (drug products), Oral Antidiabetics (drug product), ACE Inhibitors (drug product), HMG Co-A Reductase Inhibitors (drug product); Anti-Coagulants (drug product)); PBM contract with pharmaceutical manufacturer (market definitions for ACE Inhibitors (drug product), HMG Co-A Reductase Inhibitors (drug product), and Angiotensin-II Receptor Blockers (drug product)).

[26] The contracts utilized several measures of a drug's wholesale price, including the published Wholesale List Price (WLP), Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), or Net Direct Price during the relevant period. Usually, however, allowance levels were based on the WLP. *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[27] PBM Interviews.

[28] Allowance levels for the highest anticipated market share are generally the same, regardless of whether achieved by placing a drug on a closed formulary or by a PBM's interventions. *See, e.g.*, PBM contract with pharmaceutical manufacturer.

[29] Indeed, some manufacturers provided a high formulary allowance level on closed formularies but no market-share allowance, apparently with the expectation that the drug's placement on a closed formulary will yield a

1. Formulary Payments

Many manufacturers provided a flat allowance level, often referred to as a formulary or access payment. Formulary payments are a way for manufacturers to ensure that patients have access to their drugs, regardless of whether a PBM's formulary structure or interventions actively encourage utilization of the manufacturer's drug.[30]

Manufacturers generally specified a low allowance level for drugs listed on an "open" or low-control formulary. Open formularies list many drugs within a therapeutic class, and plan sponsors provide coverage for most, if not all, of these drugs. The allowance levels for drugs listed on such formularies are usually lower than those for more restrictive formularies, because open formularies do little to enhance the sales of a particular manufacturer's product.

Manufacturers specified moderate allowance levels for placement of their product on a medium-control formulary. Medium-control formularies are those that provide some drug usage control through benefit design, incentives, or "tiers" with different copayment or coinsurance levels. For such formularies, a manufacturer may provide a medium allowance level for "preferred" products that are on the highest tier available for brand drugs, generally the second tier.[31]

Manufacturers specified higher allowance levels for placement of their products on "closed" or high-control formularies. Closed formularies are those that block claims for nonformulary products and do not pay for nonformulary drugs.[32] In some cases, high control formularies specified a minimum copayment differential of at least $10 to $15 between the tier listing the manufacturer's drug and the next lower tier.[33] Allowance levels generally are higher

high market share without further intervention by a PBM. *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[30] *See, e.g.*, PBM Interviews.

[31] Generic products are generally on the first tier of such formularies, and the fourth tier is often a "lifestyle" drug with a high copayment level. Formulary requirements can be quite specific. For example, a contract may specify not only the precise placement of a drug on a multi-tier formulary, but also require that the manufacturer's drug be one of a specific number of brand products on the formulary for the particular therapeutic class, *e.g.*, one of two, three, or four. Requirements for exclusive placement on the formulary are rare. Contracts sometimes use other terms to designate the relative placement and exclusivity on the formulary, *e.g.*, preferred, co-preferred, most preferred, or equal. Other contracts specify that no competitive brand product shall have a more favorable formulary position.

[32] Closed or high control formularies often involve electronic denial of reimbursement for nonformulary drugs at the point of sale, based on the drug's National Drug Code (NDC) number. *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[33] *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

for such formularies because they strongly limit patient and physician prescribing choice and drive sales toward the formulary products.[34]

Allowance levels varied considerably based on the formulary restrictiveness, with a range of allowance levels of 0% to 10% for low control, 2% to 25% for medium control, and 3% to 27% for high control. These ranges are broad because the allowance levels were very low for some drugs, and high for others. For example, one drug had a formulary allowance of 0% for low control, 2% for medium control, and 3% for high control; another drug had a formulary allowance level of 20% for low control, 25% for medium control, and 27% for high control.[35]

2. Market-Share Payments

Most manufacturers also provided payments based on the sales of the manufacturers' drugs to members of the plans administered by the PBMs' plan sponsor clients. Such payments were based on measures of the manufacturers' "market share" and provided PBMs an incentive to increase sales of the manufacturers' drug.

Market share was calculated by taking the number of prescriptions or units of a drug dispensed to members of a plan sponsor, and dividing that number by the number of prescriptions or units of all drugs dispensed in the defined market class during the same time period. The contracts defined a class for each drug, and generally provided for the addition of newly approved competing drugs. Although market classes often were limited to a single class of chemically related drugs, they sometimes were broader, covering a pharmacological or therapeutic class used to treat a particular condition or disease.[36] Manufacturers specified higher allowance levels for larger market shares. Manufacturers appeared to prefer this approach for older drugs with relatively stable shares.[37]

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[34] *See, e.g.*, PBM contracts with pharmaceutical manufacturers. One PBM's variation on the formulary payment considers the degree of exclusivity of a product within its defined market as well as formulary type. In this arrangement, allowance levels are highest when a manufacturer's product is the exclusive product on a closed formulary, and lowest when the product is one of many products awarded formulary status on an open formulary. *See, e.g.*, PBM contract with pharmaceutical manufacturer; *see also* PBM Interview.

[35] *See* PBM contracts with pharmaceutical manufacturers.

[36] The Medicare Model Guidelines classify drugs into broad *Therapeutic Categories* related to the disease or condition; narrower *Pharmacological Classes* based on the mechanism of pharmacological action; and still narrower *Formulary Key Drug Types* of chemically related drugs. *See* U.S. PHARMACOPEIAL CONVENTION, INC., MEDICARE PRESCRIPTION DRUG BENEFIT MODEL GUIDELINES, DRUG CATEGORIES AND CLASSES IN PART D (CMS Coop. Agreement No. 18-C-92305/3-01, 2004), *at* http://www.usp.org/pdf/EN/mmg/finalModelGuidelines2004-12-31.pdf; U.S. PHARMACOPEIAL CONVENTION, INC., COMPREHENSIVE LISTING OF DRUGS IN THE USP MODEL GUIDELINES FOR DRUGS APPROVED THROUGH OCTOBER 2004, *at* http://www.usp.org/pdf/EN/mmg/comprehensiveDrugListing2004-12-31.pdf. Market class definitions are usually limited to a single Formulary Key Drug Type, but sometimes cover a Pharmacological Class or even an entire Therapeutic Category. *See, e.g.*, PBM contracts with pharmaceutical manufacturers. Only a small number of manufacturers defined markets to include generic equivalents of the manufacturer's drug, but manufacturers often defined markets to include generic versions of other manufacturers' drugs. *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[37] *See* PBM Interviews.

For newer drugs, the drug's market share was compared to the drug's national market share.[38] In these cases, manufacturers frequently paid the PBM only if the drug's market share for dispensing to plan members was greater than the drug's national market share. Allowance levels increased as the drug's market share within the client plans increased above national share.

Allowance levels were less commonly based on the increase in a drug's market share relative to a defined baseline level of market share.[39] The comparison may be to the drug's market share at the beginning of the contract term, or to the drug's market share at a time before an expected change in market conditions, such as entry of competitive products in the defined market. Manufacturers then offered increasing allowance levels to reflect improvement over the defined baseline.[40] Sometimes manufacturers used a variation of this approach and provided payments to PBMs on the condition that market share of a particular drug did not decrease from a baseline level.[41]

D. Interaction Between Formulary and Market-Share Allowance Levels

Allowance levels are a function of the parties' relative bargaining positions and skills, the competitiveness of the drug, and where a drug is in its "life cycle," which changes during different stages of the development and growth of a therapeutic class. Competition among prescription drugs may depend on a variety of factors, including the clinical equivalence or interchangeability of drugs within the class, each drug's competitive position within the class, likely generic entry, and the competitors' business and marketing strategies.[42]

When a unique, pioneer brand drug enters the market, it may be considered to be in a therapeutic class by itself. Market-share payments are not provided for such drugs, and formulary payments are either small or nonexistent because the manufacturer does not need to offer incentives for formulary placement.[43] Over time, other manufacturers may enter the class by offering chemical variants of the pioneer brand drug. In that case, PBMs may obtain

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[38] Contracts often specify that a drug's national market share be based on data from a commercial provider of national pharmaceutical information such as IMS Health, Inc. *See* IMS Health Incorporated, *at* http://www.imshealth.com/ims/portal/pages/homeFlash/us/0,2764,6599,00.html (last visited July 7, 2005).

[39] Market share may be expressed either as the drug's market share of dispensing to members of the plan/PBM, or as a comparison of that value to national market share.

[40] *See, e.g.*, PBM contracts with pharmaceutical manufacturers. Some contracts also specified a timeframe over which to expect an increase in market share.

[41] *See* PBM contract with pharmaceutical manufacturer (contract providing for a loss of pharmaceutical payments if market share was not maintained relative to national market share after generic entry).

[42] *See generally*, CBO, *supra* note 4, at 13-35.

[43] *See* HOLJO & KAMM, *supra* note 11, at 21 (noting that pharmaceutical payments are paid only on brand pharmaceuticals for which there is competition, such as Claritin, Allegra, and Zyrtec, while sole source drugs without competition, such as Viagra when it was first introduced, do not usually receive such payments).

payments on some drugs by including them on a formulary while excluding some or all other drugs in the therapeutic class. Manufacturers may compete for formulary access and favorable handling by offering substantial allowance levels for drugs in large, top-selling therapeutic classes.[44]

The following example illustrates how pharmaceutical payments can change in response to competition within a therapeutic class. One manufacturer offered a moderate formulary allowance level on a brand drug when it was the only drug in its class. After the FDA approved other drugs in the same class, the manufacturer reduced the formulary allowance level for the pioneer drug, but added a market-share payment. The sum of the reduced formulary and new market-share payments was greater than the initial formulary payment.[45]

Manufacturers use pharmaceutical payments strategically to gain or protect market shares. Some manufacturers use these payments "offensively," as an incentive for the PBM to create conditions that rapidly increase market share. For example, one manufacturer required the PBM to attain ever higher market-share levels for a newly marketed drug in order to keep the same allowance level with which it started.[46] By contrast, another manufacturer reduced market-share thresholds in response to new competition.[47]

Manufacturers also may offer formulary and market-share payments for defensive purposes. One PBM explained that manufacturers sometimes use formulary payments to discourage the PBM from acting to reduce a drug's market share through such means as therapeutic interchange, step therapy, and restrictions on the formulary.[48]

E. Generic Entry Influences Allowance Levels

The brand manufacturers generally stopped making payments upon generic entry. [49] Some manufacturers, however, continued to make payments to PBMs after a generic equivalent drug entered the market.[50]

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[44] *See, e.g.*, PBM contract with pharmaceutical manufacturer (market share scales and definitions for a variety of drugs). *See also* CBO, *supra* note 4, at 24.

[45] *See* PBM contract with pharmaceutical manufacturer. In this example, the summed allowance was not large enough to trigger a new Medicaid "best price." *See also* 42 U.S.C. § 1396r-8(c)(1) (2000) (allowances above the Medicaid minimum rebate of 15.1% may set a new "best price" and thus be available to Medicaid). PBM contracts with pharmaceutical manufacturers typically capped such payments so that they would not set a new "best price" under 42 U.S.C. § 1396r-8(c)(1)(C) (2000)). This report does not address compliance with Medicaid "best price" requirements.

[46] *See* PBM contract with pharmaceutical manufacturer.

[47] The change suggests that the manufacturer believed that its drug would not be able to maintain the market share it had prior to the new competition. *See* PBM contract with pharmaceutical manufacturer (despite absence of requirement for an annual adjustment, amendment lowers drug product share requirements because of competition).

[48] *See* PBM Interviews.

[49] *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

Brand manufacturers occasionally included generic products equivalent to *their own drugs* in the defined market for calculation of market share, and continued to make market-share payments after generic entry.[51] One manufacturer agreed to continue making market-share payments after generic entry only if the PBM maintained the drug's market share relative to national market share.[52] In another case, the manufacturer specified higher allowance levels just before generic entry, but then discontinued the payments after generic entry.[53] Another brand manufacturer had a right of first refusal to match the price offered to the PBM by any manufacturer of a generic equivalent to its drug. If the brand manufacturer matched the price of the generic drug, the PBM agreed to use the brand manufacturer as the exclusive provider of the drug for its mail-order pharmacy.[54]

Brand manufacturers more frequently included generic products equivalent to *competitors' drugs* in defined markets for calculation of market share. In one case, a manufacturer agreed to continue making payments to the PBM if the drug's market share exceeded an agreed upon baseline, but if the market share dropped below the baseline, the PBM would have to pay the manufacturer.[55]

V. MANUFACTURERS ALSO MAKE OTHER PAYMENTS TO PBMS FOR VARIOUS SERVICES

In addition to formulary and market-share payments, manufacturers paid PBMs for two other types of services: (a) administrative fees to compensate a PBM for managing the formulary and for other services on behalf of manufacturers' products; and (b) other fees to compensate PBMs for compliance, therapeutic interchange, and other programs relating to particular drugs. Certain lawsuits have alleged that PBMs sometimes categorize formulary and market-share payments as administrative or other fees to avoid a contractual obligation to pass these payments through to the plan sponsor.[56] These allegations are outside the scope of this

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[50] Some contracts gave manufacturers a right to renegotiate the agreement upon generic entry. *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[51] *See* PBM contracts with pharmaceutical manufacturers.

[52] *See* PBM contract with pharmaceutical manufacturer.

[53] *See, e.g.*, PBM contract with pharmaceutical manufacturer.

[54] *See* PBM contracts with pharmaceutical manufacturers.

[55] *See* PBM contract with pharmaceutical manufacturer.

[56] *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), *available at* http://www.oag.state.ny.us/press/2004/aug/aug4a_04.html.

study and, moreover, the data the Commission collected does not provide a basis on which to offer observations on these allegations.

Manufacturers routinely paid PBMs to administer the pharmaceutical payments program and the formularies that included the manufacturers' drug products. These fees were generally 3% of the wholesale price of all of the manufacturer's drugs dispensed to members of plans administered by the PBM.[57] Some PBMs represented in their contracts with manufacturers that they have disclosed to their client plan sponsors that they received these fees.[58] Although this representation was not universal among the study participants, nearly all of the PBM/plan sponsor contracts that the Commission staff reviewed disclosed that the PBM might receive administrative and other fees from manufacturers.[59]

Very few PBMs received manufacturer payments specifically for prescription compliance, preferred drug management programs, therapeutic interchange services, or other similar activities. Indeed, PBM strategic plans and business planning documents indicated that by late 2003 PBMs had discontinued, or were about to discontinue, many of these programs.[60]

One PBM contracted with several pharmaceutical manufacturers to undertake prescription compliance programs for a number of drugs dispensed through the PBM's owned mail-order pharmacy.[61] Payments for these programs were based on the services rendered, with set fees based on a per mailing or phone call basis — up to a specified fee cap. The fee caps, which ranged from about $100,000 to $1,000,000, typically applied to the term of the agreement, usually a year.[62] Most of these compliance programs involved drugs in large, competitive market classes, many of which included generic equivalents.

The same PBM also contracted to undertake therapeutic interchange programs for some of the same manufacturers.[63] The PBM agreed to carry out therapeutic interchanges in favor of certain formulary drugs, regardless of whether the covered drugs were dispensed by mail-order

[57] *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[58] PBM contracts with pharmaceutical manufacturers.

[59] *See, e.g.*, PBM contracts with pharmaceutical manufacturers.

[60] *See* PBM Interview.

[61] *See* PBM contract with pharmaceutical manufacturer (for patients with new or continuing prescriptions for the designated drugs, the PBM sent letters explaining the importance of therapy compliance; for patients who failed to refill their prescriptions, the PBM sent a letter and followed up with a phone consultation asking the patient to refill the prescription according to his or her physician's directions). *See also* PBM contracts with pharmaceutical manufacturers.

[62] *See, e.g.*, PBM contract with pharmaceutical manufacturer (therapy adherence program limiting a specified drug product to a $100,000/year cap); PBM contract with pharmaceutical manufacturer (therapy adherence program, listing five drug products at a $1,000,000/year cap).

[63] As discussed in Ch. V, *infra*, plan sponsors have tools to ensure that therapeutic interchange programs are beneficial to the plans and their members.

or retail pharmacies.[64] The PBM sometimes agreed to carry out an interchange program to encourage use of new formulary drugs after changes in the formulary.[65] Therapeutic interchange programs typically involved drugs in large, competitive market classes, called for set fees per PBM mailing, and had a cap on total fees. Such caps ranged from about $250,000 to $1,000,000 per year per program drug(s).[66]

Because few manufacturers specifically contracted for these programs, their impact was limited. Nonetheless, PBMs asserted that such programs, or the threat of such programs, help them control drug costs because manufacturers pay higher allowance levels to avoid having their drugs targeted for an interchange in favor of another manufacturer's drug.[67]

VI. SHARING PHARMACEUTICAL PAYMENTS WITH PLAN SPONSORS

The extent to which contracts between PBMs and their plan sponsors explicitly provided for the sharing of formulary and market-share payments with the plan sponsor clients varied among contracts. The Commission staff also obtained data on the actual amounts shared by each study participant with its plan sponsor clients in 2003.

A. Plan-Sponsor Contracts Show a Wide Range of Sharing Options

The Commission obtained plan-sponsor contracts that revealed three sharing models. Some plan sponsors required the PBM to pay the plan sponsor a specific dollar amount per brand drug prescription. For example, one contract guaranteed that the plan sponsor would be credited with $8.00 for each mail service formulary brand drug prescription and $3.00 for each retail formulary brand drug prescription filled during the prior contract year. The plan sponsor received no such compensation for generic drugs or for any prescription drug not on the PBM's formulary. Other contracts had similar provisions, but the guaranteed amount varied significantly above and below the amounts specified in this example, depending upon whether the plan utilized a two-tier or three-tier formulary, whether there was a certain copayment differential for formulary and non-formulary brand drugs (usually a minimum of a $15.00 differential), or whether the plan sponsor received other financial considerations, such as lower ingredient cost discounts or dispensing fees.

A second model required the PBM to pay the plan sponsor a specific percentage of all formulary and market-share payments that were attributable to the plan sponsor. For example, a PBM would pass through to the plan sponsor 90% of its total payments (or some other percentage, usually no less than 60%), and keep the rest as the PBM's clinical or base services fee.

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[64] *See* PBM contracts with pharmaceutical manufacturers.

[65] *See* PBM contract with pharmaceutical manufacturer (preferred drug transition program tied to a list of 3 drug products); PBM contract with pharmaceutical manufacturer (preferred drug transition program and drug choice education programs for a drug product).

[66] *See, e.g.,* PBM contracts with pharmaceutical manufacturers.

[67] *See* PBM Interview.

A third model included a guaranteed amount in addition to the pass-through requirements. For example, the plan sponsor might be entitled to 90% of the formulary and market-share payments received, but the plan sponsor would be guaranteed minimum amounts equal to $2.50 times the total number of preferred tier brand formulary prescriptions dispensed at retail and $4.50 times the total number of such prescriptions through mail. These contracts also may vary the percentage shared and the dollar guaranteed per brand prescription based on the plan design (*e.g.*, higher control plans will receive higher percentages and higher dollar guarantees). If the pass-through amounts were less than the guaranteed amount, then the PBM would be required to pay the plan sponsor the difference.

Recent contracts and amendments to older contracts generally have increased the pass-through percentages received by the plan sponsor above the percentage or level specified in the older contracts. For example, one contract in the late 1990s had a split of 80% to the plan sponsor, 20% to the PBM. In 2001, the parties amended the contract and the plan sponsor received 100% of the pharmaceutical payments and paid a $0.10 fee to the PBM for each eligible claim. In 2003, under an amended contract, the plan sponsor received 95% of the formulary and market-share payments, but no longer paid a fee per claim.[68]

Nearly all of the plan-sponsor contracts that the Commission staff reviewed granted the plan sponsor some form of audit rights to verify formulary and market-share payment sharing. The extent of these rights, however, varied considerably. For example, some PBMs granted plan sponsors general audit rights, but excluded the right to audit records or documents that were subject to the PBM's obligation to maintain confidentiality. Other audit rights required PBMs to provide plan sponsors quarterly reports summarizing pharmaceutical payment activity,[69] and allowed plan sponsors to audit appropriate records and, subject to signing a confidentiality agreement, audit the PBM's contracts with pharmaceutical manufacturers.[70] Another PBM allowed plan sponsors to audit claims records and performance data necessary to evaluate overall performance guarantees and the accuracy of the PBM's pharmacy services to the plan. This PBM specified that any audit of the PBM's agreements with pharmaceutical manufacturers "must be conducted by a third party 'big 5' public accounting firm approved by [the PBM] and whose audit department is a separate stand-alone function of its business, subject to execution of a confidentiality agreement, and shall include only those portions of such pharmaceutical manufacturer agreements as necessary to determine [the PBM's] compliance with" the agreement with respect to sharing of pharmaceutical payments.[71]

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[68] *See, e.g.*, PBM contract with plan sponsor.

[69] The PBM must provide "a report in a format that includes a line item accounting of Rebates received, including, but not limited to the drug name, NDC Code, quantity dispensed, WAC drug cost, and Rebates received for Sponsor's Eligible Members' drug utilization but not paid to Sponsor; and a line item accounting of PBM's use of such Rebates." PBM contract with plan sponsor.

[70] *See, e.g.*, PBM contract with plan sponsor. The contract included a clause allowing the PBM to hire an independent auditor at its own expense.

[71] *See, e.g.*, PBM contract with plan sponsor.

B. Retention of Total Pharmaceutical Payments Varied Among PBMs

The Commission obtained data to determine, on average, the percentage or rate of total pharmaceutical payments the PBM kept for itself and shared with its plan sponsors. The retention rate is the difference between total payments received from manufacturers minus the amount disbursed to plan sponsors, all divided by the total payments received. Thus, these retention rates are the percent of all payments made to the PBM by drug manufacturers that are not explicitly passed on to plan sponsors. The payments from manufacturers may include items, such as administrative fees, that are usually not shared and are explicitly excluded from sharing requirements in many plan-sponsor contracts. As a result, the retention rates presented in Table III-1 may not be the same as the contractually specified rates.

Table III-1. Retention Rates[72]

Category	Company	2002	2003
Large PBM	Company A	69%	64%
Large PBM	Company B	51%	46%
Large PBM	Company C	46%	51%
Large PBM	Company D	34%	35%
Large PBM	Company E	33%	32%
Small or Insurer-Owned PBM	Company F	50%	48%
Small or Insurer-Owned PBM	Company G	25%	25%
Small or Insurer-Owned PBM	Company H	42%	41%
Small or Insurer-Owned PBM	Company I	91%	91%
Retailer-Owned PBM	Company J	55%	49%
Retailer-Owned PBM	Company K	27%	37%

Table III-1 suggests that the retention rates vary considerably. The data 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 retention rate. On the high end of the scale, a small or insurer-owned PBM had rates of 91%; on the low end, another small or insurer-owned PBM had rates of 25%. PBMs with relatively high retention rates may receive greater administrative fees from manufacturers, or simply have clients who prefer to receive higher discounts on drug pricing or other benefits rather than obtain a share of a PBM's total payments from pharmaceutical manufacturers.

Examination of the contractual sharing provisions discussed immediately above, and of the actual sharing that takes place under these provisions, does not provide a basis for making inferences regarding the extent to which PBMs versus their plan sponsor clients benefit from manufacturer payments to the PBMs. For example, suppose contracts between PBMs and plan sponsor clients provided that the PBMs would retain all the manufacturer payments. Other things equal, this would encourage competing PBMs to bid more aggressively to win contracts

[72] Table III-1 does not show data from all 15 PBM study participants because certain of the study participants did not track data to allow for the Commission to calculate these rates. For confidentiality purposes, the companies identified in Table III-1 do not correspond to the same company identifiers used in other chapters or in the appendices.

with plan sponsors. In order to win contracts, the PBMs could adjust any of a large number of terms (*e.g.*, dispensing fees, discounts off of ingredient costs) to make the contracts more attractive to plan sponsors. In this way, manufacturer payments to PBMs could be passed on to plan sponsor clients through a complex array of adjustments in contract provisions relating, for example, to the services that would be provided by the PBM and the prices and fees that would be paid to PBMs by plan sponsor clients.[73] It may be in the interest of both PBMs and plan sponsor clients to have contracts that provide that the PBMs will retain a substantial share of manufacturer payments, while including other contract terms that benefit plan sponsor clients. Such an arrangement would give the PBMs an incentive to negotiate aggressively with manufacturers for formulary and other payments, to the benefit (through other contract terms) of their plan sponsor clients. For these reasons, examination of explicit contract terms governing sharing of manufacturer payments, and to the actual sharing of these payments, does not provide a basis for valid inferences regarding alleged conflict of interest.

[73] *See, e.g.*, CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 8 (1998) ("Much of the savings that PBMs achieve appear to come from the lower prices paid to pharmacies rather than the rebates offered by drug manufacturers.").

CHAPTER IV GENERIC SUBSTITUTION AND DISPENSING PATTERNS

Congress requested that the Commission examine whether mail-order pharmacies that are owned by PBMs dispense fewer generic drugs compared to single-source brand drugs within the same therapeutic class when compared to mail-order pharmacies that are not owned by PBMs.[1] Generic drugs lower overall prescription drug costs, because generic drugs are substantially less expensive than their brand drug counterparts.[2] There are approximately 10,000 brand drugs currently on the market, and approximately 8,000 have generic equivalents. Generic drugs account for nearly 50% of all prescriptions dispensed.[3]

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.[4] Pharmacists generally can substitute a generic drug for a multi-source brand drug without prior physician authorization when a consumer presents a prescription for the corresponding brand drug.

Generic Substitution Rates

Generic substitution rates (GSR) measure how frequently pharmacies dispense generic drugs *when a generic drug is available*.[5] There are multiple bases on which to measure GSRs. For example, GSRs can be calculated for a brand drug by dispensing channel, for a brand drug in all dispensing channels, or for all drugs in a particular dispensing channel. Text Box IV-1 provides an example of generic substitution calculations for the brand drug Glucophage.

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

[2] *See* Figure II-2, *supra* Ch. II.

[3] FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION i (2002) (Executive Summary and Legislative Recommendations) [hereinafter FTC GENERIC DRUG STUDY], *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[4] For a description of the generic drug approval process, *see id.* Ch. 1.

[5] 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.

Box IV-1: Generic Substitution Rates.

In January 2002, the Food and Drug Administration began to approve generic equivalents to the brand drug Glucophage, which is used to treat diabetes. Sales of the brand drug Glucophage then decreased substantially, while sales of generic Glucophage increased. The Glucophage GSR equals the number of prescriptions of generic Glucophage divided by the sum of prescriptions of generic plus brand Glucophage. Data in Appendix F, Table F-IV-2(b), show that the 2003 GSR for Glucophage (1000 mg tablet) ranged between 93.3% and 96.8% among the nine PBMs' owned mail-order pharmacies and between 88.1% and 98.9% through their retail networks.

GSRs are a reliable measure of generic usage because they measure usage when a generic drug is available. 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 PBM, small or insurer-owned PBMs, or retailer-owned PBMs) were above 80%, and even 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 their retail pharmacies than at 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 receive when they entered prior to patent expiration.

Generic Dispensing Rates

A second measure that is used to examine generic drug usage is the generic dispensing rate (GDR). GDRs measure the percentage of generic prescriptions dispensed compared to *all* brand and generic prescriptions dispensed in a given therapeutic class or dispensing channel.[6]

Comparisons of GDRs between mail and retail dispensing must account for the different mixes of drugs and different prescription sizes dispensed through each channel. Even after controlling for these issues, comparisons of mail and retail GDRs are unreliable if they do not account for differences in plan designs and formulary decisions that plan sponsors negotiate with PBMs. Plan sponsors may customize their formularies based on the safety and efficacy of brand and generic drugs within each therapeutic class, or they may seek to provide their members with a broad range of brand drugs, even within the same therapeutic class. These formulary decisions and any plan features that provide incentives for mail or retail dispensing may affect the dispensing of brand and generic drugs within a therapeutic class, and therefore, may be responsible for differences in mail and retail GDRs for each therapeutic class.

Congress requested that the Commission examine GDRs by therapeutic class to assess differences in GDRs at mail-order pharmacies owned by PBMs compared to mail-order and retail pharmacies that are not owned by PBMs. For prescriptions dispensed in December 2003, the data showed that:

- For large PBMs, ownership of the mail-order pharmacy did not significantly change the mail GDR. The weighted average GDR was 35% for *owned* mail-order pharmacies, and 36% for *not-owned* mail-order pharmacies. For retailer-owned PBMs, the weighted average GDR at *owned* mail-order pharmacies was 37%, and the GDR at *not-owned* mail-order pharmacies was 42%.

- For large PBMs, the weighted average GDR 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. As noted above, differences in plan designs and formulary composition may explain the reasons for higher retail GDRs as compared to mail GDRs.

[6] 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).

Plan Sponsors Have a Variety of Ways to Increase Generic Drug Utilization

Review of the 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 require PBMs to guarantee GSR and GDR rates. The contracts revealed that plan sponsors negotiated different guarantee 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' co-payment amounts for generic drugs as an incentive for members to choose generic prescriptions.

* * * * *

This chapter first discusses overall and product-by-product GSRs. It examines the profitability of each of the three drug types (single-source brand, multi-source brand, and generic) to show that the PBM-owned mail-order pharmacies' incentives, on average, were consistent with those of their clients in 2002 and 2003. The chapter discusses some of the deficiencies in GDRs as an accurate measure of generic usage, and it presents data on GDRs for the study participants, as requested by Congress. It then discusses various provisions in the PBM-plan sponsor contracts that plan sponsors have used to increase generic drug usage when a generic is available.

I. BACKGROUND ON GENERIC DRUGS

Some industry participants and consultants have alleged that PBM-owned mail-order pharmacies dispense generic drugs less frequently than would be in the interests of their plan sponsor clients, and less frequently than other pharmacies.[7] According to these critics, PBMs allegedly weight their formularies toward single-source brand drugs for which they obtain payments from pharmaceutical manufacturers, as discussed in Chapter III.

The GAO's analysis of pharmacy benefits for a limited set of health plans participating in the Federal Employees Health Benefit Program found that the GSRs of retail and mail-order pharmacies were similar.[8] A 2004 peer-reviewed study also showed that GSRs and GDRs, when

[7] *See* JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 1, 6-10 (2003) [hereinafter SELF-DEALING STUDY] *at* http://www.mpaginc.com/news/pbmreport.pdf. *See also* Letter from Lee L. Verstandig, Nat'l Ass'n of Chain Drug Stores, to Chairman Deborah Platt Majoras, Federal Trade Commission (FTC) (May 26, 2005).

[8] GAO reported a retail GDR of 45%, and a mail-order GDR of 34%. GAO believed that the difference may have been due, at least in part, to the types of drugs usually dispensed by the two types of distribution channels, rather than a failure of the mail-order pharmacy to substitute an available generic version. When the rate was determined for drugs for which a generic version was available, the GSR rate was 89% for retail stores and 87% for mail-order pharmacies. *See* GENERAL ACCOUNTING OFFICE (GAO), EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 14 (2003), *available at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196.

adjusted for the different types of drugs dispensed at mail and retail, displayed little difference between mail and retail.[9]

II. GENERIC SUBSTITUTION RATES

The Commission obtained data to analyze average annual GSRs (i) by dispensing channel and (ii) on a drug-by-drug basis for the PBMs' top selling multi-source drugs.[10] Analyses of both sets of data showed that PBM-owned mail-order pharmacies generally had higher average annual GSRs than both retail pharmacies and mail-order pharmacies not owned by a PBM.

A. Average Annual Generic Substitution Rates by Channel Showed High Levels of Generic Substitution Across Dispensing Channels and Channel Ownership

Study participants differed in how they classified multi-source and single-source brand drugs. Depending on the PBM category, GSR variances between PBM category (*e.g.*, large PBM, small or insurer-owned PBMs, retailer-owned PBMs) may reflect differences in those definitions rather than differences in their generic drug dispensing patterns.[11] Thus, the owned mail GSRs for large PBMs cannot be compared accurately with the owned mail GSRs for retailer-owned PBMs. Within any given PBM category type, however, the PBMs' classifications are consistent, and GSR's can be accurately compared by dispensing channels and ownership. Figures IV-1 through IV-3 show the GSRs by PBM category.

1. Large PBMs: Generic Substitution Rates

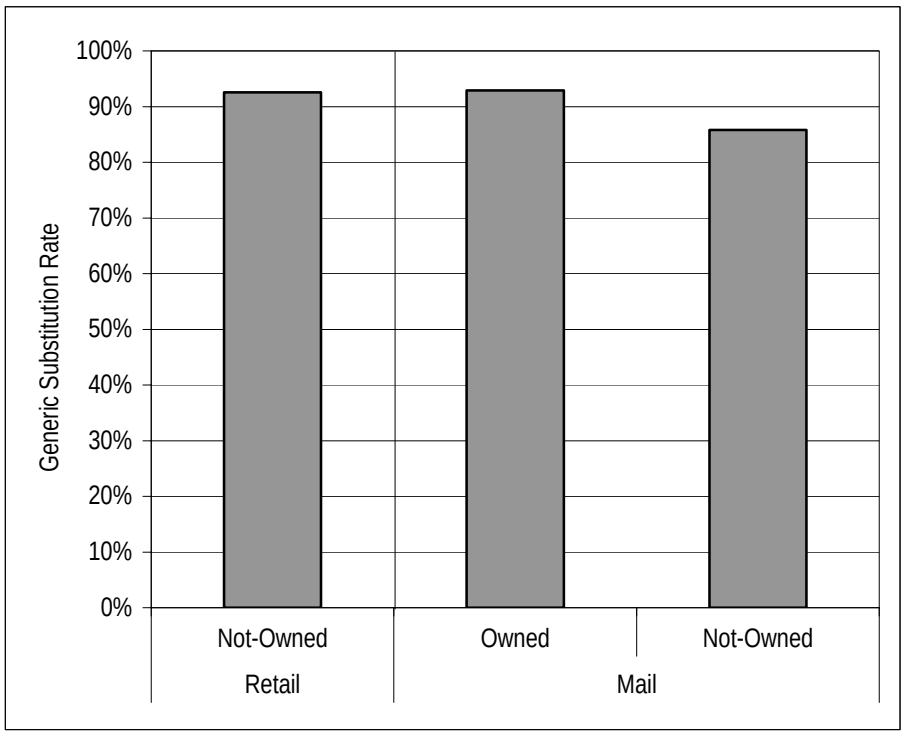
Figure IV-1 shows the average GSR for 2002 and 2003 for large PBMs. Owned mail and not-owned retail GSRs were nearly identical, and did not change significantly between 2002 and 2003. Both GSRs were higher than the not-owned mail GSR for large PBMs.

[9] *See* Marta Wosinska & Robert S. Huckman, *Generic Dispensing and Substitution in Mail and Retail Pharmacies*, 2004 HEALTH AFFAIRS (Web Exclusive) W4-409, *at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.409v1.

[10] Responses to Item 8, Part II of the Special Orders were the basis for these calculations. *See* Appendices A and B for the Special Orders.

[11] For example, three of the five large PBMs used both a combination of drug designations by First DataBank and Medi-Span, whereas the other two large PBMs supplemented the First DataBank designations with their own algorithms. By contrast, small or insurer-owned PBMs and retailer-owned PBMs primarily used Medi-Span designations.

Figure IV-1. Average Generic Substitution Rates for Large PBMs (2002 & 2003 Combined)

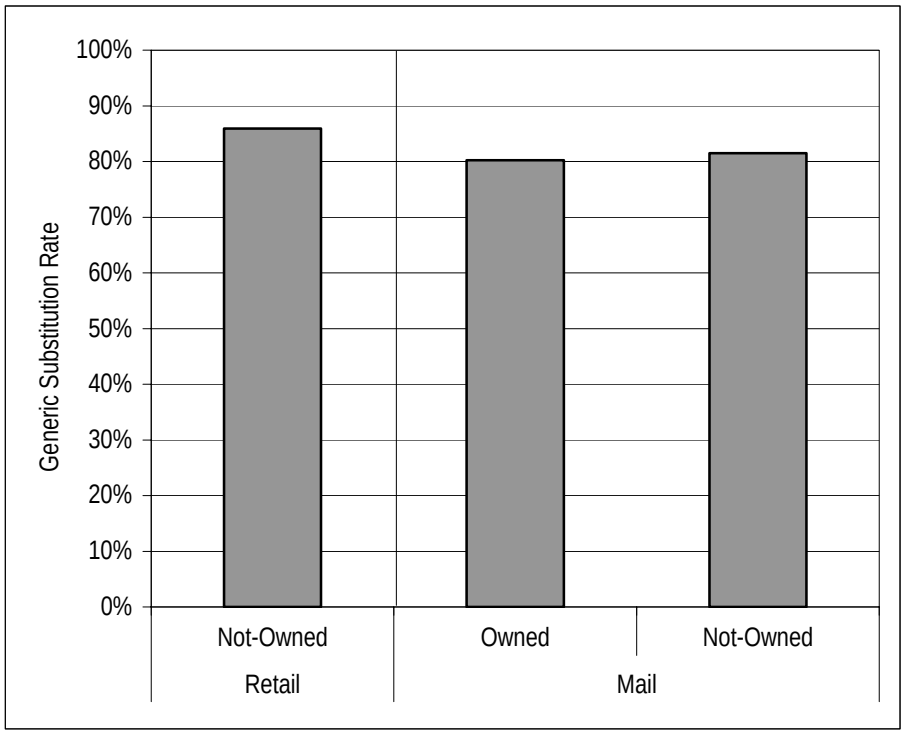


Large PBMs had their highest average annual GSRs (92.5% for 2002 and 93.3% for 2003) in the mail-order pharmacies they owned. The large PBMs' retail pharmacies had the next highest GSR (91.9% for 2002 and 93.1% for 2003). Three of the five large PBMs also used mail-order pharmacies that they did not own to provide services to their plan sponsors. These mail-order pharmacies had the lowest average annual GSRs among the dispensing channels (86.2% for 2002 and 85.6% for 2003).

2. Generic Substitution Rates: Small or Insurer-Owned PBMs

Figure IV-2 shows the average GSRs for 2002 and 2003 for small or insurer-owned PBMs by dispensing channel and channel ownership. The GSRs for each dispensing channel increased by approximately 5% from 2002 to 2003.

Figure IV-2. Average Generic Substitution Rates for Small or Insurer-Owned PBMs (2002 & 2003 Combined)

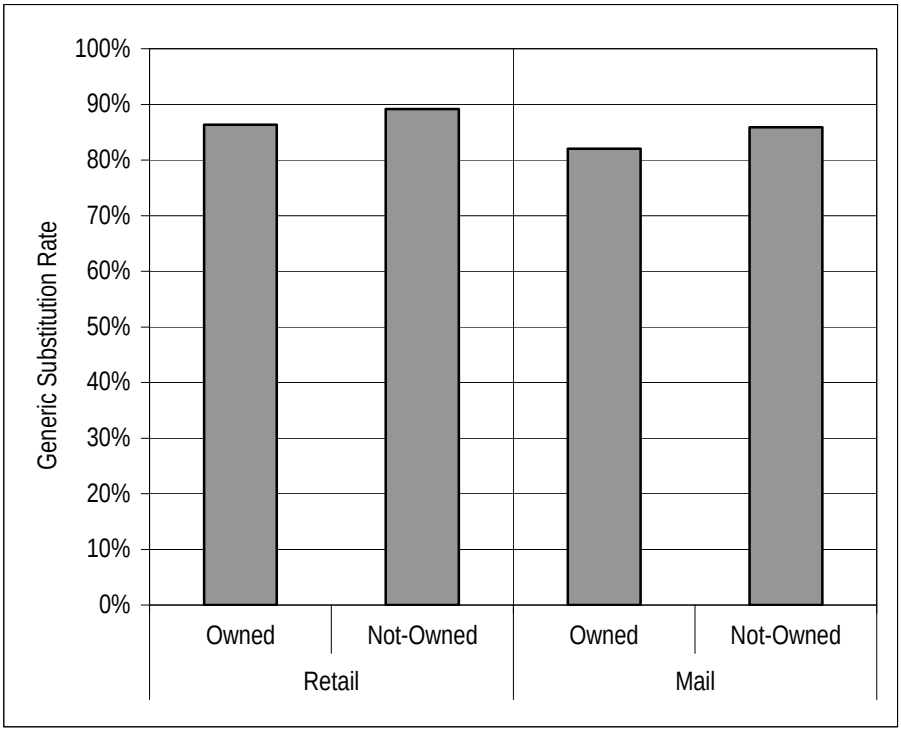


Small and insurer-owned PBMs, on average, had higher GSRs at retail than at mail, regardless of whether the mail-order pharmacy was owned by the small or insurer-owned PBM (*i.e.*, retail GSRs ranged from 83.6% to 88.4% compared to mail GSRs of 79.7% to 86.9%). Unlike the large PBMs, five of the six small or insurer-owned PBMs did not use a mix of mail-order pharmacies they owned and those they did own to serve their clients – it was one or the other.

3. Generic Substitution Rates: Retailer-Owned PBMs

Figure IV-3 shows the average GSRs for 2002 and 2003 for retailer-owned PBMs by dispensing channel and ownership. The GSRs for each dispensing channel increased by approximately 5% from 2002 to 2003.

Figure IV-3. Average Generic Substitution Rates for Retailer-Owned PBMs (2002 & 2003 Combined)



Retailer-owned PBMs had higher GSRs at retail (which ranged among the four retailer-owned PBMs from 82.9% to 90.4%) than at mail (which ranged among the four retailer-owned PBMs from 78.8% to 88.8%).

Unlike large PBMs, retailer-owned PBMs had higher average GSRs (83.3% and 88.8% for 2002 and 2003, respectively) at mail-order pharmacies they did not own than at mail-order pharmacies they owned (78.8% and 84.3% for 2002 and 2003, respectively). Moreover, retailer-owned PBMs had higher average GSRs at retail pharmacies they did not own (87.4% and 90.4% for 2002 and 2003, respectively) than at retail pharmacies they did own (82.9% and 88.7% for 2002 and 2003, respectively).

B. Average Annual Generic Substitution Rates for Top-Selling Multi-Source Brand Drugs Confirm the Trends Shown in the Annual Data Overall

The GSRs for top-selling drug products corroborated the patterns seen for the average annual GSR comparisons of mail and retail dispensing channels. Study participants submitted annual lists (2002 and 2003) of their top 50 multi-source brand drugs and their generic equivalents, identified by unique nine-digit NDCs and ranked by gross revenues.[12] Study participants also submitted financial and use information for these multi-source brand and generic drugs by dispensing channel and channel ownership type (*i.e.*, owned mail, not-owned mail, owned retail, and not-owned retail). These data enabled the Commission staff to calculate

[12] *See* Special Order, Items 20 and 21, Appendix A.

average annual GSRs for each participant's top-selling drug products by dispensing channel and channel ownership.

For each participant, the Commission staff compared each product's GSRs across dispensing channels to determine which dispensing channel had the greater number of top-selling drug products with the higher GSR. For example, most PBMs included the anti-anxiety drug Xanax (1 mg) in their lists of top selling MSB drugs. For each PBM then, the analysis below compares the following dispensing channels' GSRs for Xanax: (a) owned mail vs. not-owned mail; and (b) owned mail vs. not-owned retail.[13] Tables IV-1 and IV-2 summarize these findings for each PBM's top selling MSB drugs and Appendix F contains the full list of top-selling multi-source drugs and their GSRs that underlie the summary statistics in Tables IV-1 and IV-2. Although each PBM provided a different list of top-selling MSB drugs for 2002 and 2003, there was substantial overlap among the lists.[14]

1. PBM-Owned Mail-Order Pharmacies Had Higher GSRs for More Top Selling Drugs than Mail-Order Pharmacies Not Owned by a PBM

Table IV-1 compares the number of top-selling MSB drug products that had a higher GSR in a PBM-owned mail-order pharmacy than in a not-owned mail-order pharmacy. Five PBMs in 2002 and 2003 managed mail-order pharmacy benefits for their plan sponsor(s) through both owned and not-owned mail-order pharmacies.[15]

Table entries correspond to the number of drug products in which the GSR in that particular channel (owned mail or not-owned mail) exceeded the GSR in the other channel.[16] For example, in 2002 Company A provided information for MSB drugs represented by 84 unique 9-digit NDCs. The GSRs for 66 of these MSB drugs were higher at Company A's owned

[13] The basis for the GSR calculation for each multi-source drug product is the drug's 9-digit NDC. Some study participants, rather than using the 9-digit NDC, calculate GSRs for individual drug products based on a drug name basis. Although there are different ways to calculate individual drug GSRs, these differences do not appear to affect the conclusions drawn from this data.

[14] Another way to examine drug product GSRs would have been to request information on the same set of MSB drug products and their generic equivalents across all study participants. Such an approach, however, may have under- or over-estimated the impact of these drugs as a share of total generic revenue. A broader range of MSB drug products (as captured by different lists of top-selling MSB drugs and their generic equivalents) shows how top selling drugs can vary by PBM because of different formulary designs, plan mixes, and member profiles.

[15] PBMs that use both owned and not-owned mail-order pharmacies to serve their plan sponsor clients show substantially greater use of owned mail-order pharmacies. Gross revenues of generic drugs dispensed through not-owned mail-order pharmacies ranged from .7% to 62.8% of the gross revenues of PBM owned mail-order pharmacies.

[16] The Special Orders requested study participants to provide a list of the top 50 multi-source drug products as identified by 9-digit NDCs for each year. Some study participants, however, provided information for the top 50 multi-source drugs by drug name, rather than by NDC. As a result, these study participants provided information for more than 50 unique NDCs. For completeness, all data obtained by the Commission is summarized in Tables IV-1 and IV-2. For some companies, the total number of NDCs is less than 50, because that particular company did not dispense generic versions of the multi-source brand drug in the channels that are compared in Tables IV-1 and IV-2.

mail-order pharmacy than at the mail-order pharmacy that Company A did not own. Conversely, 18 NDCs had higher GSRs in the mail-order pharmacy not-owned by Company A than in the owned mail-order pharmacy. These 84 NDCs generated 48.9% of Company A's generic drug gross revenue through the mail dispensing channel.

Table IV-1. Comparisons of Top Selling Drug Products: Owned Mail v Not-Owned Mail[17]

Category	Company	2002				2003			
		Owned Mail	Not Owned Mail	Total Drug Products	% of Generic Revenue	Owned Mail	Not Owned Mail	Total Drug Products	% of Generic Revenue
Large PBM	A	66	18	84	48.9%	60	21	81	53.9%
Large PBM	B	52	35	87	36.9%	57	38	95	35.4%
Large PBM	C	51	35	86	37.9%	65	34	99	41.1%
Insurer/Small PBM	D	30	4	34	26.0%	19	8	27	18.4%
Retailer PBM	E	12	40	52	47.3%	21	25	46	43.4%

The data in Table IV-1 showed that, for both 2002 and 2003, with one exception, top selling drugs have higher GSRs in PBM-owned mail-order pharmacies than in not-owned mail-order pharmacies used by the PBM.

2. Comparisons of Owned Mail and Not-Owned Retail GSRs for Top Selling Drugs Do Not Show the Same Pattern for Each PBM Category

Table IV-2 compares the number of top selling MSB drug products that had a higher GSR in a PBM-owned mail-order pharmacy than in a not-owned retail pharmacy. There were nine PBMs in 2002 and 2003 for which GSR comparisons of the same drug products could be made. Table entries correspond to the number of drug products in which the GSR in that particular channel (owned mail or not-owned retail) exceeded the GSR in the other channel.[18]

[17] The "% of Generic Revenue" column may be overstated if a PBM dispensed the same set of generic drugs for different MSB drugs (*e.g.*, the MSB drugs Prinivil and Zestril can be filled with the same generic drug).

[18] Table IV-2 contains some of the same PBMs listed in Table IV-1, but labeled differently to ensure confidentiality.

Table IV-2. Comparison of Top Selling Drug Products: Owned Mail v Not-Owned Retail[19]

Type	Company	2002				2003			
		Owned Mail	Not Owned Retail	Total Drug Products	% of Generic Revenue	Owned Mail	Not Owned Retail	Total Drug Products	% of Generic Revenue
Large PBM	F	66	23	89	27.3%	77	30	107	33.3%
Large PBM	G	64	27	91	26.9%	78	27	105	33.0%
Large PBM	H	118	51	169	40.6%	125	57	182	47.5%
Large PBM	I	48	30	78	41.5%	47	43	90	43.4%
Large PBM	J	38	23	61	38.9%	37	24	61	47.9%
Insurer/Small PBM	K	46	55	101	38.9%	54	65	119	46.8%
Insurer/Small PBM	L	25	15	40	17.7%	12	22	34	13.2%
Retailer PBM	M	23	36	59	39.3%	32	27	59	36.6%
Retailer PBM	N	58	38	96	47.4%	35	44	79	43.3%

The data in Table IV-2 showed that, for both 2002 and 2003, top-selling drugs have higher GSRs in large PBM-owned mail-order pharmacies than in not-owned retail pharmacies used by the PBM. Small or insurer-owned PBMs, as well as retailer-owned PBMs, did not show a consistent pattern - some small or insurer-owned PBMs and retailer-owned PBMs had higher GSRs for more top-selling drugs dispensed through an owned mail-order pharmacy, whereas others had the converse (*i.e.*, higher GSRs for more top-selling drugs dispensed through a not-owned retail pharmacy).

C. Profit Contributions of Different Drug Types

The Commission also obtained data to look at the profit contributions of each of the three drug types (generic, multi-source brand, and single-source brand drugs). This section examines data on average profit per prescription ("spreads") for these three types of drug products for PBMs and stand-alone retailers.

1. PBM Spreads by Drug Type Show Generic Drugs Are the Most Profitable

To quantify profit contribution, the Commission staff used a measure akin to a product margin a PBM makes when a member of one of its plans fills a prescription. This report uses the term "spread" to avoid confusion with terms that may have precise accounting definitions. In simple terms, the spread measures the difference between the flows of money coming into and flowing out of a PBM as the result of a particular prescription being filled. The spread is the amount of money left over for the PBM after the inflows and outflows. It does not account for labor costs, capital expenditures, or any other revenue or cost not specifically tied to the filling of

[19] The "% of Generic Revenue" column may be overstated if a PBM dispensed the same set of generic drugs for different MSB drugs (*e.g.*, the MSB drugs Prinivil and Zestril can be filled with the same generic drug).

a particular prescription. A variety of PBM – plan sponsor contract terms (*e.g.*, guaranteed GSR and GDR rates) that are not reflected in the spreads computed here may influence the PBM's ability or incentives to dispense different types of drugs.

When the prescription is filled by a pharmacy not owned by the PBM (whether mail or retail), the spread is the amount of money the plan sponsor pays the PBM for that prescription, plus any pharmaceutical payments received by the PBM from the drug's manufacturer, less any pharmaceutical payments passed on to the plan sponsor by the PBM and any amount the PBM pays the pharmacy for the prescription. When the pharmacy is owned by the PBM, there are two changes to this calculation: (1) the amount of money the member pays the PBM for the prescription is added, and (2) the acquisition cost of the drug product is used in place of the amount paid to the pharmacy.

Table IV-3 lists the average spreads for prescriptions filled at retail pharmacies not owned by the PBM for three categories of study participants. For nearly all retail transactions, single-source brand drugs yielded the highest average spreads for PBMs in 2002 and 2003. Multi-source brand drugs typically had very small spreads at retail.

Table IV-3. PBM Spreads for Prescriptions Dispensed through Not-Owned Retail, by PBM Category and Drug Type ($ per Prescription)

PBM Category	Retail Ownership	2002			2003		
		SSB	MSB	Generic	SSB	MSB	Generic
Large PBM	NotOwned	1.78	0.33	-0.10	2.01	0.21	-0.01
Insurer PBM/Small PBM	NotOwned	2.83	0.08	2.47	2.47	-0.17	1.81
Retailer-PBM	NotOwned	2.42	0.69	2.40	2.83	0.30	2.13

Average spreads for prescriptions filled at not-owned mail-order pharmacies are listed in Table IV-4. Much like retail pharmacies not owned by the PBM, SSBs provided the largest spread of the three drug types at mail-order pharmacies not owned by the PBM. Although SSB drug spreads at not-owned mail-order pharmacies are three times as large as SSB drug spreads at retail, mail prescriptions are approximately three times as large as retail prescriptions.[20]

[20] *See* Table II-1, *supra* Ch. II.

Table IV-4. PBM Spreads for Prescriptions Dispensed through Not-Owned Mail, by PBM Category and Drug Type ($ per Prescription)

PBM Category	Mail Ownership	2002			2003		
		SSB	MSB	Generic	SSB	MSB	Generic
Large PBM	NotOwned	5.99	0.50	0.47	7.74	1.92	0.82
Insurer PBM/Small PBM	NotOwned	9.71	4.67	7.51	9.31	3.05	8.72
Retailer-PBM	NotOwned	10.41	-1.54	2.28	11.05	-2.70	0.04

Table IV-5 presents spreads at owned mail-order pharmacies. The spreads generally were much larger than the spreads at not-owned mail-order pharmacies (Table IV-4). This difference can be explained by the fact that the spreads at owned mail-order pharmacies also must cover operating expenses at these pharmacies (*e.g.*, pharmacists' labor costs, building expenses, etc.). The spreads at not-owned retail and mail-order pharmacies (Tables IV-3 and IV-4) are lower because they have operating expenses built into them.

Table IV-5. PBM Spreads for Prescriptions Dispensed through Owned Mail by PBM Category and Drug Type ($ per Prescription)

PBM Category	Mail Ownership	2002			2003		
		SSB	MSB	Generic	SSB	MSB	Generic
Large PBM	Owned	10.34	1.92	29.36	14.25	-8.61	26.46
Insurer PBM/Small PBM	Owned	22.86	11.94	30.41	19.61	13.41	32.03
Retailer-PBM	Owned	8.82	-0.59	-0.98	9.61	-1.76	-1.57

Unlike the spreads in Tables IV-3 and IV-4, in which average SSB spreads were the highest of the three drug types, the spreads for the average generic prescription dispensed through a mail-order pharmacy owned by large PBMs or small or insurer-owned PBMs were larger than the SSB or MSB drug spreads.

Average SSB spreads for retailer-owned PBMs are still higher than the average spread for generic drugs. One possible reason for this finding could be that many retail pharmacies use a central department to purchase the product from the generic manufacturer; this department then "sells" the generic drugs to each individual retail pharmacy at an internal transfer price. This internal "transfer price" may not be the actual invoice price of the drug. Mail-order pharmacies owned by large PBMs or small or insurer-owned PBMs generally do not obtain drugs from a central purchaser of this type.

2. Stand-Alone Retailers Also Make the Most Profit on Generic Drugs

Table IV-6 shows the average annual spreads for stand-alone retailers for 2002 and 2003 for customers with insurance and cash paying customers. For customers with insurance, generic spreads were much higher than for SSB and MSB drugs. For cash-paying customers, SSB and generic spreads were nearly the same. It is important to note that these spreads *do not* account for the retailers' operating expenses in administering the claims.

Table IV-6. Stand-Alone Retail Pharmacy Spreads per Prescription
by Payer Type and Drug Type ($ per Prescription)

Company Category	Payer Type	2002			2003		
		SSB	MSB	Generic	SSB	MSB	Generic
Retailer	3rd Party Insurance	7.52	6.47	12.48	8.26	6.92	12.93
Retailer	Cash	13.31	11.91	13.44	15.28	12.23	15.07

D. PBM Internal Documents Confirm Profitability of Generic Drugs

GSRs show that PBMs' owned mail-order pharmacies were generally more, rather than less, aggressive in dispensing generic drugs than were other pharmacies, despite the payments PBMs receive from pharmaceutical manufacturers for some brand drugs. This finding is consistent with the data on spreads. The largest spreads in Tables IV-4 and IV-5 were for generic prescriptions at mail-order pharmacies owned by large PBMs and small or insurer-owned PBMs. These findings indicate that PBM-owned mail-order pharmacies' incentives and dispensing behavior, on average, were consistent with the interests of their plan sponsor clients, because generic drugs were the least expensive for both plans and members (see Figure II-2).

Internal business and strategy documents from study participants confirmed the overall conclusion that generic dispensing at owned mail-order pharmacies generally is more profitable than brand dispensing. This conclusion is true even when the generic drug replaces a brand drug on which the PBM receives pharmaceutical payments. For example, one large PBM noted that "even with rebates, our gross profit is higher on generic drugs than on brand drugs, on average (and significantly higher in mail)."[21] An insurer-owned PBM noted that although high generic substitution (and less brand drug dispensing) will lessen the payments it receives from pharmaceutical manufacturers, the PBM's profitability will increase overall because it would realize higher margins with increased generic utilization.[22]

One large PBM had a "Strategic Imperative" to increase the generic dispensing rates at mail and retail. This PBM intended to expand customer participation in programs that promote the use of generic drugs and mail order; it wanted to "capitalize on anticipated branded product patent expirations to grow the [mail-order] generic dispensing rate by 1-2% annually from 2003-2005 and by [substantially more] in 2006."[23] This PBM explained that generic drugs are important for clients, members, and PBMs. According to this PBM's documents, clients save 0.6% in drug spending for every 1% increase in generic dispensing, members' out-of-pocket costs may decline 30 to 60% versus the brand, and the PBM's margin can increase

[21] Large PBM Company Document (CD). *See also* Small or Insurer-Owned PBM CD (Industry profitability per script: generics by mail order – most profitable; brand drugs by mail order – second most profitable).

[22] *See* Small or Insurer-Owned PBM CD; Small or Insurer-Owned PBM CD ("less rebate revenue due to increased use of generics, partially offset by generic mail margin") and Small or Insurer-Owned PBM (to achieve higher mail margins, need to increase switching programs from brand to generic at mail).

[23] Large PBM CD.

substantially.[24] One PBM internal document showed that it was willing to take a loss on certain brand drugs in 2001 in order to capture the profit margin of dispensing generic drugs: at retail, $6.82 for the brand and -$0.08 for the generic for a weighted retail total of 4.68; at mail, -$1.24 for the brand and $21.85 for the generic for a weighted mail total of $5.93. These margins make clear why this PBM wanted to encourage the use of generic drugs dispensed through its mail-order pharmacy.[25]

Indeed, many PBMs and plan sponsors have developed mechanisms to increase generic usage, including benefit designs, physician and member education, and PBM contractual guarantees. One large PBM opined that 80% "of adults, regardless of income, would choose a generic if the savings was $10 [per prescription] or more."[26] Another large PBM indicated that plans need at least a $10 to $15 differential to drive member behavior from one tier to the next less expensive tier.[27] An insurer-owned PBM used a benefit design that required a member who chose to remain on a brand drug to pay the difference between the AWP of the brand and equivalent generic, in addition to the usual co-payment. Several of the PBM-plan sponsor contracts linked savings guarantees to benefit designs that strongly encouraged plan members to use generic drug products.

Some contracts required PBMs to use *concurrent* drug utilization review (DUR), including computer-generated online edits informing the pharmacy when a generic is available or blocking reimbursement approval for a multi-source brand drug's NDC. Other contracts required the PBMs to conduct *retrospective* DUR to identify physicians and pharmacists with low generic dispensing or generic substitution rates. These retrospective DUR programs usually included a wide variety of clinical and education programs designed to increase generic usage. Some PBMs mail educational materials to physicians, pharmacists, and members to inform them about the safety, efficacy, and cost-effectiveness of generics. Others send reports to physicians and pharmacists showing how their generic usage compares to others. Some PBMs utilize generic sampling programs to encourage physicians and patients to try generic drug products.

Some PBM/plan sponsor contracts guarantee minimum generic dispensing and generic substitution rates. For example, one 2002 contract guaranteed that approximately 37% of total mail-order prescriptions would be dispensed with a generic product and that approximately 47% of total retail service prescriptions would be dispensed with a generic product.[28] Earlier contracts between the same PBM and client guaranteed a GSR (when a generic was available) of 70% at mail and a GDR of 31% at retail.[29] Other PBMs and plan sponsor contracts included

[24] *See* Large PBM CD (mail order brand and generic drugs account for over 50% of how the large PBM makes its money versus approximately 25 to 30% from rebates and other contracting with pharmaceutical manufacturers).

[25] *See* Large PBM CD.

[26] Large PBM CD.

[27] *See* PBM Interview.

[28] *See* PBM contract with plan sponsor.

[29] *See* PBM contract with plan sponsor.

similar provisions. Moreover, these contract provisions demonstrate that plan sponsors recognized that GDRs differ between mail and retail and that they accepted different guarantees depending on the dispensing channel. If the PBM failed to meet the guarantees by a certain percentage, they had to pay the plan sponsor a penalty, which varied from $5,000 to $30,000 per each specified percentage.

Two large PBMs have claimed that mail order increases generic substitution rates faster than retail. One PBM stated that for Glucophage and Prinivil, clients and members saved over $100 million within the first six months of patent expirations, and the PBM's incremental margin (for dispensing the generic drug rather than the brand drug) for the same period was approximately one-half of that savings amount.[30]

III. GENERIC DISPENSING RATES DO NOT RELIABLY MEASURE GENERIC DRUG USAGE

A second measure to examine generic drug usage is the GDR. GDRs measure the percentage of generic prescriptions dispensed compared to *all* brand and generic prescriptions dispensed within a therapeutic class or dispensing channel. It cannot be calculated on a drug-by-drug basis.

Comparisons of mail and retail GDRs by therapeutic class must account for the different mix of drugs and prescription sizes dispensed through each channel. Figure II-5 showed that the mix of drugs dispensed through mail-order and retail pharmacies differs substantially. Drugs to treat chronic conditions are dispensed with greater frequency at mail. Moreover, Figure II-1 showed that mail prescriptions are generally three times as large as retail prescriptions. Thus, any comparison of mail and retail GDRs must account for these differences.

One other issue that makes comparison of mail and retail GDRs less reliable than a GSR comparison is that GDRs do not account for differences in plan designs and formulary decisions that plan sponsors negotiate with PBMs. Plan sponsors may customize their formularies based on the safety and efficacy of brand and generic drugs within each therapeutic class, or they may seek to provide their members with a broad range of brand drugs, even within the same therapeutic class. These formulary decisions and any plan features that provide incentives for mail or retail dispensing may affect the dispensing of brand and generic drugs within a therapeutic class, and therefore, may be responsible for differences in mail and retail GDRs for each therapeutic class.

Congress requested that the Commission examine GDRs by therapeutic class to assess the differences in GDRs at mail-order pharmacies owned by PBMs compared to mail-order and retail pharmacies that are not owned by PBMs. The following analysis used the December 2003 claims data from the 5 large PBMs and 2 retailer-owned PBMs to determine a GDR for each

[30] Large PBM CD.

therapeutic class by dispensing channel and ownership.[31] For example, one of the most commonly dispensed therapeutic classes of drugs in December 2003 was the ACE-inhibitor class, used to treat high blood pressure. Brand drugs in this class that had generic versions available during December 2003 included: Aceon, Capoten, Monopril, Prinivil, Univasc, Vasotec, and Zestril. Other brand drugs in this class, such as Accupril, Altace, Mavik, and Lotensin did not have generic equivalents at this time. In December 2003, 57% of the prescriptions dispensed in the ACE-inhibitor class through a large PBM-owned mail-order pharmacy were for generic drugs. Similarly, 60% of the prescriptions dispensed in this class by retail pharmacies not owned by a large PBM were for generic drugs. GDRs can be calculated similarly for all therapeutic classes in December 2003. Commission staff summarized these GDRs by calculating a weighted average GDR by dispensing channel where each GDR for a class in a channel is weighted by the share of all prescriptions in both channels that come from that class.[32] This weighted average, therefore, accounts for differences in drug mix and prescription sizes dispensed through mail and retail pharmacies.

A. Comparison of Weighted Average GDRs: Owned Mail v. Not-Owned Mail

For large PBMs, the weighted average GDR at owned mail-order pharmacies was 35%, and the GDR at not-owned mail-order pharmacies was 36%.[33] For retailer-owned PBMs, the weighted average GDR at owned mail-order pharmacies was 37%, and the GDR at not-owned mail-order pharmacies was 42%.

B. Comparison of Weighted Average GDRs: Owned Mail v. Not-Owned Retail

For large PBMs, the weighted average GDR 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. Weighted average GDRs at retail are consistently higher than at mail-order pharmacies for both PBM categories.

Differences in plan designs and formulary decisions may explain the differences in these GDRs. For example, the mail versus retail price comparisons discussed in Chapter II may partially explain these differences in mail and retail weighted average GDRs. Plan sponsors save more money on SSB drugs than generic drugs through mail rather than retail. For example, Figure II-7 shows that plans saved approximately $14 when a 90-unit prescription of a SSB drug was filled at mail rather than retail. The same figure shows that plans saved approximately $3 when a 90-unit generic drug prescription was filled at mail rather than retail. These data may indicate that plans have relatively more incentive to encourage members to obtain SSB

[31] This analysis used the first four digits of Medi-Span's Generic Product Indicator (GPI) to define therapeutic classes.

[32] This analysis normalized the number of prescriptions to account for the differing size of mail and retail prescriptions – each mail prescription is counted three times when counting the number of normalized prescriptions. *See* Figure II-1, *supra* Ch. II.

[33] These two weighted average GDRs are based on the three large PBMs that serviced plan sponsors at both owned and not-owned mail pharmacies.

prescriptions through mail order rather than retail. Because each plan is different, however, it is difficult to determine with certainty the reasons for these differences.

IV. EXPLANATIONS FOR DIFFERING MAIL AND RETAIL GENERIC SUBSTITUTION RATES ON DRUG PRODUCT BY PRODUCT BASIS

The data revealed two factors that help to explain why average annual GSRs for each multi-source brand drug at mail and retail are not closer to 100%. First, analysis of the prescriptions with a "dispense as written" (DAW) instruction showed that certain prescribing physicians continue to write prescriptions for which a generic substitute is not allowed. The data revealed that from 5% to 15% of the prescriptions dispensed included a DAW instruction. Moreover, the data showed that DAW prescriptions were more prevalent at mail-order pharmacies (regardless of ownership and PBM type) than at retail pharmacies.

Second, several PBMs have used a "house brand" strategy when there is only one generic drug on the market. For example, in certain circumstances, PBMs have obtained payments from the pharmaceutical manufacturers that lower the price of the brand drug below that of the generic drug. Use of the brand drug in this situation would not raise the cost to the plan sponsors.

A. Dispense As Written Instructions Reduce Generic Substitution Rates

DAW orders on prescriptions for multi-source drugs require the pharmacist to dispense the brand drug for which the prescription is written rather than a generic substitute. Thus, neither pharmacists nor PBMs have the discretion to substitute a generic drug for a brand drug unless they persuade the physician and/or patient to allow generic substitution. DAW orders occur most frequently when a physician writes on the prescription that no substitution is allowed. This instruction is coded in pharmacy and PBM computer systems as a "DAW 1." The patient also can require that the brand drug, and not the generic drug, be dispensed. This instruction is coded as a "DAW 2." Finally, if a pharmacy does not have a generic version of a multi-source drug, but does have the brand version, the brand drug is sometimes dispensed and billed as if a generic drug were dispensed. This action is coded as a "DAW 5." These three possible DAW prescriptions help explain why GSRs are not closer to 100% and why a multi-source brand drug sometimes is dispensed instead of the generic drug.

Table IV-7 shows the average percentage of PBMs' total prescriptions that have one of these three DAW codes. The total column shows the percentage of prescriptions that have any of the three DAW codes. This total percent varies from 5% to 15%, depending on the type of PBM and the dispensing channel. DAW 1 instructions are more common than DAW 2 and DAW 5 instructions combined. For example, for large PBMs, approximately 3% of prescriptions dispensed at retail stores not owned by the PBM have a DAW 1 code, whereas only 2% have DAW 2 and there were practically no DAW 5 codes.

Table IV-7. DAW Prescriptions as a Percent of Total Prescriptions – PBM Data (2002 & 2003)

Category	Channel	Ownership	DAW 1	DAW 2	DAW 5	Total
Large PBM	Retail	Not Owned	3%	2%	0%	5%
Large PBM	Mail	Owned	5%	1%	1%	7%
Large PBM	Mail	Not Owned	13%	2%	0%	15%
Small/Insurer PBM	Retail	Not Owned	3%	2%	0%	5%
Small/Insurer PBM	Mail	Owned	9%	4%	0%	13%
Small/Insurer PBM	Mail	Not Owned	5%	1%	0%	6%
Retailer-PBM	Retail	Owned	3%	4%	1%	8%
Retailer-PBM	Retail	Not Owned	4%	3%	1%	8%
Retailer-PBM	Mail	Owned	12%	1%	1%	14%
Retailer-PBM	Mail	Not Owned	9%	2%	0%	11%

Table IV-7 also shows that mail-order pharmacies (regardless of ownership) have a higher percentage of DAW prescriptions than retail pharmacies. This observation holds for all three PBM categories.

Table IV-8 shows the percentage of stand-alone retailers' prescriptions that have a DAW code. The retail pharmacies' data show the same trends observed in the PBM data. DAW 1 codes are the most frequent instructions and mail prescriptions have a higher percentage of DAW codes than retail prescriptions.

Table IV-8. DAW Prescriptions as a Percent of Total Prescriptions – Stand-Alone Retailer Data (2002 & 2003)

Payer Type	Channel	DAW 1	DAW 2	DAW 5	Total
Third Party	Retail	1%	2%	0%	3%
Third Party	Mail	3%	1%	0%	4%
Cash	Retail	1%	1%	0%	2%
Cash	Mail	4%	2%	0%	6%

B. House Brand Strategies May Reduce Mail Generic Substitution Rates

Some PBMs used "house brand" strategies to address limited generic price competition. This practice may affect the mail versus retail generic substitution rates. When the first generic product comes to market prior to expiration of the brand name drug's last remaining patent, the generic entrant is permitted a 180-day exclusive marketing period.[34] During this 180-day period, one PBM noted that the generic price may be only 10% lower than the brand drug price.[35] PBMs can lose money on generic drugs through their owned mail-order pharmacies during this

[34] For a discussion of generic entry, *see* FTC GENERIC DRUG STUDY, *supra* note 3.

[35] *See* Large PBM CD. A 10% discount may be atypical of discounts that generic companies provide off of the brand drug price.

period. Provisions of a PBM's contracts with plan sponsors generally require a PBM to charge the plan sponsor the generic drug discounted rate (*e.g.*, AWP - 50%) immediately upon generic entry, regardless of the price the PBM's mail-order pharmacy paid to acquire the drug from the generic manufacturer.[36]

To avoid losses, some PBMs negotiated payments from the brand drug manufacturer that lower the price of the brand drug to a level below the generic drug price during the 180-day period. Thus, the PBM can dispense the brand drug through their mail-order pharmacy to avoid losing money on the drug during periods of limited competition, or in some cases, to avoid disrupted supplies due to limited availability of the generic product.

The brand drug Prilosec illustrates this "house brand" strategy. The FDA approved a generic version of Prilosec in October of 2002, and a consortium of generic manufacturers began commercial marketing by January 2003.[37] Appendix F, Table F-IV-2(b), shows that the 2003 annual GSR for Prilosec for three of the five large PBMs (Companies F, G, and H) was substantially lower for their owned mail-order pharmacy compared to not-owned retail pharmacies. For example, for Company F, the annual mail GSR for Prilosec was 10.0% and the retail GSR was 77.6%. During the first nine months of 2003 for two of the three PBMs, the average mail price for the brand product (less 100% of pharmaceutical payments received) was lower than the generic price. It is impossible to determine the actual price the plans paid for the brand product during this period because plans differ in how they share pharmaceutical payments with plan sponsors. Nonetheless, most plan sponsor agreements require the PBM to offer generic pricing upon generic entry. For most mail-order pharmacies, this pricing was commonly set at approximately AWP-50%. For retail pharmacies, the pricing was also specified as approximately AWP-50% until the drug was added to a MAC list. Thus, the PBMs were contractually required to charge the plan sponsors the contract price for generic drugs regardless of which brand the PBM dispensed or how much it cost.

A variation of this strategy was employed by Companies I and J for Prilosec. These two PBMs purchased the brand drug at a deep discount from the manufacturer and dispensed it as a generic drug from the PBM-owned mail-order pharmacy, thus ensuring availability of a "generic" version of the drug. These two PBMs also used each plan's generic pricing discounts to price this drug during this period so that plan sponsors were indifferent as to whether they received an actual generic or a "house" generic. A comparison of mail and retail GSRs shows the effectiveness of this strategy. The mail GSRs (based on the rate charged to plan sponsors) of Companies I and J for Prilosec exceeded the GSR at retail by a significant amount (*i.e.*, 94.2% vs. 80.4% and 88.4% vs. 75.4% for Companies I and J, respectively).

[36] *Id.*

[37] On June 20, 2003, the FDA approved an over-the-counter version of Prilosec. Proctor & Gamble, Inc., began to market this version in September 2003, after the generic prescription version had been on the market for nearly 9 months.

CHAPTER V THERAPEUTIC INTERCHANGE

Congress requested the Commission to examine whether mail-order pharmacies owned by PBMs switch patients from lower-priced drugs to higher-priced drugs more frequently than mail-order pharmacies not owned by PBMs. Switching patients from one drug to another drug, after obtaining the permission of the prescribing physician, 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 chemically distinct drug in the same therapeutic class that is on the formulary. Text Box V-1 provides two examples of TIs.

Study participants explained that it is easier to conduct TIs at mail than at retail because, at mail, the customer has no expectation of receiving the prescription immediately. Thus, the mail-order pharmacist can obtain the prescribing physician's permission for the interchange without the pressure of the patient standing at the pharmacy counter waiting for the medication.[1]

Box V-1: Therapeutic Interchange

Therapeutic interchange refers to situations in which a pharmacy dispenses a preferred drug rather than the prescribed drug. There are two types of interchanges. The first type involves brand drug-to-brand drug interchanges ("brand-to-brand"). For example, a patient presents a prescription for the cholesterol-lowering drug Crestor, but the pharmacy, after obtaining physician approval, fills the prescription with Lipitor instead. The second type involves brand drug-to-generic drug interchanges in which a generic drug that is therapeutically equivalent, but chemically distinct, from the prescribed brand drug is interchanged ("brand-to-different generic"). For example, with the prescribing physician's approval, generic Prozac is dispensed for a prescription for Zoloft.

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

- Data from study participants showed limited use of TI. Two large PBMs' data 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.

[1] *See, e.g.*, Large PBM Company Document (CD) ("Interventions pursuant to therapeutic interchange programs are more prevalent at mail order than retail. . . At retail, because the pharmacist typically has a shorter time to attempt to contact the physician to seek to implement the change, therapeutic substitution is less likely to occur.").

- 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 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.[2]

* * * * *

This chapter first explains why TI has come under fire from its critics and discusses the data the Commission collected to explore the frequency of TI and its effect on plan sponsor spending. The chapter then discusses the Commission's findings on the frequency of TI among the study participants and the effect that TI could potentially have on a plan sponsor's prescription drug costs. The chapter concludes with a discussion of the tools that plans can use to avoid TIs that may increase their overall prescription drug spending.

I. INTRODUCTION

A. Allegations of a Conflict of Interest

Some in the pharmaceutical industry have speculated that pharmaceutical payments may encourage use of TIs that enhance PBMs' profits, but do not provide savings for plan sponsors or their members.[3] Some have alleged that savings on TIs have been difficult to quantify because the costs of drugs not dispensed generally are not tracked.[4]

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[2] 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.

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

[4] *See* GENERAL ACCOUNTING OFFICE (GAO), EFFECTS OF USING PHARMACY BENEFIT MANAGERS ON HEALTH PLANS, ENROLLEES, AND PHARMACIES 12-14 (2003), *available at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196. In addition, information was not available to determine when interchanges may have been made for reasons of safety, such as to avoid adverse drug interactions, and the costs incurred in such cases. *Id.*

The SELF-DEALING STUDY alleged that PBMs used TI to inflate their profits at the expense of plans and their members by switching members from multi-source brand drugs (which have a generic equivalent available) to higher-priced, single-source brand drugs for which PBMs receive pharmaceutical rebates. Although the SELF-DEALING STUDY presented no direct evidence of this practice, it concluded, on the basis of calculations of generic dispensing rates, theoretical list prices, and offers of pharmaceutical payments, that such switching occurs more frequently at PBM-owned mail-order pharmacies than at not-owned ones.[5] Lawsuits and some settlements have raised similar allegations.[6]

The information collected in this study, however, does not support allegations that plan sponsors and their members either pay more for therapeutically interchanged drugs in general or pay more for therapeutically interchanged drugs at PBMs' owned mail-order pharmacies. Indeed, many plans have negotiated various safeguards to ensure that PBM-initiated TIs have a neutral or beneficial financial effect on the plan and its members.

B. Data Collected

Prior to crafting the Special Orders, staff interviewed several prospective study participants to determine how they maintained TI records. At that time, these potential participants indicated one of two problems with their TI records: (1) they did not keep systematic records that showed how frequently an interchange occurred between any given drug pair, or (2) they did not track the price of the prescribed drug - they indicated that their claims data track the drug dispensed, not the drug originally prescribed.

The Commission's Special Orders, therefore, sought data to provide an overview of the *potential*, rather than actual effects of any given interchange. To this end, the Special Orders required each study participant to provide each pair of drugs, as identified by nine-digit NDCs, for which it had authorized a program to switch (for example, through formulary compliance, letters, or telephone calls to doctors or enrollees) from a prescribed drug to a therapeutically similar branded drug product (a "preferred drug").

Each study participant provided all drug pairs for which it had TI programs during 2002 and 2003, and information on whether a generic version was available for the prescribed drug product. Because brand drugs have unique nine-digit NDCs for each dosage strength and form, one brand-to-brand TI pair (*e.g.*, interchange of Lipitor for Zocor) could be represented by

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[5] SELF-DEALING STUDY, *supra* note 3, at 5.

[6] *See supra* Ch. I, Introduction and Background; *see also* 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), *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. *See also* Press Release, Office of New York State Attorney General 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.

multiple 9-digit NDC combination pairs. Each participant also provided information to calculate 2002 and 2003 average member and plan prices per day (on an NDC basis) for each prescribed, preferred, and available generic drug product by dispensing channel and ownership status of the dispensing channel.[7]

From this information, the Commission staff calculated average annual plan and member prices to determine whether the TIs, *if implemented*, would have resulted in a savings or loss to the plans and their members. One large PBM explained, however, that its "data do not match specific NDC-pairs that were approved for interchange. They represent all of the NDCs for any drug name that was part of the [therapeutic interchange program], potentially including dosages that were never part of the program."[8] As a result, the possible savings or loss calculations are not based on actual TIs implemented for plan sponsors. Nonetheless, the data came as close as possible to evaluating the *possible* effect of TI programs that PBMs have adopted.

II. THERAPEUTIC INTERCHANGES APPEAR TO BE RELATIVELY RARE

In early 2005 after responding to the Special Orders, two large PBMs submitted data on the actual number of interchanges during 2002 and 2003. For these two large PBMs, TI affected less than one-half of one percent (0.5%) of prescriptions dispensed at retail and at PBMs' owned mail-order pharmacies. For example, one large PBM interchanged approximately 0.33% and 0.25% of mail prescriptions in 2002 and 2003 respectively. The percentages at retail (0.03% in 2002 and 0.02% in 2003) were even smaller. These figures do not include refills or renewals of interchanged prescriptions.[9] Another large PBM interchanged less than 0.5% of prescriptions dispensed at its owned mail-order pharmacy.[10]

One PBM indicated that it regards the real value of TI programs as a negotiating tool with manufacturers to obtain higher pharmaceutical payments or allowance rates. Some pharmaceutical manufacturers try to avoid having PBMs authorize their drugs for interchanges, which could result in lost sales, by offering higher allowances to lower the cost of their drugs. Interchange programs are expensive, and PBMs prefer not to use TI if they can achieve lower drug costs in other ways.[11] This PBM explained that it does not implement every therapeutic interchange program approved by the P&T committee. A PBM's decision to implement a TI program is based upon whether it will provide incremental leverage with the pharmaceutical

[7] *See* Appendix A, Items 14 and 15 of the PBM Special Orders for the questions relating to therapeutic interchange.

[8] Large PBM CD.

[9] These data relate to therapeutic interchange involving brand-to-brand interchanges. Large PBM CD.

[10] Large PBM CD.

[11] Large PBM CD; PBM Interview.

manufacturer or move sufficient market share to or from a drug to outweigh the program's costs.[12]

III. RESULTS OF THE DATA ANALYSIS

A. Overview of Mail and Retail Therapeutic Interchange by Therapeutic Category

The Commission limited its analysis of TI to several therapeutic classes in the top 10 therapeutic categories, which represent substantial prescription volume and dollar expenditures. Table V-1 shows the therapeutic categories and therapeutic classes examined.

Table V-1. Therapeutic Categories and Classes

Therapeutic Category	Therapeutic Class
1 Antidepressant	Selective Serotonin Reuptake Inhibitors (SSRIs); Other
2 Antidiabetic	Glitazones; Metformins; Sulfonylureas; Sulfonylureas II
3 Antihistamines	Antihistamines
4 Antiinfectives	Quinolones
5 Anti-inflammatory	COX-II Inhibitors
6 Antiulcer	Proton Pump Inhibitors
7 Autonomic	Long Acting Beta Agent; Miscellaneous
8 Cardiac	ACE Inhibitors; Angiotensin Receptor Blockers II; Beta Blockers; Calcium Channel Blockers (Dihydropyridine Class); Calcium Channel Blockers (Verapamil Class)
9 Lipid Lowering	Statins
10 Osteoporosis	Bisphosphonate; Estrogens

B. Range of Brand-to-Brand Therapeutic Interchanges in Ten Therapeutic Categories

Of the 15 PBM study participants, nine had brand-to-brand TI programs in 2002 and 2003. These nine varied as to the therapeutic categories and the number of categories covered by their brand-to-brand TI programs. For example, one PBM's TI program involved brand drugs in three therapeutic categories, while another PBM's TI programs involved drugs in all 10 categories.[13]

[12] Large PBM CD.

[13] Table G-V-1, Appendix G, shows the ten therapeutic categories for which of 7 of the 9 PBMs conducted brand-to-brand TI through mail-order pharmacies in each category in 2002 and 2003. Table V-2, *infra*, also summarizes the number of therapeutic categories in which study participants had TI programs. Two study participants are not shown in Table V-2 to protect confidentiality.

All but two of the nine PBMs' TI programs involved the same number of drug products for TI at their owned mail pharmacies and through their retail pharmacy networks. Only one PBM's TI program involved substantially more brand products for interchange at its owned mail pharmacy than through its retail network. For the remaining PBM, its TI program involved more brand products for interchange at retail than mail.

C. The Majority of Therapeutic Interchanges Had the Potential to Lower a Plan's Prescription Costs in the Ten Therapeutic Categories Examined by the Commission Staff

To calculate the possible financial impact of each study participant's TIs, staff compared the total price of the prescribed and preferred drugs to determine whether the TI would save the plan and member money on a per day basis. Table V-2 shows the percentage of NDC pairs, by dispensing channel and channel ownership,[14] for which the preferred drug's average total price (plan price plus member copayment) was lower than the prescribed drug's average total price, and thus the TI would have saved money for the plan and member.[15] ***The data do not correspond to the actual number of interchanges that occurred in 2002 and 2003, and do not provide the actual effect of any given therapeutic interchange for any specific client plan sponsor.*** Rather, this information shows how often a TI would be beneficial to the plan if the TI were actually performed based on average prices PBMs charged all of their plans.

[14] The retail category combines PBM-owned and not-owned retail pharmacies, although only the retailer-owned PBMs reported data from owned retail pharmacies. Not-owned mail-order pharmacies showed similar savings rates as owned mail pharmacies, but are not shown in Table V-2 to protect study participant confidentiality.

[15] Tables G-V-2(a) – G-V-2(d), Appendix G, show by dispensing channel a further breakdown of the possible magnitude of savings and losses resulting from TIs. On average, each unique brand-to-brand TI paid at mail had 8 NDC pairs and each unique brand-to-brand TI paid at retail had 15 NDC pairs.

Table V-2. Share of Possible Therapeutic Interchanges
that Result in Savings to Plans and Members in Ten Therapeutic Categories

Company	Type	Number of Therapeutic Categories with TI Programs	2002		2003	
			Owned Mail	Retail	Owned Mail	Retail
Company A	Large PBM	3	45.1%	44.7%	49.4%	44.7%
Company B	Large PBM	7	65.8%	56.0%	67.6%	59.9%
Company C	Large PBM	7	49.7%	55.6%	71.4%	60.6%
Company D	Large PBM	6	86.6%	85.0%	87.3%	81.8%
Company E	Large PBM	10	49.3%	57.4%	52.2%	52.3%
Company F*	Retailer-PBM	4	77.4%	80.3%	84.1%	77.9%
Company G* **	Retailer-PBM	5	54.3%	55.8%	54.9%	53.2%

* These companies could not provide information about how much of their pharmaceutical payments they passed on to their plan sponsor clients. As a result, the data may understate the savings their clients could obtain through TIs.
** This company's data were provided on a per prescription, rather than per day basis.

A large PBM (Company D) had the largest percentage of TIs that had the potential to result in overall, combined savings to the member and plan. In 2002, this PBM's brand-to-brand TIs (as measured by unique NDC pairs) through its owned mail-order pharmacy had the potential to save its clients money for 86.6% of the interchanges. Interchanges at the PBM's retail network of pharmacies showed a similar high frequency of potential savings (85%). The 2003 data are similar. Three of the other large PBMs' TI programs had the potential to save money approximately 50% to 70% of the time, again with owned mail-order pharmacies having a slightly higher rate, with one exception (Company E, 2002).[16] The fifth large PBM's TI programs had the potential to save money 40% to 50% of the time.

The two retailer-owned PBMs showed similar patterns. In 2002, one retailer-owned PBM's (Company F) TI programs potentially saved money 80.3% of the time at retail, and 77.4% of the time at its owned mail-order pharmacies. The second retailer-owned PBM (Company G) showed similar patterns, but at the lower end in terms of savings potential. In 2002, its TI programs potentially saved money 55.8% of the time at retail and 54.3% of the time at owned mail-order pharmacies. (Again, the 2003 data for each were similar.)

[16] The data for the two small or insurer-owned PBMs that engaged in TIs, which are not shown in Table V-2 to protect confidentiality, showed that interchanges at their owned mail-order pharmacies had potential to provide savings to plan sponsors more often than interchanges through their retail networks.

In sum, 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 in 2002 and 2003. These summary data viewed in a vacuum, however, present an incomplete, and perhaps distorted, picture of the financial effect of these TIs. For example, the small degree of variance in the results based upon distribution channel suggests that PBMs are not using their owned mail-order pharmacies in a manner that is adverse to plan sponsors. In fact, in most cases the potential savings at mail and retail were nearly the same. Moreover, as discussed later in this chapter, the data do not reflect the fact that plan sponsors' contracts with PBMs often included protections against losses from therapeutic interchanges.[17]

D. Therapeutic Interchanges Rarely Occurred If an Equivalent Generic Drug was Available for the Prescribed Drug

In the top ten therapeutic categories studied, PBMs rarely had a TI program for a brand drug for which a generic equivalent of the prescribed drug was available. These data conform to the findings in Chapter IV that showed very high generic substitution rates once a generic drug becomes available. For example, if a prescribed drug had a generic equivalent available (*e.g.*, a multi-source drug such as the cholesterol-lowering drug Mevacor, which had a generic available – lovastatin), rarely was that brand drug included in a TI program (*i.e.*, in only rare circumstances was Mevacor interchanged for another brand drug, *e.g.*, Lipitor).

Table V-3 presents the number of brand drugs involved in PBM TI programs (in the 10 therapeutic categories shown in Table V-1) in which a generic version of the brand drug was available. In 2002, no single PBM had more than six drugs, and in 2003, the maximum number of drugs was five.

Table V-3. Number of Brand Drugs, with an Available Generic Drug, for TI in the Ten Therapeutic Categories Examined by FTC Staff

PBM	Type	2002	2003
Company A	Large PBM	0	0
Company B	Large PBM	5	5
Company C	Large PBM	5	5
Company D	Large PBM	4	1
Company E	Large PBM	6	3
Company F	Retailer-Owned PBM	4	0
Company G	Retailer-Owned PBM	3	3

One large PBM (Company A) stated that the "interchange of an MSB drug to an SSB drug by [Company A] is generally only attempted when a physician writes a prescription for an MSB drug to be DAW; in these cases, a mail-service pharmacist may attempt to contact the

[17] *See* discussion *infra* Sec. IV.A of this chapter.

physician to recommend substitution of the available generic. Only failing that will the pharmacist suggest a lower-cost branded drug as an alternative."[18]

The lack of TI when a generic version of a brand drug is available is consistent with the "spread" data presented in Chapter IV. The spread data showed that generic drugs provide PBMs with the greatest average profit margin per prescription dispensed, even when pharmaceutical payments were considered.[19]

E. Range of Brand-to-Generic Therapeutic Interchanges in Ten Therapeutic Categories

In addition to brand-to-brand TIs discussed in the four preceding sections, some PBMs had TI programs that interchanged a therapeutically equivalent, but chemically distinct, generic drug for a prescribed single-source brand drug ("brand-to-different generic").[20] For example, if a member had a prescription for the anti-depressant brand drug Zoloft, the PBM might seek to interchange it with generic Prozac.

Eight of the 15 study participants had brand-to-different generic TI programs. Four PBMs' brand-to-different generic TI programs involved 6 of the 10 therapeutic categories the Commission examined. The other 4 PBMs' brand-to-different generic TI programs involved drugs in 2 categories (2 PBMs) or 3 categories (2 PBMs).

These brand-to-different generic TIs were most frequently found in therapeutic classes with a large number of generic drugs. For example, the data revealed that these TI programs involved drugs in the ACE inhibitor therapeutic class of cardiac drugs and the proton pump inhibitor therapeutic class of antiulcer drugs. Because generic drugs are substantially less expensive than single-source brand drugs, these types of interchanges have the potential to save money for plan sponsors and their members.[21]

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[18] Large PBM CD. It is also theoretically possible that such a therapeutic interchange program might be implemented if a P&T Committee concluded that a more expensive SSB was more efficacious than a less expensive MSB, and that use of the SSB product could result in better disease management and lower overall health care costs. *See, e.g., id.* (because the P&T Committee found a particular asthma drug more efficacious than the other products in the category, this PBM might offer its clients the option of implementing an interchange program to switch from a lower priced branded product to the higher priced, but more efficacious product).

[19] *See* discussion *supra* Ch. IV.C.

[20] This type of TI is different from the generic substitution examined in Chapter IV and in Section D of this Chapter because the generic drug interchanged does not have the same active drug ingredient as the prescribed brand drug.

[21] *See* Figure II-2, *supra* Ch. II.

IV. PLAN SPONSORS HAVE A VARIETY OF TOOLS TO PROTECT AGAINST COSTLY THERAPEUTIC INTERCHANGES

PBMs, working with plan sponsors, have used a variety of tools to manage pharmacy benefits. The formulary is the centerpiece around which the other tools work.[22] Plan sponsors generally decide how strongly they want the PBM to enforce compliance with the formulary and, based on that decision, the PBM can recommend benefit design options to promote the desired level of formulary compliance.[23] Therapeutic interchange programs are just one of the tools PBMs used to enforce formulary compliance.[24]

A. A Plan Sponsor Can Obtain Contractual Protection Against Therapeutic Interchanges That Do Not Produce Savings

Review of 26 plan sponsor-PBM contracts showed that plan sponsors protected their interests in several ways. First, plan sponsors and PBMs often agreed that the PBM would obtain the sponsor's approval to use any TI program.[25] Second, some PBMs offered financial guarantees regarding sharing of pharmaceutical manufacturer payments and/or the financial savings from the therapeutic interchange programs. Such guarantees help to align the incentives of the PBM and plan sponsor: if an interchange would reduce the savings to the plan sponsor below the guaranteed level, the PBM would have to pay the plan.[26]

For example, one large PBM's contracts explicitly allowed therapeutic interchange, allowed the PBM to contact members, and acknowledged the PBM's various relationships with manufacturers:

> Formulary Program. (i) Provide a supply of formulary brochures listing the Client's preferred brand-name product in each of a number of therapeutic categories; (ii)

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[22] *See, e.g.*, Small or Insurer-Owned PBM CD (continue to use a "Rigorous P & T committee process producing an outcomes based formulary" as one way to enhance PBM's reputation for clinical excellence and integrity). *See also* discussion *supra* Ch. I (Introduction and Background).

[23] *See, e.g.*, PBM contract with plan sponsor, which specifies the dollar amount for pharmaceutical payments for Years 1, 2, 3 of the contract, and the payments vary depending on whether the plan sponsor uses a 2-tier or 3-tier formulary plan. The higher payments for the 3-tier option required the client to implement and maintain copayment levels with at least a $15 differential between the lower copayment for formulary brand drug prescriptions and the higher copayments for non-formulary brand drug prescriptions which have formulary brand-name equivalents. Other PBMs' contracts contained similar provisions. *See, e.g.*, PBM contracts with plan sponsors.

[24] *See, e.g.*, PBM contract with plan sponsor.

[25] In addition to, or in place of, direct savings or pharmaceutical payments to PBMs, some PBMs offer deeper discounts off AWP if the plan agrees to certain benefit designs, including generic and therapeutic interchange programs that increase formulary compliance.

[26] Savings can occur in at least two ways: (1) the interchanged drug has a lower AWP than the originally prescribed drug; or (2) the interchanged drug increases the pharmaceutical manufacturer payments that are passed through to the plan sponsor.

> periodically distribute the brochures directly to prescribers; and (iii) contact prescribers, as appropriate, to obtain approval for substitution of formulary drugs. As a component of the plan design, Client will use [PBM's] Preferred Drug List, as amended from time to time, as the formulary for prescription drugs under the plan. . . . [PBM] may hold contracts with the manufacturers of products covered under this Agreement and in connection with such contracts, [PBM] may have a financial relationship with such manufacturers and may receive rebates from such manufacturers. In addition, [PBM] may contact Covered Members regarding therapeutic compliance, therapeutic education, or similar programs. [PBM] may receive compensation from pharmaceutical manufacturers for certain of these services.[27]

This PBM's contracts offered programs at mail and retail that, if implemented by the plan, would require the PBM to analyze prescription data, determine the appropriateness and cost-effectiveness of current prescriptions, and contact physicians where appropriate to suggest modifications to a drug therapy, including the use of therapeutic or generic equivalents. Some contracts referred to these programs as concurrent or retrospective case management and generic utilization management. Some of the contracts required that the plan sponsor pay a specified amount either per member per month or per prescription. The PBM, however, guaranteed that the savings would be a specified dollar amount that was generally at least twice as much as the plan sponsor paid for the program. If the savings did not meet or exceed the amount the PBM guaranteed, the PBM would have to pay the plan sponsor the difference. If the savings exceeded the guarantee, most contracts allowed the PBM to keep a percentage of the savings, generally varying from a 25% to 50% share.[28]

Another large PBM's plan sponsor contracts frequently included a prescription management program whereby the PBM and the network providers would:

> work together to encourage the use of Preferred Drugs by (i) identifying appropriate opportunities for converting a prescription from a non-preferred to a Preferred Drug, and (ii) contacting the member and the prescriber to request that the prescription be changed to the Preferred Drug. A Preferred Drug is one on the Performance Drug

[27] *See, e.g.*, PBM contract with plan sponsor.

[28] *See, e.g.*, PBM contract with plan sponsor (The plan sponsor paid the PBM a monthly fee of $2.15 per mail prescription dispensed for the program and the PBM guaranteed that the savings would be at least $4.90 per mail prescription on a contract year basis. The PBM would receive 25% of any additional savings and the client would keep 75% (after paying the dollar amount to the PBM). If the savings fell below the guarantee, the PBM would have to pay the client the difference. For this program at retail, the plan sponsor paid the PBM $0.15 per retail prescription or the program and the PBM guaranteed that the savings realized would be at least $0.35 per retail prescription. The PBM received 25% of any additional savings above this amount.). *See also* PBM contracts with plan sponsors (plan sponsors paid the PBM for the program by sharing 50–50 in the savings for both mail and retail); PBM contract with plan sponsor (plan sponsor paid the PBM 40% of all savings realized as a result of PBM's program at mail and a fee of $0.20 per active or retired employee per month for the PBM's program for retail services).

> List, which has been developed by [PBM] as a clinically appropriate and economically advantageous subset of the [PBM] clinical formulary.[29]

This same PBM's contract with one sponsor explicitly provided for therapeutic interchange programs, stating that: "The program is cost-effective because members receive the lowest cost, preferred medication that provides the same clinical benefits as the higher cost, non-preferred medication." This contract allowed the plan sponsor to participate on a drug-by-drug basis and required prior written approval from the plan sponsor. The contract specifically set forth program procedures, including the use of prior authorization and prospective, retrospective, and concurrent drug utilization review programs.[30] This PBM also offered plan sponsors therapeutic interchange programs for which it charged a fee per intervention, as well as a share of the savings resulting from the interchange.[31]

Yet a third large PBM's contracts guaranteed:

> that brand-to-brand formulary intervention programs will yield cost savings from such programs, prior to Formulary Rebates. Within forty-five (45) days of the end of each full Calendar Quarter, [PBM] will calculate and report to [plan sponsor] the aggregate brand-to-brand intervention savings, calculated as the difference between the aggregated discounted AWP of all preferred drugs dispensed as a result of such interchange programs. If the aggregated discounted AWP of all the original non-preferred drugs is less than the aggregated discounted AWP of all preferred drugs dispensed as a result of the interchange program, [PBM] will pay [plan sponsor] any such differential.[32]

The PBM guaranteed that this plan sponsor would save an amount equal to 1.5 times the total charge for participating in the program as long as the plan sponsor participated and cooperated fully in the program. The PBM and the plan sponsor would share equally any savings in excess of 1.5 times the charge.[33]

B. PBM Policies and Business Practices Indicate That Plan Sponsors Can Benefit From Therapeutic Interchanges

PBM internal documents prepared in the regular course of business to inform high level management decisions are consistent with the data analysis presented above. One small or insurer-owned PBM's internal business documents suggested that plan sponsors likely benefited

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[29] *See, e.g.*, PBM contract with plan sponsor. Many of the contracts also offered managed access, managed drug limitations, and prior authorization programs to better manage the plan sponsor's drug benefits.

[30] *See* PBM contract with plan sponsor.

[31] *See* PBM contract with plan sponsor (the plan sponsor received 60% of the savings).

[32] *See* PBM contract with plan sponsor.

[33] *See* PBM contract with plan sponsor (guaranteed savings were 1 time the charge).

from therapeutic interchange programs. This PBM had discontinued therapeutic substitution in the late 1990s "to eliminate all appearances of impropriety."[34] The PBM concluded that this was a disservice to its customers because "[c]ustomers pay PBMs to identify clinically equivalent drugs and steer membership to appropriate lower costs [sic] solutions. The PBMs never change a physician's suggested therapy without the approval of the physician. By steering market share to one drug over another, PBMs drive down acquisition costs."[35] As a result of this assessment, this PBM's management recommended reinstating therapeutic substitution programs.[36] Another small or insurer-owned PBM also believed TI was a positive for plan sponsors and PBMs, noting that one of its initiatives for 2003 was to "enhance outbound therapeutic switch and compliance programs to increase revenue and decrease client spend."[37]

One large PBM's business documents listed the principles that governed its therapeutic interchange program. First, the drugs presented to physicians as possible alternatives must meet criteria for general interchangeability. Second, some drugs are screened out as appropriate therapeutic alternates based upon patient attributes, medical histories, drug profiles, and other factors that might make interchanges inappropriate. Third, the P&T committee determines interchangeability based on clinical grounds and the screen outs. Finally, the interchange program cannot adversely affect any plan or member financially.[38]

Another large PBM described its formulary compliance efforts as follows:

> There is an immediate need to transition our clients into a set of programs that shift utilization towards formulary products (brand and generic).[39] . . . As plan sponsors shift costs to consumers, [we] will need to respond with formulary tier recommendations, member communications that explain the benefit from a consumer perspective and effective programs for switching members to generic or preferred drugs and mail pharmacy service to help control member out-of-pocket costs as well. This will also result in lower costs for the plan sponsor (and better formulary control leading to more leverage with manufacturers which will drive rebates and further reduce costs). Overall, the role served by the PBM will be needed now more than ever.[40]

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[34] Small or Insurer-Owned PBM CD.

[35] Small or Insurer-Owned PBM CD.

[36] *See* Small or Insurer-Owned PBM CD (also noted it would disclose these programs to clients and likely share some portion of the increased pharmaceutical payments with them).

[37] Small or Insurer-Owned PBM CD.

[38] *See* Large PBM CD.

[39] Large PBM CD.

[40] Large PBM CD.

This PBM also noted the need to encourage pharmacies and physicians to comply with formulary recommendations. It suggested educating retail pharmacies using point-of-service online messages and edits, retail report cards, and a pharmacy portal,[41] and educating physicians about lower-cost prescription drugs, mail, select clinical programs, and the benefits of electronic prescribing.[42]

Another large PBM explained that its "substitution initiatives focus on the education of providers and members as to which products offer the best outcomes for the lowest cost."[43] For example, one of its physician education letters explained the results of several clinical trials and stated that one manufacturer's statin drug had a preferred status on its formulary, noting that the medication offers the lowest pricing in its class with an AWP up to 50% lower than any other HMGs or "statin" medications.[44]

C. PBM Interchanges of a More Costly Drug for the Prescribed Drug May Not Adversely Affect Plan Sponsors or Their Members

Several large PBMs have adopted policies and customer commitments in the past few years that prohibit them from conducting formulary interchanges in which a lower cost drug is switched to a higher cost drug.[45] Some PBMs have stopped therapeutically interchanging high AWP drugs for low AWP drugs, at least in part because it could cause confusion and misunderstandings with their customers.[46] As one large PBM's customer savings guarantee stated: "For new prescriptions, and subsequent renewals and refills of those prescriptions, on or after the Effective Date, [PBM] guarantees that no formulary interchanges will be conducted where a low cost drug is switched to a higher cost drug, unless agreed upon by SPONSOR and [PBM]."[47] E-mails between the PBM and a plan sponsor regarding possible substitution between two antiulcer drugs confirmed this policy. Although the preferred drug's AWP was slightly higher, the savings to the plan after sharing of pharmaceutical payments would be significantly higher if it was interchanged for the other.[48] Moreover, as in this case, AWP comparisons are not necessarily meaningful. AWP is often referred to as the "undiscounted

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[41] *See* Large PBM CD.

[42] *See* Large PBM CD.

[43] Large PBM CD.

[44] *See* Large PBM CD.

[45] Some of the large PBMs provided additional documents and explanatory material concerning contracting practices that were implemented after the 2002-2003 time frame for material requested in the FTC's study. *See* Large PBM CD.

[46] *See* Large PBM CDs.

[47] Large PBM CD.

[48] *See* Large PBM CD (e-mails between PBM and plan sponsor seeking, and receiving, approval to therapeutically interchange two antiulcer drugs even though the preferred drug's ingredient cost was slightly higher).

sticker price" for a particular drug product.[49] AWP does not reflect actual transaction costs, such as the pharmaceutical payments received on each sale.

Finally, in order to calculate the net benefit of any particular TI, the PBM and plan must factor in not just the AWPs of the two drugs, but also the products' market shares. For example, if a manufacturer offered a formulary or market-share payment on a drug with a slightly higher AWP and the drug had an 80% market share, then plan sponsors would receive the benefit of the pharmaceutical payments on 80% of the prescriptions dispensed. If the plan and PBM chose to favor the drug with the lower AWP, then they would receive only the savings on 20% of the prescriptions and they would lose the pharmaceutical payments on 80% of the prescriptions. Thus, the PBM and the plan sponsor often look at the "but for" world and what will happen under different scenarios. Sometimes a plan sponsor does not save money by using TI to a higher-priced, higher market share drug, but it loses less than it would if it did nothing or preferred the less expensive, but less popular drug.[50]

[49] *See* CONG. BUDGET OFFICE (CBO), PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS 3 (2005), *available at* http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf.

[50] *See, e.g.*, Large PBM CD; PBM Interview.

CHAPTER VI REPACKAGED DRUGS AND THEIR IMPACT ON PLAN SPONSORS' DRUG PRICES

Congress requested that the FTC answer: (1) 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; and (2) whether mail-order pharmacies owned by PBMs (or entities owned by PBMs) sell repackaged drugs at prices above the manufacturer's average wholesale price.[1]

Repackaged drugs are drugs manufactured by FDA-licensed manufacturers and purchased in bulk by FDA-regulated repackaging companies. Those companies then repackage the drugs, usually in quantities typical of the prescriptions dispensed for that drug. The repackaging company assigns a new national drug code (NDC) number to the repackaged drug, and reports an AWP for the new NDC to companies that maintain this information for industry use, such as Red Book, First Data Bank, and Medi-Span.

The Commission requested data from the study participants to quantify the extent to which repackaged drugs were provided to plan sponsors' members, and to consider the financial ramifications, if any, of this practice. The study data support several conclusions, including:

- PBMs rarely dispensed repackaged drugs through their 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. The financial impact on plan drug spending was insignificant.

- 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 large PBMs repackaged drugs itself through an 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, inflated AWPs. The clients of this PBM paid less, on average, for the repackaged drugs dispensed by mail pharmacies than they paid for the non-repackaged version of the same drugs at retail pharmacies.

Background

Repackagers often report AWPs that differ substantially from the original manufacturer's AWP. For example, *Mosby's Drug Consult*[2] lists, in addition to the manufacturer (Pfizer), eight

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

[2] *See Celecoxib (3427), in* MOSBY'S DRUG CONSULT (Elsevier), *at* http://www.mosbysdrugconsult.com/DrugConsult/Top_200/Drugs/e3427.html (last visited July 14, 2005).

repackagers of 200 mg capsules of Celebrex.[3] The AWP per capsule reported by Mosby's for this drug ranged from $2.42 to $5.47.[4] The AWP listed for Celebrex from Pfizer was $3.11 per capsule. The SELF-DEALING STUDY alleged that PBM-owned mail-order pharmacies increase their profits by repackaging drugs and selling them at a higher per unit AWP.[5] 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.[6]

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The chapter first discusses how infrequently PBMs in the study dispensed repackaged versions of the top 10 selling drugs at both PBM-owned mail-order pharmacies and non-owned retail pharmacies. It also discusses the small impact that repackaged versions of the top 10 drugs had on plan sponsor and member prices. The chapter then examines the repackaging of one drug – Celebrex – to illustrate how infrequently repackaging occurred. The chapter examines the repackaging practices of the one large PBM with an FDA-regulated repackaging facility, and it shows that this PBM billed its clients based on the manufacturer's AWP. Finally, the chapter discusses public information that suggests that repackagers sell primarily to physicians who dispense drugs for their patients.

I. REPACKAGING OF TOP TEN DRUGS BY PBM MAIL-ORDER PHARMACIES IS RARE

A. Analytical Approach

The Commission requested from each PBM study participant a list of top-selling repackaged drugs dispensed to members of any plan the PBM administered in 2002 and 2003.[7] The Commission received very little information through this general request. To verify that PBMs dispensed very few repackaged drugs, the Commission obtained December 2003 claims data from 10 study participants (eight PBMs and two stand-alone retailers) to assess repackaging practices for the top ten drugs based on sales as reported by IMS Health. These drugs are

[3] The repackagers listed in *Mosby's Drug Consult* are Allscripts Healthcare Solutions, DHS Inc., Direct Dispensing Inc., PD-RX Pharmaceuticals, Pharma Pac, Physicians Total Care, Southwood Pharmaceuticals Inc., and St. Mary's MPP.

[4] In some cases, the repackagers place the capsules in blister packs or provide some other value-added service that might explain a higher AWP. A full exploration of the practice of pharmaceutical repackaging and its costs and benefits, however, is beyond the scope of this study.

[5] *See* JAMES LANGENFELD & ROBERT MANESS, THE COST OF PBM "SELF-DEALING" UNDER A MEDICARE PRESCRIPTION DRUG BENEFIT 1, 5-6, 11-13 (2003), *at* http://www.mpaginc.com/news/pbmreport.pdf.

[6] *Id*.

[7] *See* Appendix A, Item 19 of the PBM Special Order.

Lipitor, Zocor, Prevacid, Procrit, Zyprexa, Epogen, Nexium, Zoloft, Celebrex, and Neurontin.[8] For each of the top ten drugs, the Commission staff examined how frequently a PBM dispensed the repackaged drug through its owned mail-order pharmacies and not-owned retail pharmacies. For this analysis, a claim was counted as having had a repackaged drug dispensed if the NDC for which the plan was billed did not belong to the original manufacturer of the drug.[9]

B. Repackaged Drugs Account for Far Less Than 1 Percent of Prescriptions for the Top 10 Drug Products

The PBM data showed that none of their owned mail-order pharmacies dispensed repackaged drugs to fill more than one one-thousandth of one percent (0.001%) of the prescriptions for the top 10 drugs. Put another way, the owned mail-order pharmacy that dispensed repackaged drugs most frequently dispensed a repackaged drug for only roughly one out of every 100,000 prescriptions for the top ten drugs. As low as this percentage is, other owned mail-order pharmacies had much lower repackaged dispensing rates. For all eight mail-order pharmacies combined, repackaged drugs accounted for only roughly 1 out of every 1,000,000 dispensed prescriptions for the top 10 drugs. For retail prescriptions[10] filled for members of plans administered by these eight PBMs, repackaged drugs accounted for *no more* than 0.024% of the prescriptions dispensed for these top ten drugs at any of the PBMs. Aggregating over all eight PBMs, repackaged drugs accounted for only 172 out of every 1,000,000 dispensed retail prescriptions for the top 10 drugs. These results showed that repackaged drugs were very rarely dispensed through retail pharmacies to members of plans

[8] According to the IMS data, these drugs collectively accounted for 16% of the drug expenditures in the United States in 2003. *See* IMS, *Leading 20 Products by U.S. Sales, 2003* (Feb. 2004), *at* http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_42720942_44304277,00.html.

[9] The Commission staff identified every claim in which the drug name contained either the brand name of the drug or the generic ingredient name. The staff identified NDCs that corresponded to the original manufacturer(s) of the drug, and classified as repackaged the drugs with NDCs indicating a labeler other than the original manufacturer. By cross-checking with the FDA's online NDC Directory (CTR. FOR DRUG EVALUATION & RESEARCH, FDA, NATIONAL DRUG CODE DIRECTORY, *at* http://www.fda.gov/cder/ndc/database/ (last updated July 15, 2005)) staff verified that the NDCs that were classified as repackaged came from companies that are known as suppliers of repackaged drugs. Although this procedure potentially could miss some claims if the drug name field did not contain either the actual drug name or the ingredient name, the staff performed a secondary check based on matching Generic Product Identifiers to verify that all prescriptions for each of the drugs were identified. This database included information only for the drug NDCs for which the plan was billed. If a pharmacy repackaged a drug or bought a repackaged drug, but billed the plan for an NDC from the manufacturer, the data would not indicate that this drug had been repackaged. The analysis was designed to detect circumstances where plans were charged a different price for a drug because it was repackaged and given a new NDC with an AWP that differed from the original.

[10] The "retail" category could more accurately be called "not-mail" because the Commission staff could not distinguish between a retail pharmacy and a dispensing physician or clinic based on the data available. Congress requested the Commission to determine whether repackaging was being used extensively by PBMs in their mail-order pharmacies, which does not appear to be the case. Analysis of claims data from retail pharmacy chains, however, did detect some dispensing of repackaged drugs. See discussion *infra*.

administered by PBMs, and contrary to the allegations made in the SELF-DEALING STUDY, were much less frequently dispensed through the PBMs' owned mail-order pharmacies.[11]

The same analysis using the two stand-alone retailers' data showed that one retailer had not dispensed any repackaged versions of the top 10 drugs in December of 2003. The second retailer dispensed repackaged drugs for only roughly 16 out of every 1,000,000 prescriptions the stand-alone retailer filled for these drugs in December of 2003. This analysis also indicated that customers with insurance coverage were no more likely to receive repackaged drugs than were cash-paying customers.

Because plans were billed very infrequently for repackaged drugs, it appears unlikely that repackaging would have any substantial financial impact – positive or negative – on price to either plans or PBMs. Nonetheless, the Commission staff calculated the average price for each strength of the original and repackaged versions of the nine drugs for which repackaged versions appeared in the PBM claims data.[12] The average total price (plan plus member) per unit for a repackaged drug, averaged across all eight PBMs, varied by strength and drug from approximately 50% below the total price paid for the original manufacturer's drug to 20% above it. Despite these price differences, it is apparent that PBMs are not using these repackaged drugs to increase their profits on a systematic basis at the expense of their clients because repackaged drugs are very rarely dispensed, and even more rarely dispensed by mail-order pharmacies owned by the PBMs.

II. REPACKAGING OF CELEBREX IS RARE

The SELF-DEALING STUDY specifically suggested that the existence of repackaged versions of the anti-inflammatory drug Celebrex implied that PBM clients were being charged excessive prices for this drug, primarily in mail-order pharmacies owned by PBMs. Although PBMs rarely charge clients for repackaged drugs, the Commission staff analyzed the data for repackaged Celebrex to test the SELF-DEALING STUDY's assertions.

The Commission staff focused its analysis on the most common strength of Celebrex (200 mg) according to the December 2003 claims data. None of the eight PBMs' claims data for their mail-owned pharmacies included any claim for repackaged versions of Celebrex 200 mg. All mail pharmacy claims were billed to an NDC belonging to Pfizer, the manufacturer of Celebrex. In addition, the claims data from the two stand-alone retailers did not include any claim for repackaged Celebrex.

[11] Congress specifically asked for a comparison of the dispensing of repackaged drugs at mail-order pharmacies owned by the PBM to those not owned by the PBM. Relatively little data from mail-order pharmacies not owned by the PBMs was available. Out of roughly 27,000 prescriptions for the top 10 drugs dispensed at mail pharmacies not owned by the PBMs, only one prescription was filled for a repackaged drug. Strictly speaking, repackaged drugs were dispensed relatively more frequently at mail-order pharmacies not owned by the PBM than at mail-order pharmacies owned by the PBM, but the frequency is negligible at both types of mail-order pharmacies and, thus, is not probative.

[12] The December 2003 claims data for all eight PBMs did not contain repackaged NDCs for one of the drugs in the top ten, thus the average price calculations are based on nine drug products.

The eight PBMs' data on claims filled at retail pharmacies, however, did include some repackaged Celebrex. In the aggregate, retail pharmacies dispensed only 7,494 capsules of the various versions of repackaged Celebrex 200 mg to members of plans managed by the PBMs. By comparison, this same group of pharmacies, in the aggregate, dispensed nearly 28 million capsules of the Pfizer-packaged Celebrex. Based on these dispensing statistics, the repackaged versions accounted for 0.03% of the quantity dispensed.[13]

The total price paid by the plan and the member for each Pfizer-packaged capsule dispensed at retail, averaged across all eight PBMs, was $2.57, exclusive of any manufacturer pharmaceutical payment. The average total price paid for each repackaged capsule dispensed at retail was $2.50, again excluding manufacturer pharmaceutical payment. The repackaged drugs, on average, were approximately 3% less expensive than Pfizer's version.

The price differential between the Pfizer NDCs and the repackaged NDCs varies substantially across PBMs. For one PBM, the repackaged drugs were 20% less expensive, on average, than the Pfizer version. For another PBM, the repackaged drugs were 31% more expensive, on average. All other PBMs in the study were somewhere in between. In the aggregate, the PBM's clients that paid the extra 31% experienced a very small financial impact as a result of being billed for the repacked Celebrex. If all of the prescriptions that had been filled with the repackaged drugs under that PBM's plans had been filled at the average price those plans actually paid for the Pfizer version of the drug, the total savings to that PBM's plans would have been $208. That PBM's plans spent over $1.4 million on 200 mg capsules of Celebrex in December 2003. Thus, replacing the repackaged prescriptions with Pfizer prescriptions would have reduced costs for Celebrex by only about one hundredth of one percent (0.01%). Similar calculations were performed for each of the seven other PBMs, and none of their collective books of business would have saved more than two thousandths of a percent off of their expenditures on Celebrex 200 mg tablets if no repackaged Celebrex had been dispensed.

III. ONLY ONE PBM STUDY PARTICIPANT HAD AN FDA-REGULATED REPACKAGING FACILITY

Only one of the PBM study participants - Caremark Rx - has an FDA-regulated repackaging facility. This company reported that in the fourth quarter of 2003 it repackaged 153 drug products as identified by 9-digit NDCs. During this quarter, the 153 NDCs for which the PBM reported dispensing repackaged drugs accounted for roughly one out of every six prescriptions dispensed from its mail-order pharmacies.[14] This PBM, however, billed its clients

[13] The claims data contained Celebrex NDCs from nine repackagers in addition to Pfizer. These repackagers were Allscripts, DHS Inc., DRX Pharmaceuticals, Nucare, PDRX Pharmaceuticals, Pharma Pac, Physician's Total Care, Quality Care, Southwood Pharmaceuticals, and St. Mary's MPP.

[14] The data obtained by the Commission only indicate the NDCs for which this PBM's owned mail-order pharmacy dispensed some repackaged product. The data do not indicate whether all of the prescriptions for these NDCs were repackaged, or only some of them. All mail prescriptions for the 153 NDCs for which the company dispensed repackaged prescriptions were counted as being repackaged in this analysis.

using the original manufacturers' NDCs, and consequently, the original manufactuers' AWPs.[15] Thus, these claims were not counted as being for repackaged drugs in the analysis presented above.

To determine if the prices of these repackaged drugs were higher than non-repackaged versions of the same drug, Commission staff compared mail-order repackaged prices to the retail prices for the manufacturers' versions of these drugs for prescriptions dispensed in December 2003. The data revealed that the average total price for a repackaged, 30-unit prescription at mail was 12.1% lower than the average total price paid for a non-repackaged, 30-unit prescription of the same drug dispensed at a retail pharmacy.[16] Likewise, for 90-unit repackaged prescriptions, the average total price paid was 6.2% lower than the average total price paid for the same drug from the original manufacturer dispensed at a retail pharmacy.

IV. PUBLIC INFORMATION SUGGESTS THAT REPACKAGERS SELL PRIMARILY TO PHYSICIANS THAT DISPENSE DRUGS TO THEIR PATIENTS

The analyses presented above cast a strong doubt on the claim in the SELF-DEALING STUDY that PBMs use repackaged drugs in their owned mail-order pharmacies to inflate revenues. However, these same analyses and much public information suggests that repackaged versions of popular drugs do exist and that repackagers assign new NDC numbers for the drugs that often have higher AWPs than the original manufacturer's AWP. This leaves unanswered the question of why these drugs get repackaged. Information from the repackagers' financial reports and websites strongly suggests that repackagers primarily sell to physicians, who dispense the repackaged drug products to their patients.

A search of websites and annual reports (when available online) of eight repackagers provides insights into repackagers' primary customer base and their relationship to other entities in the pharmaceutical industry. Six repackagers' public information explicitly stated that they sell to dispensing physicians, and some also marketed to urgent care or specialty clinics. One

[15] Manufacturers and/or wholesalers may assign different AWPs to the same drug product based on the package size purchased. For example, if a pharmacy buys a large quantity of a drug from the manufacturer, the AWP per unit on that package size may be lower than if the pharmacy had purchased the drug in a smaller package size. As described in Chapter II, plans have the ability to specify in their contract with the PBM the package size that will be used to determine the AWP off of which they will be billed. The AWP at which they are billed is not necessarily the one corresponding to the quantity purchased by the pharmacy. Pharmacies may be able to generate profits by buying in large quantities and billing based on AWPs for smaller quantities. The extent to which plan sponsors may have been harmed by PBMs executing this strategy in their owned mail pharmacies would have shown up in the average prices reported in Chapter II, where prices at pharmacies owned by the PBMs were generally found to be lower than prices at pharmacies not owned by the PBMs.

[16] Chapter II presented analysis comparing the average price paid for 30-unit and 90-unit prescriptions through different dispensing channels. This analysis uses the same methodology. First, Commission staff identified only claims for 30-unit prescriptions and then eliminated any drug, identified by a 9 digit NDC, not dispensed at both mail and retail. Second, Commission staff computed and compared the average mail and retail prices for a common basket of the remaining drugs. Third, Commission staff identified the drugs among those remaining that the PBM repackaged for the PBM's mail pharmacy. Finally, Commission staff calculated the average mail and retail prices of a common basket of these drugs.

repackager's primary clients included the Department of Defense, the Veteran's Administration, and acute care clinics. This company was the only one to suggest that it had the ability to supply to wholesalers as customers. None of the companies' public information mentioned pharmacies as customers. For example, Allscripts reported in its 2004 10-K (filed with the SEC) that it "has over 15,000 physician customers nationwide and provides physician groups, urgent care clinics, and occupational health centers the ability to provide medications at the point of care."[17] Allscripts' 10-K does not discuss selling drugs to pharmacies.

The following passage from a Rand Institute for Civil Justice and Health working paper describes the services that repackagers provide to physicians and the extent to which physicians are adopting these services.

> Many of the larger repackagers, including Allscripts, Southwood, and Physicians Total Care, also market computerized medical management systems that include inventory control, information on commonly prescribed medications for given conditions, drug interactions, conflicts with payer formularies, etc. The advent of sophisticated software to support point-of-service dispensing and aggressive marketing by repackagers has increased the percentage of physicians dispensing drugs to an estimated 7-10 percent of practices.[18]

The merits of repackaging and physician dispensing, however, are beyond the scope of this study.[19]

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[17] *See* Allscripts Healthcare Solutions, Inc., SEC File No. 000-32085, 10-K for the fiscal year ended Dec. 31, 2004, *available at* http://www.allscripts.com/resources/docs/2004filings/43850ACL.PDF.

[18] BARBARA O. WYNN, RAND INSTITUTE FOR CIVIL JUSTICE & RAND HEALTH , PAYING FOR REPACKAGED DRUGS UNDER THE CALIFORNIA WORKERS' COMPENSATION OFFICIAL MEDICAL FEE SCHEDULE (Working Paper No. WR-260-1-ICJ, May 2005), *at* http://www.rand.org/pubs/working_papers/2005/RAND_WR260-1.pdf. According to another published report, it is possible for a single physician to make as much as $60,000 per year dispensing prescriptions for his or her patients, though typical physicians were reported to make considerably less. Using a computerized dispensing system licensed from a repackager, the physician is able to accept the same managed care insurance cards accepted at many retail pharmacies. In addition to providing packages of the drugs with quantities suitable for dispensing, the repackager may provide computer hardware and software to help in the dispensing process, as well as printing barcodes on the bottle labels to help with billing and inventory. Deborah Borfitz, *Dispense the Drugs You Prescribe?*, 22 MED. ECON. 44 (Nov. 19, 2001), *available at* http://www.memag.com/memag/article/articleDetail.jsp?id=118244.

[19] Both a former FTC Chairman and the FTC staff have commented on legislative proposals to restrict physician dispensing, suggesting that physician dispensing may provide some consumer and competition benefits. *See, e.g.*, *Physician Dispensing of Drugs: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong. 8-12 (1987) (statement of Daniel Oliver, Chairman, Federal Trade Commission); Letter from FTC Staff to Jeffrey W. Moran, New Jersey Assemblyman (April 12, 1991) (In commenting on Senate Bill No. 2051, the staff suggested that before restricting physician dispensing of prescription drugs, the New Jersey state legislature "may wish to consider whether the risk of potential over prescribing requires that consumers forego the benefits of increased convenience and possibly increased competition."). *See* Press Release, FTC, FTC Staff Advises Caution on Proposed New Jersey Restrictions on Physician-Dispensed Medicine, *available at* http://www.ftc.gov/opa/predawn/F93/physdrug.txt.

APPENDIX A. PBM SPECIAL ORDER

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Timothy J. Muris, Chairman
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary
Pamela Jones Harbour

ORDER TO FILE SPECIAL REPORT

File No. P042111

Pursuant to a resolution of the Federal Trade Commission dated March 19, 2004, entitled "Resolution Directing The Use Of Compulsory Process," a copy of which is enclosed, Company A, hereinafter referred to as "the company,[1]" is ordered to file a Special Report with the Commission not later than June 25, 2004, containing the information specified herein. The enclosed "Pharmacy Benefit Manager Conflict of Interest Study Public Notice" describes the purpose and scope of the information collection.

The Special Report is required to be subscribed and sworn to by an official of the company who has prepared or supervised the preparation of the Special Report from books, records, documents, correspondence, and other data and material in the company's possession. The Special Report should restate each item of this Order with which the corresponding answer is identified. If any question cannot be answered fully, give the information that is available and explain in detail in what respects and why the answer is incomplete.

The company may find it useful to provide the response to Item 4 of this Order promptly to be able to discuss limiting the required search for documents (for example, to respond to Items 6 and 7), with the Commission representative identified at the end of this Order before a search for documents is begun.

Unless modified by agreement in writing with the staff of the Federal Trade Commission,

[1] The term "the company" also includes any domestic and foreign parents, predecessors, divisions, subsidiaries, affiliates, partnerships and joint ventures, all directors, officers, employees, agents and representatives of the foregoing. The terms "subsidiary", "affiliate", and "joint venture" refer to any person in which there is partial (25 percent or more) of total ownership or control between the company and any other person.

all numerical data submitted in response to Items 8 through 34 must be submitted in a spread sheet format both on paper and on machine-readable diskettes or CDs, and the format must be the one used in the spreadsheets provided on diskette in this Order. The Commission will accept database and spreadsheet data in the following formats: MS Excel, MS Access, tab-delimited or fixed width text files. All financial information required to be submitted by this Order should be in whole dollar amounts. If the information is not kept in the form requested, the company is encouraged to contact the Commission representative to discuss alternative formats in which the information may be provided.

Please supply written answers in English or the appropriate documents (translated into English if applicable) in response to the following items:

Part I

1. The subscriber to your report is to give his or her full name and business address and state his or her official capacity.

2. State the full name of the company and its official address, and its date and state of incorporation.

3. State whether the company is a subsidiary company; whether the company has a subsidiary company(ies); and report the same information specified in item (2) regarding each parent or subsidiary.

4. Submit one copy of each organization chart and personnel directory in effect since January 1, 2002, (a) for the company as a whole and, (b) for each of the company's divisions involved in the pharmacy benefit manager services business.

5. State the time periods for which the company maintains detailed information by plan and drug category. Also state the company's definition of the terms "generic drug," "branded drug," "single-source drug," and "multi-source drug." For instance, if the company defines any of these terms with reference to a particular data base (*e.g.*, First DataBank), indicate such data base indicator or field. The company is required to use these same definitions in responding to the Items in this Order.

6. Submit all business plans, strategic plans, planning documents, industry studies, analyses, and consultant reports which were prepared for any officer(s) or director(s) (or in the case of unincorporated entities, individuals exercising similar functions) between January 1, 2001 and the date of this Order and that relate[2] to

[2] The term "relate" means in whole or in part constituting, containing, concerning, discussing, describing, analyzing, identifying, or stating.

the following: (a) generic substitution;[3] (b) therapeutic interchange;[4] (c) repackaging of pharmaceuticals;[5] (d) strategies and business practices to increase the company's mail order pharmacy revenues and/or to move business from retail pharmacies to the company's mail order pharmacy; (e) company strategies and business practices affecting the company's profits on the sale of PBM services; (f) guidelines or analyses regarding how the financial terms of bids for contracts with potential PBM plan clients may influence the company's profits or the plan sponsor's costs; and (g) competition in the PBM market. Also submit annual historical profit and loss statements for strategic business units, business segments, and/or divisions engaged in the provision of pharmacy benefit management services for the years 2002 and 2003. For each document, indicate (if not contained in the document itself) the date of preparation, the name and title of each individual who prepared the document, and the recipient of the document.

7. Submit any and all business plans, strategic plans, planning documents, industry studies, analyses, and consultant reports which were prepared between January 1, 2003 and the date of this order for any officer(s) or director(s) (or in the case of unincorporated entities, individuals exercising similar functions) that (a) relate to the voluntary prescription drug benefit under new Part D of Title XVIII of the Social Security Act that takes effect January 1, 2006 (the "Medicare Prescription Drug Benefit") as enacted in the Medicare Prescription Drug, Improvement, and Modernization Act; (b) discuss competition in the provision of PBM services and how that competition relates to the Medicare Prescription Drug Benefit; and (c) discuss utilization of PBM services in providing the Medicare Prescription Drug Benefit, and indicate (if not contained in the document itself) the date of preparation, the name and title of each individual who prepared the document, and the recipient of the document.

Parts II-V

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[3] The term "generic substitution" (also sometimes called generic efficiency) refers to the proportion of prescriptions that were dispensed with a generic drug product when a generic drug product was available.

[4] The term "therapeutic interchange" means any action in which the entity fulfilling a prescription dispenses a different branded pharmaceutical drug product or a different generic drug product for the prescribed pharmaceutical drug product.

[5] The term "repackaging of pharmaceuticals" means any action in which the party dispensing the drug has purchased a product (as identified by an 11-digit National Drug Code (NDC)), has subsequently altered the packaging and/or relabeled the product, and has issued a new NDC to the new product.

The company is required to provide responses to the Items 8 through 22 separately for four different types of pharmacy benefit plans that the company may administer: (1) pharmacy benefit plans that include integrated retail and mail order pharmacy benefits, excluding Medicaid business in which a government entity is the payer; (2) pharmacy benefit plans for Medicaid beneficiaries in which a government entity is the payer; (3) pharmacy benefit plans that include only mail order pharmacy benefits; and (4) pharmacy benefit plans that include only retail pharmacy benefits. Certain de minimis exceptions apply to these requirements as described below.

For Part II of this Order, the company is required to provide responses to Items 8 through 22 based on the pharmacy benefit plans that the company administers that include integrated retail and mail order pharmacy benefits, excluding Medicaid business in which a government entity is the payer. For example, in response to Item 8(a) "by the company as a whole" refers to the company's pharmacy benefit plans that include an integrated retail and mail order pharmacy benefit.

For Part III of this Order, the company is required to provide responses to Items 8 through 22 based on the pharmacy benefit plans the company administers for Medicaid business in which a government entity is the payer. If the company gross revenues attributable to such Medicaid business is less than 10 percent of company gross revenues (where company gross revenues are as defined in Item 8 below), the company is not required to complete Part III of this Order, it must still, however, separate out its Medicaid business for purposes of Part II of this Order.

For Part IV of this Order, the company is required to provide responses to Items 8 through 22 based on the pharmacy benefit plans that the company administers that include only mail order pharmacy benefits. There is no de minimis exception for Part IV.

For Part V of this Order, the company is required to provide responses to Items 8 through 22 based on the pharmacy benefit plans that the company administers that include only retail pharmacy benefits. For example, the company may have plans in which the mail order component is handled by a different company. There is no de minimis exception for Part V.

Part II

Overall Information for PBM Services Offered (Responses to Items 8 through 10 and 13 should be on a monthly basis for calendar years 2002 and 2003.)

8. State separately for subsections 8(a) through 8(i) the (1) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (2) total co-payments or co-insurance remitted by plan enrollees, (3) administrative fees received from plan sponsors, (4) pharmaceutical rebates received based on the

transactions responsible for the revenue in subsection (1)[6], (5) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues),[7] (6) cost of goods sold,[8] (7) discounts and allowances attributable to cost of goods sold,[9] (8) co-payments or co-insurance credited by the company, (9) dispensing fees paid to retail pharmacies, (10) pharmaceutical rebate disbursements[10] due to plan sponsors based on the transactions responsible for the revenue in subsection (1), (11) average quantity dispensed per fill, and (12) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered:

(a) for the company as a whole;

(b) through mail order pharmacies (segregated by mail order operations owned by the company and those not owned by the company);

(c) through retail pharmacies (segregated by those retail pharmacies owned by the company and those not owned by the company);

(d) through mail order pharmacies that were generic pharmaceutical products (segregated by mail order operations owned by the company and those not owned by the company);

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[6] The term "pharmaceutical rebates" includes the dollar amounts received from pharmaceutical manufacturers for items including, but not limited to, rebates, administrative fees, volume discounts, patient conversion payments, market share movement payments, formulary placement fees, disease management program payments, and promotional allowances. The term "pharmaceutical rebates" does not include "discounts and allowances" (which is defined in footnote 9 below).

[7] The sum of subsections (1) - (5) is referred to as "gross revenues."

[8] The term "cost of goods sold" refers to the dollar amount of payments made to non-company owned pharmacies as reimbursement for prescriptions drugs the pharmacies dispense and payments made for purchases as measured by gross invoice price of pharmaceutical drug products that are dispensed by company owned pharmacies pursuant to a pharmacy benefit plan administered by the company.

[9] The term "discounts and allowances" refers to the dollar amount of purchase discounts based upon invoiced purchase terms. The term "discounts and allowances" does not include the costs described in subsection (10) or Item 11 which refers to pharmaceutical rebates.

[10] The term "pharmaceutical rebate disbursements" refers to the dollar amount of pharmaceutical rebates disbursed to plan sponsors. The term "pharmaceutical rebate disbursements" does not include "discounts and allowances."

(e) through retail pharmacies that were generic pharmaceutical products (segregated by those retail pharmacies owned by the company and those not owned by the company);

(f) through mail order pharmacies that were single-source branded pharmaceutical products (segregated by mail order operations owned by the company and those not owned by the company);

(g) through retail pharmacies that were single-source branded pharmaceutical products (segregated by those retail pharmacies owned by the company and those not owned by the company);

(h) through mail order pharmacies that were multi-source branded pharmaceutical products (segregated by mail order operations owned by the company and those not owned by the company); and

(i) through retail pharmacies that were multi-source branded pharmaceutical products (segregated by those retail pharmacies owned by the company and those not owned by the company).

9. State separately for subsections 9(a) through 9(c) the dollar amounts of (1) costs attributable to any therapeutic interchange program, (2) total operating expenses, and (3) sales, general, and administrative (SG&A) expenses related to pharmacy benefit plans that the company administered:

(a) for the company as a whole;

(b) through mail order pharmacies (segregated by those owned by the company and those not owned by the company);

(c) through retail pharmacies (segregated by those owned by the company and those not owned by the company).

10. State any dollar amounts paid by the company or credited by the company to plan sponsor(s), *e.g.*, consulting fees, compensation paid to the plan sponsor to help defray the costs of switching to the company at the start of a new contract or bonus amounts to obtain or retain the plan sponsor as a customer. Identify to whom the payments were made. The dollar amounts stated in response to this item should not include any dollar amounts included in response to Item 9.

11. For each drug product as identified by a 9-digit National Drug Code (NDC) on which the company received or recovered any pharmaceutical rebates for calendar year 2003, state separately the (1) NDC, (2) drug name, (3) manufacturer, (4)

pharmaceutical rebates amount for calendar year 2003, (5) gross revenues (as defined in Item 8) for calendar year 2003, (6) cost of goods sold for calendar year 2003, (7) average quantity dispensed per fill for calendar year 2003, and (8) total number of prescriptions filled for enrollees of all pharmacy benefit plans administered by the company for calender year 2003. Provide copies of the contracts or agreements by which any of these payments are made.

12. For calendar year 2003, state separately for subsections 12(a) through 12(d) the (1) number of plans, (2) covered lives included in these plans, (3) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by plan enrollees, (5) administrative fees received from plan sponsors, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) co-payments or co-insurance credited by the company, (11) dispensing fees paid to retail pharmacies, (12) pharmaceutical rebate disbursements due to plan sponsors based on the transactions responsible for the revenue in subsection (3), (13) average quantity dispensed per fill, and (14) the total number of prescriptions filled for enrollees of all pharmacy benefit plans administered by the company that use

    (a) two-tier open formularies with fixed or flat co-payments;

    (b) three-tier open formularies with fixed or flat co-payments;

    (c) four-tier open formularies with fixed or flat co-payments; and

    (d) other formulary configurations if total number of prescriptions is greater than 5 percent of the total number of prescriptions of (a) - (c). Also include a description of each such formulary configuration identified in this subsection (d).

13. State lists for subsections 13(a) through 13(c) of the top 30 pharmaceutical drugs products as identified by the 10-digit GPI[11] (ranked by (1) gross revenues and (2) total prescriptions filled) dispensed pursuant to any pharmacy benefit plan that the company administered:

    (a) for the company as a whole;

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[11] The term “GPI” refers to Medi-Span’s Generic Product Identifier, which is a 14-digit cade identifying a particular drug product. The term “10-digit GPI” refers to the first 10 digits of a particular product’s GPI.

(b) through mail order pharmacies (segregated by those owned by the company and those not owned by the company);

(c) through retail pharmacies (segregated by those owned by the company and those not owned by the company).

For each of the 11-digit NDCs within the ranked 30 10-digit GPIs, state separately the (1) 11-digit NDC, (2) drug name, (3) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by plan enrollees, (5) administrative fees received from plan sponsors, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) co-payments or co-insurance credited by the company, (11) dispensing fees paid to retail pharmacies, (12) pharmaceutical rebate disbursements due to plan sponsors based on the transactions responsible for the revenue in subsection (3), (13) average quantity dispensed per fill, and (14) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered.

Therapeutic Interchange Information (Responses to Items 14 and 16 should include interchange practices for the calendar years 2002 and 2003. Responses to Items 15 and 17 should be on a monthly basis for the calendar years 2002 and 2003.)

14. For each prescribed branded drug product as identified by a 9-digit NDC for which there has been interchange (for example, through formulary compliance, letters or telephone calls to doctors or enrollees) for a therapeutically equivalent branded drug product, state

    (a) the prescribed branded drug product name and its 9-digit NDC;

    (b) the interchanged branded drug product name and its 9-digit NDC; and

    (c) whether an A-rated generic drug product(s) is (are) available for the prescribed drug product and, if so, the generic drug name and its 9-digit NDC.

15. State separately for subsections 15(a) - (c) the (1) 9-digit NDC, (2) drug name, (3) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by plan enrollees, (5) dollar amount of administrative fees received from plan sponsors, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from plan sponsors (state separately

and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) co-payments or co-insurance credited by the company, (11) dispensing fees paid to retail pharmacies, (12) pharmaceutical rebate disbursements due to plan sponsors based on the transactions responsible for the revenue in subsection (3), (13) average quantity dispensed per fill, and (14) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered for each of the drug products identified in 14(a) - 14(c) above:

(a) by the company as a whole;

(b) through mail order pharmacies (segregated by those owned by the company and those not owned by the company); and

(c) through retail pharmacies (segregated by those owned by the company and those not owned by the company).

16. For each prescribed branded drug product identified by a 9-digit NDC for which there has been interchange (for example, through formulary compliance, letters or telephone calls to doctors or enrollees) for a therapeutically equivalent generic drug product that is not A-rated to the prescribed branded drug product, state

(a) the prescribed branded drug product name and its 9-digit NDC; and

(b) the interchanged generic drug product name and its 9-digit NDC.

17. State separately for subsections 17(a) - (c) the (1) 9-digit NDC, (2) drug name, (3) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by plan enrollees, (5) administrative fees received from plan sponsors, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) co-payments or co-insurance credited by the company, (11) dispensing fees paid to retail pharmacies, (12) pharmaceutical rebate disbursements due to plan sponsors based on the transactions responsible for the revenue in subsection (3), (13) average quantity dispensed per fill, and (14) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered for each of the drug products identified in 16(a) and 16(b) above

(a) by the company as a whole;

(b) through mail order pharmacies (segregated by those owned by the company

and those not owned by the company); and

(c) through retail pharmacies (segregated by those owned by the company and those not owned by the company).

Repackaging Practices (Responses to Items 18 and 19 should be on a monthly basis for the calendar years 2002 and 2003.)

18. Does the company have a repackaging license from the Food and Drug Administration (FDA)?

If yes, provide two separate lists for 18(a) - 18(c) of the top 25 drugs repackaged[12] by the company (identified by 9-digit NDC) that the company dispensed, one list ranked by gross revenues and the second list ranked by highest number of prescriptions filled, pursuant to any pharmacy benefit plan that the company administered that include the (1) 9-digit NDC, (2) drug name, (3) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by plan enrollees, (5) administrative fees received from plan sponsors, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) co-payments or co-insurance credited by the company, (11) the dollar dispensing fees paid to retail pharmacies, (12) pharmaceutical rebate disbursements due to plan sponsors based on the transactions responsible for the revenue in subsection (3), and (13) average quantity dispensed per fill and (14) total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered

(a) for the company as a whole;

(b) through mail order pharmacies owned by the company; and

(c) through retail pharmacies owned by the company.

19. Does the company purchase pharmaceutical products from an FDA-licensed repackager?

If yes, provide two separate lists for 19(a) - 19(c) of the top 25 repackaged drugs, where the company was not the repackager (identified by 9-digit NDC), that the company dispensed, one list ranked by gross revenues and the second list ranked

[12] The term “repackaged drug” includes those drug products in which the party dispensing the drug has purchased a product, repackaged it, and issued a new NDC number.

by highest number of prescriptions filled, pursuant to any pharmacy benefit plan that the company administered that include the (1) 9-digit NDC, (2) drug name, (3) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by plan enrollees, (5) administrative fees received from plan sponsors, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) co-payments or co-insurance credited by the company, (11) dispensing fees paid to retail pharmacies, (12) pharmaceutical rebate disbursements due to plan sponsors based on the transactions responsible for the revenue in subsection (3), and (13) the average quantity dispensed per fill and (14) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered

(a) for the company as a whole;

(b) through mail order pharmacies (segregated by those owned by the company and those not owned by the company);

(c) through retail pharmacies (segregated by those owned by the company and those not owned by the company).

Generic Substitution Information (Responses to Items 20 and 21 should be on a monthly basis for calendar years 2002 and 2003.)

20. For each of the top 50 prescribed multi-source drug products (ranked by gross revenues as defined in Item 8) as identified by a 9-digit NDC for which an A-rated generic product is available, state

    (a) the multi-source branded drug product name and its 9-digit NDC; and

    (b) the A-rated generic drug product name(s) and its(their) 9-digit NDC.

21. State separately for subsections 21(a) through 21(c) the (1) 9-digit NDC, (2) drug name, (3) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by plan enrollees, (5) administrative fees received from plan sponsors, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) co-payments or co-insurance credited by the company, (11) dispensing fees paid to retail pharmacies, (12) pharmaceutical rebate disbursements due to plan sponsors based

on the transactions responsible for the revenue in subsection (3), (12) average quantity dispensed per fill, and (13) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered for each of the drug products identified in 20(a) - 20(b) above:

(a) by the company as a whole;

(b) through the company's mail order operation (segregated by mail order operations owned by the company and those not owned by the company); and

(c) through retail pharmacies (segregated by those owned retail pharmacies owned by the company and those not owned by the company).

22. For calendar year 2003, state the total number prescriptions with codes DAW 1, DAW 2, and DAW 5 for any pharmaceutical benefit plan administered by the company. Also state for these DAW codes, the total number of these prescriptions on which authorization was obtained to switch the prescription to another drug product

(a) by the company as a whole;

(b) through the company's mail order operations (segregated by mail order operations owned by the company and those not owned by the company);

(c) through retail pharmacies (segregated by those owned retail pharmacies owned by the company and those not owned by the company).

Parts III-Part V: Please respond to Items 8 - 22 based on the descriptions of each part discussed above. Identify separately the responses and to which parts they are responsive.

Part VI

The Company as a Mail Order Claims Processor (Responses to Item 23 should be on a monthly basis for calendar years 2002 and 2003.)

23. If the company processes claims for third party PBMs through its mail order operations, state separately for subsections 23(a) through 23(c) the dollar amount of (1) revenue received from plan sponsors as reimbursement for prescription drugs dispensed, (2) total co-payments or co-insurance remitted by plan enrollees, (3) administrative fees received from plan sponsors, (4) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (1), (5) other revenues from plan sponsors (state separately and label each other revenue source if greater than 5 percent of gross revenues), (6) cost of goods sold,

(7) discounts and allowances attributable to cost of goods sold, (8) co-payments or co-insurance credited by the company, (9) dispensing fees paid to retail pharmacies, (10) pharmaceutical rebate disbursements due to plan sponsors based on the transactions responsible for the revenue in subsection (1), (11) average quantity dispensed per fill, and (12) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company administered:

(a) through its mail order operation as a whole;

(b) through the company's mail order operation that were generic pharmaceutical products;

(c) through the company's mail order operation that were branded pharmaceutical products.

PBM Clients, Customers, and Contracts with Integrated Mail Order and Retail Pharmacy Benefit Plans (Responses to Items 24-28 should be on an annual basis for calendar year 2003. The only plans to be considered for Items 24-28 should be plans that offer both mail order and retail pharmacy benefits. The responses should exclude contracts that are mail order or retail only.)

24. Submit lists of the company's top 10 customers (plan sponsors) (one list ranked by total annual gross revenue, one list ranked by total cost of goods sold, and one list ranked by the number of prescriptions filled) for pharmacy benefit plans. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate[13] for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these customers. There should be three lists.

25. Submit lists of the company's 10 customers for a pharmacy benefit plan with the highest usage of mail-order pharmacy services (one list ranked by the percent of total annual gross revenue from the customer that relates to mail order service and one list ranked by the percentage of total prescriptions dispensed that are filled through mail order). For each customer, state the company's annual gross revenue

[13] The term "generic dispensing rate" refers to the percentage of generic products dispensed as a percentage of total pharmaceutical (both generic and branded) prescriptions filled for enrollees of any pharmacy benefit plan administered by the company.

(as defined in Item 8) corresponding to the customer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these customers. There should be two lists.

26. Submit lists of the company's 10 customers for a pharmacy benefit plan with the lowest usage of mail-order pharmacy services (one list ranked by the percent of total annual gross revenue from the customer that relates to mail order service and one list ranked by the percentage of total prescriptions dispensed that are filled through mail order). For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these customers. There should be two lists.

27. Submit lists of the company's 10 customers for a pharmacy benefit plan with the highest generic dispensing rates going through the mail order operations and through retail pharmacies. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these customers. There should be two lists.

28. Submit lists of the company's 10 customers for a pharmacy benefit plan with the lowest generic dispensing rates going through the mail order operations and through retail pharmacies. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total

number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these customers. There should be two lists.

PBM Clients, Customers, and Contracts with Mail Order Pharmacy Benefits Only (Responses to Items 29 through 31 should be on an annual basis for calendar year 2003. The only plans to be considered for Items 29 through 31 should be plans that offer mail order pharmacy benefits only.)

29. Submit lists of the company's top 10 customers (plan sponsors) (one list ranked by total annual gross revenue, one list ranked by total cost of goods sold, and one list ranked by the number of prescriptions filled) for pharmacy benefit plans. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, and the generic dispensing rate for prescriptions filled for this customer. Submit the contracts associated with these customers. There should be three lists.

30. Submit lists of the company's 10 customers for a pharmacy benefit plan with the highest generic dispensing rates. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, and the generic dispensing rate for prescriptions filled for this customer. Submit the contracts associated with these customers. There should be one list.

31. Submit lists of the company's 10 customers for a pharmacy benefit plan with the lowest generic dispensing rates. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, and the generic dispensing rate for prescriptions filled for this customer. Submit the contracts associated with these customers. There should be one list.

PBM Clients, Customers, and Contracts with Retail Pharmacy Benefits Only (Responses to Items 32 through 34 should be on an annual basis for calendar year 2003. The only plans to be considered for Items 32 through 34 should be plans that offer mail order pharmacy benefits only.) If the company's gross revenues attributable to pharmacy benefit plans that include only retail pharmacy benefits is less than 10 percent of the company's gross revenues (see Part V above), the company is not required to complete Items 32-34 of this Order.

32. Submit lists of the company's top 10 customers (plan sponsors) (one list ranked by total annual gross revenue, one list ranked by total cost of goods sold, and one list ranked by the number of prescriptions filled) for pharmacy benefit plans. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, and the generic dispensing rate for prescriptions filled for this customer. Submit the contracts associated with these customers. There should be three lists.

33. Submit lists of the company's 10 customers for a pharmacy benefit plan with the highest generic dispensing rates. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, and the generic dispensing rate for prescriptions filled for this customer. Submit the contracts associated with these customers. There should be one list.

34. Submit lists of the company's 10 customers for a pharmacy benefit plan with the lowest generic dispensing rates. For each customer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, and the generic dispensing rate for prescriptions filled for this customer. Submit the contracts associated with these customers. There should be one list.

You are advised that penalties may be imposed under applicable provisions of federal law for failure to file special reports or for filing false reports.

Any questions you have relating to the scope or meaning of anything required by this Order, or suggestions for possible modifications thereto, should be directed to Michael S. Wroblewski, Federal Trade Commission, Office of General Counsel, 600 Pennsylvania Ave, NW, Washington, DC 20580, (202) 326-2155, <mwroblewski@ftc.gov>. **Two copies** of the Special Report shall be filed with the Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Ave., NW Washington, DC 20580 by 5:00 p.m. on June 25, 2004.

By direction of the Commission.

Timothy J. Muris
Chairman

SEAL
Date of Order: May ___, 2004

APPENDIX B. STAND-ALONE RETAILER SPECIAL ORDER

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Timothy J. Muris, Chairman
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary
Pamela Jones Harbour

ORDER TO FILE SPECIAL REPORT

File No. P042111

Pursuant to a resolution of the Federal Trade Commission dated March 19, 2004, entitled "Resolution Directing The Use Of Compulsory Process," a copy of which is enclosed, Company A, hereinafter referred to as "the company,[1]" is ordered to file a Special Report with the Commission not later than June 25, 2004, containing the information specified herein. The enclosed "Pharmacy Benefit Manager Conflict of Interest Study Public Notice" describes the purpose and scope of the information collection.

The Special Report is required to be subscribed and sworn to by an official of the company who has prepared or supervised the preparation of the Special Report from books, records, documents, correspondence, and other data and material in the company's possession. The Special Report should restate each item of this Order with which the corresponding answer is identified. If any question cannot be answered fully, give the information that is available and explain in detail in what respects and why the answer is incomplete.

The company may find it useful to provide the response to Item 4 of this Order promptly to be able to discuss limiting the required search for documents (for example, to respond to Items 6 and 7), with the Commission representative identified at the end of this Order before a search for documents is begun.

Unless modified by agreement in writing with the staff of the Federal Trade Commission, all numerical data submitted in response to Items 8 through 19 must be submitted in a spread sheet format both on paper and on machine-readable diskettes or CDs, and the format must be

[1] The term "the company" also includes any domestic and foreign parents, predecessors, divisions, subsidiaries, affiliates, partnerships and joint ventures, all directors, officers, employees, agents and representatives of the foregoing. The terms "subsidiary", "affiliate", and "joint venture" refer to any person in which there is partial (25 percent or more) of total ownership or control between the company and any other person.

the one used in the spreadsheets provided on diskette in this Order. The Commission will accept database and spreadsheet data in the following formats: MS Excel, MS Access, tab-delimited or fixed width text files. All financial information required to be submitted by this Order should be in whole dollar amounts. If the information is not kept in the form requested, the company is encouraged to contact the Commission representative to discuss alternative formats in which the information may be provided.

Please supply written answers in English or the appropriate documents (translated into English if applicable) in response to the following items:

Part I

1. The subscriber to your report is to give his or her full name and business address and state his or her official capacity.

2. State the full name of the company and its official address, and its date and state of incorporation.

3. State whether the company is a subsidiary company; whether the company has a subsidiary company(ies); and report the same information specified in item (2) regarding each parent or subsidiary.

4. Submit one copy of each organization chart and personnel directory in effect since January 1, 2002, (a) for the company as a whole and, (b) for each of the company's divisions involved in the pharmacy business.

5. State the time periods for which the company maintains detailed information by plan and drug category. Also state the company's definition of the terms "generic drug," "branded drug," "single-source drug," and "multi-source drug." For instance, if the company defines any of these terms with reference to a particular data base (*e.g.* First DataBank), indicate such data based indicator or field. The company is required to use these same definitions in responding to the Items in this Order.

6. Submit all business plans, strategic plans, planning documents, industry studies, analyses, consultant reports, and other documents that were prepared for any officer(s) or director(s) (or in the case of unincorporated entities, individuals exercising similar functions) between January 1, 2001 and the date of this Order and that relate[2] to the following: (a) generic substitution;[3] (b) therapeutic

[2] The term "relate" means in whole or in part constituting, containing, concerning, discussing, describing, analyzing, identifying, or stating.

[3] The term "generic substitution" (also sometimes called generic efficiency) refers to the proportion of prescriptions that were dispensed with a generic drug product when a generic

interchange;[4] (c) repackaging of pharmaceuticals;[5] (d) company strategies and business practices affecting the company's profits on the sale of retail pharmacy services; and (e) competition in the pharmacy market. For each document, indicate (if not contained in the document itself) the date of preparation, the name and title of each individual who prepared each such document, and the recipient of the document.

7. Submit any and all business plans, strategic plans, planning documents, industry studies, analyses, consultant reports, and other documents that were prepared between January 1, 2003 and the date of this order for any officer(s) or director(s) (or in the case of unincorporated entities, individuals exercising similar functions) that (a) relate to the voluntary prescription drug benefit under new Part D of Title XVIII of the Social Security Act that takes effect January 1, 2006 (the "Medicare Prescription Drug Benefit") as enacted in the Medicare Prescription Drug, Improvement, and Modernization Act; (b) discuss competition in the provision of pharmacy services as it relates to the Medicare Prescription Drug Benefit; and (c) discuss utilization of pharmacy services in providing the Medicare Prescription Drug Benefit, and indicate (if not contained in the document itself) the date of preparation, the name and title of each individual who prepared each such document, and the recipient of the document.

Parts II-III

The company is required to provide responses to the Items 8 through 20 separately for the two types of payers that may reimburse the company for pharmacy services it provides. For Part II of this Order, the company is required to provide responses to Items 8 through 20 based on the pharmacy services it provides in which it is reimbursed by a private third-party payer, excluding Medicaid business. Examples of such third-party payers include pharmacy benefit managers, group health plans, etc. For Part III of this Order, the company is required to provide responses to Items 8 through 20 based on the pharmacy services it provides for Medicaid enrollees.

Overall Information for Pharmacy Services Offered (Responses to Items 8, 9, and 11 should be on a monthly basis for calendar years 2002 and 2003.)

8. State separately for subsections 8(a) through 8(i) the dollar amount of (1) revenue

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drug product was available.

[4] The term "therapeutic interchange" means any action in which the entity fulfilling a prescription dispenses a different branded pharmaceutical drug product or generic drug product for the prescribed pharmaceutical drug product.

[5] The term "repackaging of pharmaceuticals" means any action in which the party dispensing the drug has purchased a product (as identified by an 11-digit National Drug Code (NDC)), has subsequently altered the packaging and/or relabeled the product, and has issued a new NDC number to the new product.

received from third-party payers[6] as reimbursement for prescription drugs dispensed, (2) total co-payments or co-insurance remitted by beneficiaries, (3) dispensing fees received from third-party payers, (4) pharmaceutical rebates[7] received based on the transactions responsible for the revenue in subsection (1), (5) other revenues from third-party payers (state separately and label each other revenue source if greater than 5 percent of gross revenues),[8] (6) cost of goods sold,[9] (7) discounts and allowances attributable to cost of goods sold,[10] (8) average quantity dispensed per fill, and (9) the total number of prescriptions filled for enrollees of plans reimbursed by third-party payers that the company serviced:

(a) by the company as a whole;

(b) through mail order pharmacies;

(c) through retail pharmacies;

(d) through mail order pharmacies that were generic pharmaceutical products;

(e) through retail pharmacies that were generic pharmaceutical products;

(f) through mail order pharmacies that were single-source branded pharmaceutical products;

(g) through retail pharmacies that were single-source branded pharmaceutical products;

(h) through mail order pharmacies that were multi-source branded

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[6] For Part II of this Order, the term "third-party payers" refers to private pharmacy benefit managers, health plans, etc. For Part III of this Order, the term "third-party payers" refers to payers providing benefits to Medicaid recipients.

[7] The term "pharmaceutical rebates" includes dollar amounts received from pharmaceutical manufacturers for items including, but not limited to, rebates, administrative fees, volume discounts, patient conversion payments, market share movement payments, formulary placement fees, disease management program payments, and promotional allowances. The term "pharmaceutical rebates" does not include "discounts and allowances" (which is defined in footnote 10 below).

[8] The sum of subsections (1) - (5) is referred to as "gross revenues."

[9] The term "cost of goods sold" refers to the dollar amount of payments made for purchases of prescription drugs dispensed as measured by gross invoice price.

[10] The term "discounts and allowances" refers to the dollar amount of purchase discounts based upon invoiced purchase terms. The term "discounts and allowances" does not include pharmaceutical rebates.

pharmaceutical products; and

(i) through retail pharmacies that were multi-source branded pharmaceutical products.

9. State separately for subsections 9(a) through 9(c) the dollar amounts of operating expenses and sales, general, and administrative (SG&A) expenses related to pharmacy services provided:

(a) by the company as a whole;

(b) through mail order pharmacies; and

(c) through retail pharmacies.

10. For each pharmaceutical drug product as identified by a 9-digit National Drug Code (NDC)) on which the company received or recovered any pharmaceutical rebates, state separately the (1) NDC, (2) drug name, (3) manufacturer, (4) pharmaceutical rebates amount for calendar year 2003, (5) gross revenues (as defined in Item 8) for calendar year 2003, (6) cost of goods sold for calendar year 2003, (7) average quantity dispensed per fill for calendar year 2003, and (8) total number of prescriptions filled for enrollees of all pharmacy benefit plans serviced by the company for calender year 2003. Provide copies of the contracts or agreements by which any of these payments are made.

11. State lists for subsections 11(a) through 11(c) of the top 30 pharmaceutical drugs products as identified by the 10-digit GPI[11] (ranked by (1) gross revenues and (2) total prescriptions filled) dispensed pursuant to any pharmacy benefit plan that the company serviced:

(a) for the company as a whole;

(b) through mail order pharmacies;

(c) through retail pharmacies.

For each of the 11-digit NDCs within the ranked 30 10-digit GPIs, state separately the (1) 11-digit NDC, (2) the drug name, (3) revenue received from third-party payers as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by beneficiaries, (5) dispensing fees received from third-party payers, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in

[11] The term "GPI" refers to Medi-Span's Generic Product Identifier, which is a 14-digit cade identifying a particular drug product. The term "10-digit GPI" refers to the first 10 digits of a particular product's GPI.

subsection (3), (7) other revenues from third-party payers (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) average quantity dispensed per fill, and (11) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company serviced.

Repackaging Practices (Responses to Items 12 and 13 should be on a monthly basis for the calendar years 2002 and 2003.)

12. Does the company have a repackaging license from the Food and Drug Administration (FDA)?

If yes, provide two separate lists for 12(a) - 12(c) of the top 25 drugs repackaged[12] by the company (identified by 9-digit NDC) that the company dispensed, one list ranked by gross revenues and the second list ranked by highest number of prescriptions filled, that include the (1) 9-digit NDC code, (2) drug name, (3) revenue received from third-party payers as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by beneficiaries, (5) dispensing fees received from third-party payers, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from third-party payers (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) average quantity dispensed per fill, and (11) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company serviced:

(a) for the company as a whole;

(b) through mail order pharmacies;

(c) through retail pharmacies.

13. Does the company purchase pharmaceutical products from an FDA-licensed repackager?

If yes, provide two separate list for 13(a) - 13(c) of the top 25 repackaged drugs, where the company was not the repackager (identified by 9-digit NDC), that the company dispensed, one list ranked by gross revenues and the second list ranked by highest number of prescriptions filled, that include the (1) 9-digit NDC code, (2) drug name, (3) revenue received from third-party payers as reimbursement for

[12] The term “repackaged drug” includes those drug products in which the party dispensing the drug has purchased a product in bulk and has subsequently repackaged it and issue a new NDC number.

prescription drugs dispensed, (4) total co-payments or co-insurance remitted by beneficiaries, (5) dispensing fees received from third-party payers, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from third-party payers (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) average quantity dispensed per fill, and (11) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company serviced:

(a) for the company as a whole;

(b) through mail order pharmacies; and

(c) through retail pharmacies.

Generic Substitution Information (Responses to Items 14 and 15 should be on a monthly basis for calendar years 2002 and 2003.)

14. For each of the top 50 prescribed multi-source drug products (ranked by gross revenues as defined in Item 8) as identified by a 9-digit NDC for which an A-rated generic product is available, state

    (a) the multi-source branded drug product name and its 9-digit NDC; and

    (b) the A-rated generic drug product name(s) and its (their) 9-digit NDC.

15. State separately for subsections 21(a) through 21(c) the (1) 9-digit NDC, (2) drug name, (3) revenue received from third-party payers as reimbursement for prescription drugs dispensed, (4) total co-payments or co-insurance remitted by beneficiaries, (5) dispensing fees received from third-party payers, (6) pharmaceutical rebates received based on the transactions responsible for the revenue in subsection (3), (7) other revenues from third-party payers (state separately and label each other revenue source if greater than 5 percent of gross revenues), (8) cost of goods sold, (9) discounts and allowances attributable to cost of goods sold, (10) average quantity dispensed per fill, and (11) the total number of prescriptions filled for enrollees of all pharmacy benefit plans that the company serviced for each of the drug products identified in 14(a) - 14(b) above:

    (a) by the company as a whole;

    (b) through mail order operation; and

    (c) through retail pharmacies.

16. For calendar year 2003, state the total number prescriptions with codes DAW 1,

DAW 2, and DAW 5 for any pharmaceutical benefit plan serviced by the company. Also state for these DAW codes, the total number of these prescriptions on which authorization was obtained to switch the prescription to another drug product

(a) by the company as a whole;

(b) through the company's mail order operations; and

(c) through retail pharmacies.

Part III: Please response to Items 8 through 16 based on the pharmacy services it provides for Medicaid enrollees.

Part IV

The company is required to provide responses to the Items 8 through 20 for cash paying customers. Because cash paying customers do not have third-party insurance, certain subsections requiring revenue information in Items 8, 11, 12, 13, and 15 are inapplicable. For Item 8, revenues from cash paying customers should be recorded in subsection (1) rather than revenue from third-party payers. Subsections (2), (3), and (5) (co-pays, dispensing fees, and other revenues) should be zero. This same instruction also applies to the relevant revenue subsections in Items 11, 12, 13, and 15.

Part V

Responses to Items 17 through 19 should be on an annual basis for calendar year 2003.

17. Submit lists of the company's top 10 third-party payers (excluding those in which a government is the payer) with which the company does business (one list ranked by total annual gross revenue (as defined in Item 8), one list ranked by total cost of goods sold, and one list ranked by the number of prescriptions filled). For each third-party payer, state the company's annual gross revenue corresponding to the third-party-payer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate[13] for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these third-party payers. There should be three lists.

[13] The term "generic dispensing rate" refers to the percentage of generic products dispensed as a percentage of total pharmaceutical (both generic and branded) prescriptions filled for enrollees of any pharmacy benefit plan administered by the company.

18. Submit a list of the 10 third-party payers (excluding those in which a government is the payer) with which the company does business that have the highest generic dispensing rates going through retail pharmacies. For each third-party payer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these third-party payers.

19. Submit a list of the third-party payers (excluding those in which a government is the payer) with which the company does business that have the lowest generic dispensing rates going through retail pharmacies. For each third-party payer, state the company's annual gross revenue (as defined in Item 8) corresponding to the customer, the proportion of that revenue received relating to services rendered through the company's mail order operations, total annual cost of goods sold relating to this customer, the total number of prescription filled for this customer, the percentage of those prescriptions filled through mail order, the generic dispensing rate for prescriptions filled for this customer through mail order pharmacies, and the generic dispensing rate for prescriptions filled for this customer through retail pharmacies. Submit the contracts associated with these third-party payers.

You are advised that penalties may be imposed under applicable provisions of federal law for failure to file special reports or for filing false reports.

Any questions you have relating to the scope or meaning of anything required by this Order, or suggestions for possible modifications thereto, should be directed to Michael S. Wroblewski, Federal Trade Commission, Office of General Counsel, 600 Pennsylvania Ave, NW, Washington, DC 20580, (202) 326-2155, mwroblewski@ftc.gov. **Two copies** of the Special Report shall be filed with the Secretary, Federal Trade Commission, Room H-159, 600 Pennsylvania Ave., NW Washington, DC 20580 by 5:00 p.m. on June 25, 2004.

By direction of the Commission.

Timothy J. Muris
Chairman

SEAL

Date of Order: May ___, 2004

APPENDIX C. CLAIMS DATA REQUEST

March 1, 2005

Via Facsimile and Mail

Counsel – Litigation
Company A
Street Address
City, State, Zip Code

RE: Special Report of Company A, FTC File No. P042111

Dear Counsel:

This letter requests that Company A (the "Company") provide additional information in response to the Order to File a Special Report referenced above. In the March 26, 2004 Public Notice announcing the Pharmacy Benefit Manage Conflict of Interest Study, the Commission indicated that it would pursue a two-step data collection process to answer fully the questions posed by Section 110 of the Medicare Modernization Act. We have reviewed carefully the data submitted by the Company in the first round of data collection and we request that Company provide the following additional information.

The Company is requested to supply claims data for December 2003 for pharmacy benefit plans that include integrated retail and mail order pharmacy benefits (plans included in Part II of the Order To File Special Report). Please include the following data items in this supplemental request:

1. 11-digit NDC (as billed)
2. Drug Name
3. 14 digit GPI
4. Plan or Client ID
5. NABP Number
6. Pharmacy Mail/Retail
7. Pharmacy Owned/Not Owned
8. Quantity Dispensed
9. Days Supply Dispensed
10. DAW code
11. Patient Co-pay Amount
12. Patient Co-Insurance Amount
13. Patient Deductible Amount

14. Patient DAW2 Cost
15. Total Patient Cost
16. Total Plan Cost (exclude Total Patient Cost)
17. Amount Paid to Pharmacy (exclude Total Patient Cost)
18. AWP as billed
19. Usual and Customary Amount Submitted by the Pharmacy

I would like to discuss with you the timing and format for this data submission at your earliest convenience.

We appreciate the Company's continued cooperation with the FTC's study of the PBM industry. If you have any questions, please do not hesitate to call me at 202-326-2155.

Sincerely,

Michael S. Wroblewski
Assistant General Counsel for Policy Studies

APPENDIX D. COMPARISON OF CASH RETAIL PRICES TO PBM-OWNED MAIL PRICES

It has been suggested that the use of a discount off of AWP for pricing generic prescriptions filled at PBM-owned mail-order pharmacies for members of their plans can lead to these plans paying more for these prescriptions than cash paying customers would pay at retail pharmacies.[1] An analysis of the claims data from December of 2003 obtained from the PBM and stand-alone retailer study participants showed that the total price paid by PBMs' clients for mail prescriptions are lower, on average, than the prices paid by cash customers at retail pharmacies.

The analysis that leads to this conclusion is similar to the analyses discussed in Chapter II, Section III. For both the mail-order pharmacies owned by PBMs and the stand-alone retail pharmacies, all prescriptions of a common size were analyzed (both 30-unit prescriptions and 90-unit prescriptions). For each unique drug (identified by a 9-digit NDC) that was dispensed in both channels, an average price for each channel was calculated. For the stand-alone retail pharmacies, the average calculated price equaled the cash price the patient paid for the prescription (*i.e.*, patients that did not have insurance coverage). For the PBM-owned mail-order pharmacies, the average calculated price equaled the total price paid by the member and the plan.[2] After the average prices for each unique drug were calculated, the average cash retail price for that drug was divided by the average total plan mail price to obtain a cash-to-owned-mail ratio. If this ratio was less than one, the cash price was lower than the owned mail price. If this ratio was greater than one, the cash price was higher.

Figures D-1 depicts the distribution of these ratios for 30-unit prescriptions, where the weight each drug gets in the distribution depends on the total number of prescriptions filled for that drug. In the figure, the gray bars show the distribution of this ratio for generic drugs and the hatched bars show the distribution for single-source brand drugs.[3]

The large majority of generic drugs had cash-to-owned-mail ratios between 0.8 and 2.8. The average ratio for generic drugs was 1.94, meaning that cash prices were 94% higher than owned mail prices for 30-unit generic prescriptions on average. One feature of this distribution worth noting is that roughly 3% of the generic drugs had a ratio in the range centered at 0.6.

Figure D-1 also shows the distribution of cash-to-owned-mail ratios for single-source brand drugs. Over 70% of the drugs had a ratio in the range centered at 1.4. These ratios were much less dispersed than the generic ratios. Also, the average ratio for single-source drugs was

[1] *See* Vanessa Fuhrmans, *Employers Join to Push Drug Managers for Full Disclosure*, THE WALL STREET JOURNAL, B1 (Aug. 10, 2005).

[2] The plan price does not include any share of pharmaceutical manufacturer payments that the PBM may have received and passed through to its clients. As a result, the prices shown here may be overstated compared to the prices actually paid by the plan, especially for brand drugs.

[3] The distribution for multi-source brand drugs was not included in these figures because these drugs accounted for only 2% of all the prescriptions in this data. *See, e.g.*, Figures D-3 and D-4.

1.41, which means that average cash prices were 41% higher than average total prices at PBM-owned mail pharmacies.

Figure D-1: Comparison of Retail Cash Price to PBM-Owned Mail Total Price: 30 Unit Prescriptions

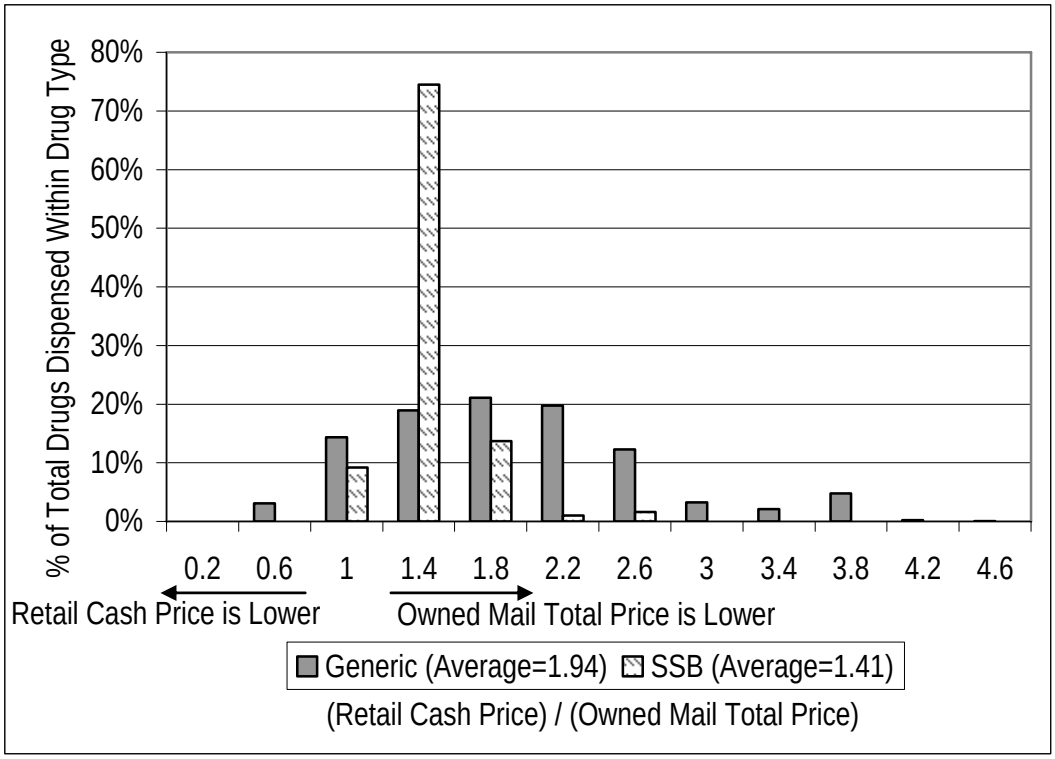
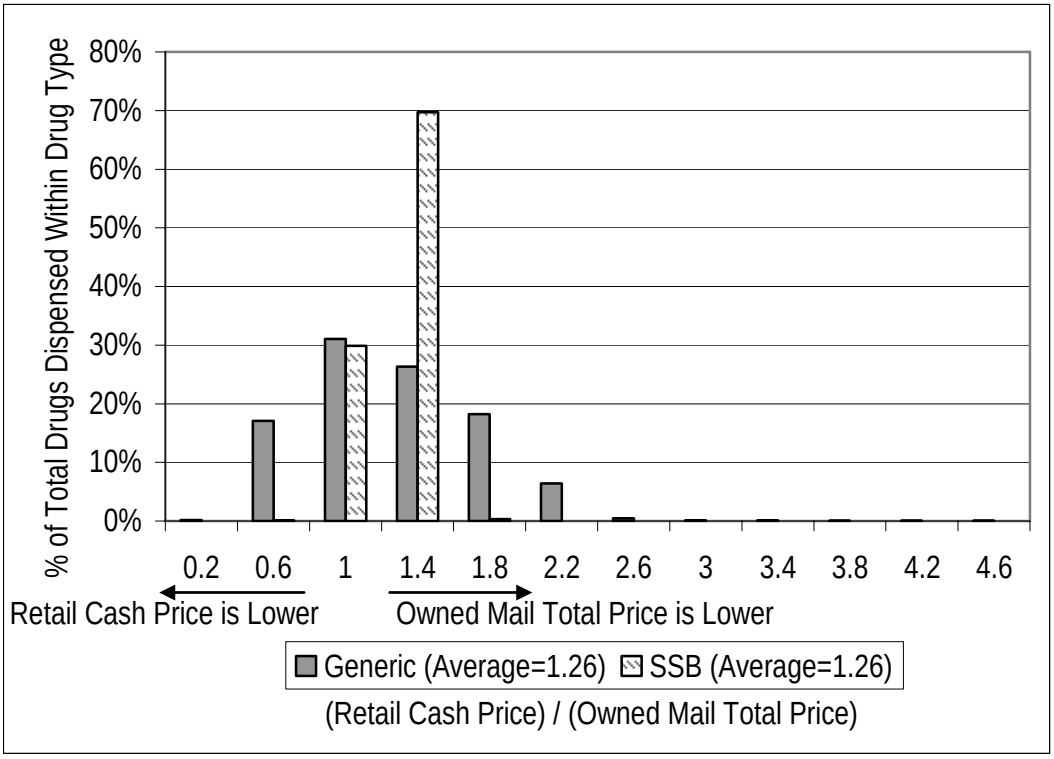


Figure D-2 presents a similar analysis based on 90-unit prescriptions instead of 30-unit prescriptions. The ratios for generic drugs again show considerably more dispersion than the ratios for single-source brand drugs. However, the dispersion in each distribution, generic and single-source brand, was considerably smaller than in the 30-unit analysis. Second, the average ratios for both generic and single-source brand drugs moved closer to one.

Figure D-2: Comparison of Retail Cash Price to PBM-Owned Mail Total Price: 90 Unit Prescriptions



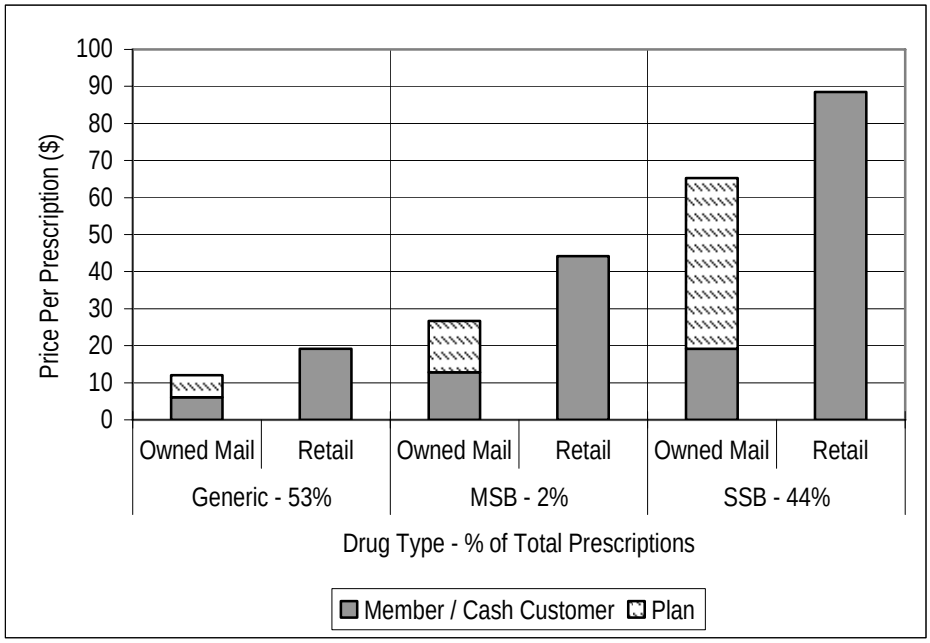
One explanation for why there may be so much more dispersion in the generic cash-to-owned-mail ratios than for the single-source drugs is based on a characteristic of many contracts between PBMs and plans. The prices paid by plans for mail-order prescriptions frequently are based on the AWP for generic drugs, and almost always for branded drugs. Cash prices for both types of drugs presumably depend on a number of factors, including, but not limited to, the level of competition between retail pharmacies, characteristics of demand for the drug, and the actual wholesale price of the drug. As noted in a study by the Department of Health and Human Services (HHS), actual wholesale prices paid can often differ substantially from the AWP.[4] HHS found that not only are generic drugs typically acquired at much steeper discounts relative to AWP than single-source drugs, but there is much more dispersion in the amount of that discount with generic drugs. Since contracted prices between PBMs and their clients are often based on AWPs and retail prices presumably depend somewhat upon acquisition costs, this analysis by HHS may suggest more dispersion should be seen in the cash-to-owned-mail ratios for generic drugs than for single-source drugs, which is consistent with Figures D-1 and D-2.

Figure D-3 and D-4 show the average total (member plus plan) owned mail prescription price compared to the stand-alone retailer cash prescription price by drug type for prescriptions

[4] *See* DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, MEDICAID DRUG PRICE COMPARISONS: AVERAGE MANUFACTURER PRICE TO PUBLISHED PRICES l (June 2005), *available at* http://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf.

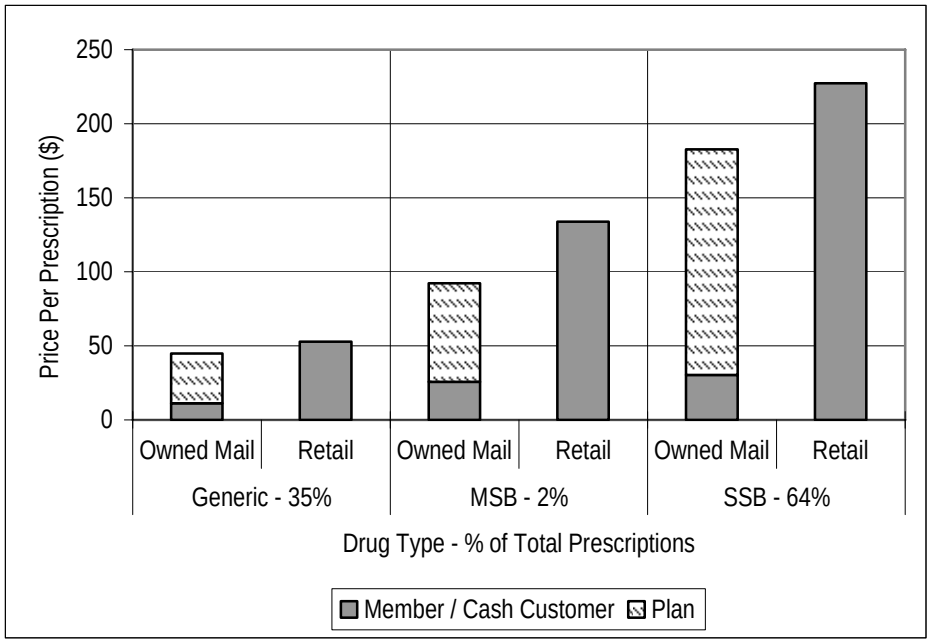
dispensed in December 2003 for 30-unit and 90-unit prescriptions.[5] These two figures show that for all three drug types (G, MSB, and SSB), cash customers on average paid more than customers who obtain prescriptions through a PBM-owned mail-order pharmacy.

Figure D-3: Cash Prices at Stand-Alone Retailers versus Total Prices at PBM-Owned Mail Pharmacies: Average Prices for 30 Unit Prescriptions



[5] The average price for a drug type within a given channel is calculated by taking the weighted average of the prices of all the drugs, where each price is weighted according to the total number of prescriptions dispensed for that drug in both channels combined.

Figure D-4: Cash Prices at Stand-Alone Retailers versus Total Prices at PBM-Owned Mail Pharmacies: Average Prices for 90 Unit Prescriptions



APPENDIX E. PBM USE OF OTHER PBMS TO ADMINISTER THEIR PAYMENTS FROM PHARMACEUTICAL MANUFACTURERS

Four of the study participants ("client PBMs") did not have agreements with individual pharmaceutical manufacturers in 2003, but relied on other PBMs ("administrator PBMs") to manage formularies and negotiate any pharmaceutical manufacturer payments due to them based on drugs dispensed to their clients' members. Two of the client PBMs contracted with large PBMs and the other two contracted with small or insurer-owned PBMs. The contracts were generally similar to one another and to the contracts that plan sponsors negotiate with PBMs.[1]

These four PBMs received a substantial portion of the pharmaceutical manufacturer payments attributable to the plans that they administered. The administrator PBM retained a small portion (generally in the 4% to 8% range) of the total dollar amounts.[2] In addition, the administrator PBM guaranteed a certain level of payment, which the contracts defined as a dollar amount per claim. The guarantees ranged from approximately $2.00 to $8.00 per eligible brand claim. The guarantees varied according to the benefit design adopted by the plan (*e.g.*, closed and highly managed formularies garnered higher rebate guarantees), and claims volume (some PBMs offered bonus guarantees based on higher claims volume).[3] Finally, one of the administrator PBMs paid its client PBM(s) additional lump sums for renewing the contract or implementing various formulary management programs.[4]

In these contracts, the administrator PBM gains effective control or a strong influence over the formulary of the client PBM's plans. In two contracts, the administrator PBM controls the formulary. In two other contracts, the dollar amount guarantees depend on the client PBM including on its formulary a very high percentage of the drugs on the administrator PBM's formulary. Three of the contracts included performance standards with penalty provisions for failing to meet those standards. These standards included timeliness of reports to the client and the accuracy of the administrator PBM's estimates of, and actual payments of, amounts due to the client PBM. Other standard provisions include reporting provisions, audit provisions, and exclusivity provisions (*e.g.*, the administrator PBM has the right to negotiate with individual pharmaceutical manufacturers without interference from the client PBM).[5]

[1] *See* discussion regarding plan sponsor contracts, *infra* at Chapter III.

[2] Administrator contracts.

[3] Administrator contracts.

[4] Administrator contracts.

[5] Administrator contracts.

APPENDIX F. COMPARISON OF TOP SELLING DRUG PRODUCTS' GSRS

TABLE F-IV-1(a). Top Selling Drug Products Examined By FTC Staff – 2002 Data
Comparison of Owned Mail vs. Not-Owned Mail

Drug	NDC9	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
ACTIGALL CAP 300MG	780319	93.4%	86.5%								
ADALAT CC	268841			92.7%	97.0%	89.9%	93.3%	90.5%	79.3%		
ADALAT CC	268851			91.6%	93.9%	88.5%	93.9%	86.7%	72.7%		
ADDERALL TAB 10MG	585210032	61.7%	38.6%	47.5%	51.6%	48.7%	49.5%			58.1%	60.0%
ADDERALL TAB 20MG	585210033	61.5%	40.2%	48.1%	50.0%	50.7%	45.5%			59.2%	75.0%
ADDERALL TAB 5MG	585210031	59.7%	37.0%								
ALESSE TAB - 28	82576	76.1%	74.7%	72.6%	66.8%	69.9%	62.1%	67.3%	62.9%	73.3%	72.5%
ATIVAN TAB 1MG	80064	95.1%	90.2%								
AUGMENTIN TAB 875MG	296086			9.0%	31.6%	8.9%	43.8%				
AXID CAP 150MG	657260144			87.7%	40.5%	86.4%	43.6%			35.1%	56.5%
AZULFIDINE	130102	11.3%	44.3%								
BETAPACE TAB 80MG	504190105	93.8%	89.9%								
BUSPAR TAB 10MG	870819	93.6%	85.8%	82.9%	82.3%	83.2%	79.1%				
BUSPAR TAB 30MG	870824	77.3%	81.1%	84.4%	88.9%	84.5%	90.7%				
BUSPAR TAB 15MG	870822	92.5%	87.1%	87.7%	95.7%	88.6%	87.8%	86.0%	87.8%	91.7%	97.7%
CARDIZEM CD CAP 240MG/24	881797	94.3%	88.6%	92.0%	91.0%	89.1%	87.9%	90.9%	85.8%		

Drug	NDC9	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
CLEOCIN	93329	15.2%	37.7%								
CLIMARA DIS 0.05MG	504190451	52.2%	32.7%	51.2%	39.5%	49.3%	41.4%			39.4%	27.0%
CLIMARA DIS 0.1MG	504190452			35.2%	36.0%	37.2%	24.9%			23.8%	22.7%
CORDARONE	84188	96.0%	93.1%								
COUMADIN	560168	72.5%	51.9%	73.0%	63.8%	72.7%	64.4%				
COUMADIN	560173			72.2%	48.0%	71.4%	59.1%				
COUMADIN	560174			70.3%	61.0%	66.7%	67.0%				
COUMADIN	560188			74.7%	79.0%	73.5%	61.9%				
COUMADIN	560189			69.1%	71.1%	72.6%	69.8%				
COUMADIN TAB 1MG	560169	75.4%	56.0%	76.4%	69.6%	75.8%	68.9%				
COUMADIN TAB 2.5MG	560176	72.3%	51.2%	71.9%	78.1%	72.7%	56.3%			62.0%	67.5%
COUMADIN TAB 2MG	560170	72.7%	56.6%	71.9%	69.1%	71.6%	62.4%			65.5%	75.7%
COUMADIN TAB 5MG	560172	71.6%	52.5%	69.2%	64.4%	69.9%	59.9%	75.6%	60.3%	81.2%	82.9%
CREON 20	321220									53.1%	83.3%
DARVOCET-N 100 TABLET	20363	94.4%	89.9%	89.3%	87.1%	89.0%	91.0%	93.0%	91.1%		
DEMADEX TAB 20MG	40264			45.8%	27.0%	50.2%	47.3%				
DEMULEN 1/35-28 TABLETS	250161	86.1%	84.5%								
DESOGEN 28 DAY TABLET	520261	90.0%	77.8%	86.5%	87.2%	82.5%	71.9%				
DILANTIN CAP 100MG	710362	60.2%	42.9%	60.9%	48.7%	58.7%	51.3%	58.9%	51.9%	52.3%	47.4%
DYAZIDE	73650							93.2%	89.7%		
DYNACIN CAP 75MG	992070499			19.6%	60.0%	21.2%	52.2%				

Drug	NDC9	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
ELOCON OINTMENT	850370			37.3%	50.0%	35.7%	66.7%				
ESTRACE	870755	90.8%	86.7%								
ESTRADERM	832320							6.3%	0.4%		
FIORICET	780084	90.5%	88.3%								
FLORINEF ACETATE	30429	34.1%	51.9%								
GLUCOPHAGE TAB 1000MG	876071	86.7%	82.1%	83.2%	79.9%	81.8%	84.4%			73.6%	89.7%
GLUCOPHAGE TAB 850MG	876070			82.7%	79.8%	80.5%	82.8%	90.0%	66.9%	70.2%	81.0%
GLUCOPHAGE TAB 500MG	876060	87.2%	80.6%	82.6%	80.4%	81.2%	83.2%			72.7%	83.8%
GOLYTELY	522680100			95.5%	50.0%	99.1%	66.7%				
HUMULIN	28315	13.0%	17.8%								
HYTRIN CAP 5MG	743807	94.2%	85.0%								
IMDUR	851153			1.6%	87.5%						
IMDUR	853305					81.5%	85.0%				
IMDUR	853306			93.8%	94.2%	92.1%	92.8%				
IMDUR	854110			93.5%	90.3%	93.1%	91.4%				
K-DUR TAB 20MEQ CR	850787			91.8%	88.2%	89.9%	91.3%	89.5%	73.6%	89.0%	92.2%
KLONOPIN	40058	93.2%	90.9%							91.3%	98.3%
KLONOPIN	40068	94.6%	89.6%							91.1%	95.4%
KLONOPIN	40098									91.0%	80.0%
LANOXIN	1730242			88.7%	67.1%	88.9%	84.3%				
LANOXIN TAB 0.25MG	1730249	66.1%	62.8%	86.7%	53.3%	86.4%	83.8%				
LO/OVRAL TAB -28	82514	80.2%	69.2%	79.9%	79.9%	76.5%	61.8%	75.8%	68.9%		
LOESTRIN FE TAB 1.5/30	710917	71.7%	58.1%	70.8%	60.1%	68.2%	54.8%			64.2%	47.7%
LOESTRIN FE TAB 1/20	710913			74.1%	53.2%	70.4%	46.0%			53.5%	13.8%

Drug	NDC9	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
LOPRESSOR	280051	96.9%	94.6%								
LORTAB TABLETS	504740907	95.1%	92.9%								
METADATE ER TABLETS	530140593					6.1%	7.1%				
MIRCETTE 28 DAY TABLET	520281	47.7%	30.2%	43.9%	39.1%	44.9%	35.4%	63.4%	45.9%	68.1%	49.8%
MODICON	621714			86.2%	78.3%	82.0%	75.2%				
MS CONTIN	340515					89.2%	90.9%				
MS CONTIN	340516	81.8%	66.7%	63.5%	18.2%						
MS CONTIN TAB 100MG CR	340517	14.9%	19.2%	18.8%	25.0%	23.1%	64.3%				
NEORAL CAP 100MG	780248	47.3%	47.1%	43.2%	29.4%	33.5%	41.2%	19.3%	31.7%	38.7%	70.0%
NEORAL CAP 25MG	780246	44.3%	49.4%	41.8%	34.1%	29.8%	40.1%	20.2%	28.6%	34.4%	75.0%
NITRO-DUR	853310			91.6%	85.9%	88.6%	93.1%				
NITRO-DUR	853320	55.6%	86.2%	93.1%	73.6%	89.8%	91.9%				
NITRO-DUR	853330			91.2%	74.6%	89.7%	98.3%				
NIZORAL	504580221			86.6%	77.6%	83.2%	89.1%				
NORDETTE-28 TAB	82533			85.8%	87.2%	84.7%	67.3%				
NORINYL 1+35	525440259			98.4%	98.5%	98.4%	98.6%				
OCUPRESS	587680001			74.5%	87.8%	71.0%	85.9%				
ORTHO-CEPT TAB 28	621796	84.2%	80.9%	87.1%	83.5%	85.2%	74.2%			86.4%	86.8%
ORTHO-CYCLEN TAB 0.25/35	621901	13.8%	6.5%	13.6%	14.5%	13.2%	8.7%			10.9%	1.1%
ORTHO-NOVUM	621332			83.6%	55.6%	77.4%	71.5%				
ORTHO-NOVUM TAB 1/35-28	621761			86.6%	88.9%	82.3%	75.0%				

Drug	NDC9	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
PARLODEL TAB 2.5MG	780017										
PEPCID TAB 20MG	60963			87.2%	90.5%	86.3%	86.1%	90.8%	79.4%		
PERCOCET TAB 5-325MG	634810623	88.6%	94.1%								
PERCOCET TABLETS	634810621	14.7%	75.0%								
PLAQUENIL	241562	94.1%	92.8%					90.8%	92.4%		
PRILOSEC CAP 20MG CR	1860742	0.0%	3.2%			0.0%	3.5%				
PRINIVIL TAB 10MG	60106							92.3%	73.3%		
PRINIVIL TAB 20MG	60207							91.9%	74.7%		
PROCARDIA XL TAB 60MG CR	692660	90.0%	85.2%	89.0%	91.2%	87.3%	85.0%			75.8%	88.9%
PROZAC CAP 10MG	7773104	91.8%	88.5%	86.3%	83.2%	84.5%	83.9%	84.5%	74.7%		
PROZAC CAP 20MG	7773105	91.7%	89.5%	86.7%	88.4%	85.7%	84.7%	86.4%	77.9%	84.2%	95.3%
PROZAC CAP 40MG	7773107	89.7%	89.2%	87.7%	85.6%	85.0%	84.4%	87.8%	82.7%	86.4%	93.4%
PSORCON	660071			81.1%	73.7%	79.5%	85.5%				
RELAFEN TAB 500MG	294851	92.3%	87.7%	87.9%	90.9%	85.0%	87.0%				
RELAFEN TAB 750MG	294852	93.3%	88.5%	87.0%	84.7%	84.5%	85.2%				
RETIN-A	620165			85.4%	71.7%	84.5%	80.0%				
RETIN-A	620175			78.0%	88.0%	75.1%	82.9%				
RETIN-A	620275			76.1%	75.0%	73.2%	87.5%				
RITALIN TABLETS	830003	78.6%	77.6%								
RYTHMOL	445022	88.2%	72.5%								
SANDIMMUNE CAP 100MG	780241	21.5%	17.3%							89.2%	94.9%

Drug	NDC9	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
SINEMET CR TAB 50/200	560521	88.0%	82.7%	84.3%	90.4%	83.9%	69.2%	87.4%	79.2%		
SOMA TAB 350MG	372001	95.5%	93.3%	93.5%	97.5%	91.7%	95.5%				
STADOL NS SOL 10MG/ML	875650	38.9%	46.2%								
SYNTHROID	481020									18.8%	34.2%
SYNTHROID	481060									14.5%	64.0%
SYNTHROID	481080									14.0%	47.1%
SYNTHROID	481100									12.0%	35.3%
SYNTHROID TAB 100MCG	481070									14.0%	46.5%
SYNTHROID TAB 125MCG	481130									13.9%	50.0%
SYNTHROID TAB 150MCG	481090									12.2%	51.6%
SYNTHROID TAB 200MCG	481140									10.4%	36.7%
SYNTHROID TAB 50MCG	481040									17.2%	51.9%
SYNTHROID TAB 75MCG	481050									16.6%	51.2%
TAMBOCOR TAB 100MG	890307	50.9%	30.2%	45.1%	28.9%	45.7%	38.9%			48.9%	20.0%
TEGRETOL TAB 200MG	830027	67.6%	63.6%	70.0%	70.6%	69.9%	56.3%			70.3%	88.9%
TENORMIN TAB 50MG	3100105	98.2%	96.2%	97.7%	97.8%	96.9%	97.1%				
TRIPHASIL 28 TAB	82536	81.9%	68.9%	82.4%	79.1%	79.2%	59.7%	72.5%	71.6%		
ULTRAM TAB 50MG	450659	34.9%	41.8%	44.1%	32.1%	49.5%	46.2%	75.9%	71.0%		
VALIUM TAB 10MG	1400006	87.4%	77.6%	82.5%	83.3%	82.7%	84.1%				

Drug	NDC9	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
VALIUM TAB 5MG	1400005	90.4%	81.7%	87.6%	82.0%	86.9%	86.5%				
VASERETIC	60720	90.8%	83.2%								
VASOTEC TAB 10MG	60713	92.8%	91.3%								
VASOTEC TAB 20MG	60714	92.9%	92.5%								
VICODIN ES	741973	96.7%	95.2%								
VICODIN ES TAB 7.5-750	440728	94.1%	85.8%							90.6%	83.3%
VICOPROFEN TABLETS	742277	51.7%	68.8%								
VIVELLE-DOT	780346							5.2%	0.4%		
XANAX TAB 0.25MG	90029	96.1%	89.6%								
XANAX TAB 0.5MG	90055	94.5%	89.7%	92.5%	93.5%	90.1%	89.4%	93.1%	90.0%	91.7%	95.2%
XANAX TAB 1MG	90090	93.4%	88.7%	89.0%	94.2%	88.5%	88.2%				
ZANAFLEX TAB 4MG	590750594	40.9%	38.0%	45.3%	41.1%	49.4%	44.5%			45.7%	37.5%
ZANTAC TAB 150MG	1730344	95.6%	90.6%	93.3%	93.2%	90.5%	92.0%	95.0%	88.3%	92.8%	99.5%
ZESTORETIC	3100145									64.6%	65.9%
ZESTORETIC TAB 20-12.5	3100142			47.0%	42.3%	52.8%	45.9%	44.3%	22.3%	60.4%	70.6%
ZESTRIL TAB 10MG	3100131	48.0%	52.5%	46.0%	41.6%	50.8%	48.6%	47.4%	19.1%	65.0%	79.0%
ZESTRIL TAB 20MG	3100132	49.1%	53.6%	46.8%	37.0%	51.6%	47.6%	46.8%	19.5%	67.6%	83.3%
ZESTRIL TAB 40MG	3100134	49.6%	56.2%	49.3%	44.0%	53.1%	50.8%	48.8%	21.2%	84.1%	91.9%
ZESTRIL TAB 5MG	3100130	47.6%	55.0%	46.0%	35.1%	50.4%	46.2%	45.9%	19.7%	79.8%	85.0%
Total		**66**	**18**	**52**	**35**	**51**	**35**	**30**	**4**	**12**	**40**

TABLE F-IV-1(b). Top Selling Drug Products Examined By FTC Staff – 2003 Data
Comparison of Owned Mail vs. Not-Owned Mail

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
ADALAT CC	268841			95.2%	93.3%	94.1%	92.5%				
ADALAT CC	268851			94.0%	95.1%	91.0%	96.0%				
ADDERALL TAB 10MG	585210032	87.8%	75.9%	80.3%	76.7%	79.8%	78.3%				
ADDERALL TAB 20MG	585210033	88.3%	80.7%	77.8%	79.4%	76.1%	68.9%				
ADDERALL TAB 5MG	585210031	86.7%	70.0%								
ALESSE TAB - 28	82576	87.8%	67.8%	81.1%	78.8%	76.4%	67.6%	73.0%	76.0%	82.0%	60.0%
ATIVAN TAB 1MG	80064	95.3%	92.6%								
AUGMENTIN TAB 875MG	296086					78.9%	86.5%				
AXID CAP 150MG	657260144			83.4%	83.1%	89.7%	87.2%			89.8%	72.2%
AZULFIDINE	130102	64.3%	78.8%								
BETAPACE	504190105	94.8%	98.0%								
BUSPAR	870819	94.2%	97.7%	91.7%	87.7%	92.7%	91.0%				
BUSPAR	870824	95.2%	92.2%	91.2%	94.6%	86.8%	91.2%				
BUSPAR TAB 15MG	870822	95.8%	92.0%	92.6%	96.5%	92.9%	92.0%	92.6%	91.8%	96.9%	98.8%
CARDIZEM CD CAP 240MG/24	881797	94.7%	93.2%	94.4%	92.6%	93.0%	93.0%	91.9%	93.4%		
CLARITIN	850458			0.1%	1.3%						
CLIMARA DIS 0.05MG	504190451	54.9%	35.8%	51.9%	51.5%	53.0%	41.9%			47.1%	30.4%
CLIMARA DIS 0.1MG	504190452			36.7%	32.5%	39.0%	28.8%			34.3%	12.5%
CORDARONE	84188	97.2%	95.9%								
COUMADIN	560168	74.1%	73.1%	75.4%	64.2%	75.7%	67.8%				

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
COUMADIN	560173			77.1%	48.1%	73.3%	61.5%				
COUMADIN	560174			74.9%	67.3%	70.2%	63.6%				
COUMADIN	560188			78.9%	64.7%	77.5%	67.7%				
COUMADIN	560189			74.1%	54.8%	77.2%	65.3%				
COUMADIN TAB 1MG	560169	76.6%	70.4%	79.0%	72.5%	77.6%	70.8%	73.2%	72.3%		
COUMADIN TAB 2MG	560170	75.1%	70.1%	75.9%	71.8%	77.0%	67.2%				
COUMADIN TAB 5MG	560172	73.6%	70.3%	73.7%	65.1%	73.0%	62.9%	74.0%	61.9%	85.0%	80.2%
COUMADIN TAB 2.5MG	560176	71.6%	68.8%	76.0%	67.9%	73.3%	59.8%				
DARVOCET-N TAB 100	20363	95.0%	89.4%	90.3%	87.7%	90.0%	91.3%				
DEMADEX	40264			89.8%	82.9%	88.5%	89.5%				
DESOGEN	520261	92.0%	88.2%	90.0%	88.8%	87.9%	87.2%				
DILANTIN CAP 100MG	710362	61.3%	62.0%	61.4%	42.5%	58.2%	53.9%	61.5%	47.1%	60.2%	42.9%
DYNACIN CAP 100MG	992070498										
DYNACIN CAP 75MG	992070499			75.8%	93.8%	70.2%	68.0%				
ELOCON	850370					78.5%	95.4%				
ESTRACE	870755	92.7%	88.7%								
ESTRADERM	832310							16.5%	4.7%		
ESTRADERM	832320							10.8%	2.6%		
FIORICET TAB	780084	89.1%	87.8%								
FLORINEF ACETATE	30429	85.1%	81.9%								
GLUCOPHAGE TAB 1000MG	876071	96.5%	95.5%	96.0%	92.7%	93.3%	95.1%			94.6%	97.5%

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
GLUCOPHAGE TAB 500MG	876060	96.4%	93.9%	95.6%	92.6%	93.2%	94.1%			93.5%	94.4%
GLUCOPHAGE TAB 850MG	876070			95.1%	94.4%	92.1%	94.3%	93.5%	91.4%		
GLUCOPHAGE TAB XR 500MG	876063			5.9%	5.6%	6.1%	7.3%				
HYTRIN	743807	93.8%	90.6%								
IMDUR	853306			95.9%	95.5%	95.2%	96.1%				
IMDUR	854110			95.1%	90.5%	94.8%	92.3%				
IMURAN TAB 50MG	654830590										
K-DUR TAB 20MEQ CR	850787			95.9%	96.4%	94.9%	94.9%				
KLONOPIN TAB 0.5MG	40068	94.8%	91.2%								
KLONOPIN TAB 1MG	40058	93.9%	91.6%								
LANOXIN	1730242			92.1%	64.1%	93.2%	89.9%				
LANOXIN TAB 0.25MG	1730249	72.2%	83.6%	90.6%	57.4%	91.6%	87.7%				
LO/OVRAL TAB -28	82514	86.5%	81.0%	84.2%	82.0%	82.1%	81.4%	78.4%	78.6%		
LOESTRIN FE TAB 1.5/30	710917	84.8%	67.0%	77.1%	77.8%	75.1%	66.7%				
LOESTRIN FE TAB 1/20	710913			79.5%	79.1%	75.0%	65.1%				
LOPRESSOR TAB 50MG PP	280051	97.2%	96.5%								
MIRCETTE TAB 28	520281	77.7%	53.6%	68.0%	73.1%	65.5%	58.6%	65.2%	61.8%	87.4%	78.1%
MODICON	621714			79.0%	96.3%	78.9%	44.3%				
MS CONTIN	340514					87.2%	93.3%				
MS CONTIN TAB 100MG CR	340517	41.8%	45.5%	86.7%	60.0%	51.7%	90.5%				
MS CONTIN TAB 30MG CR	340515					90.3%	85.2%				

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
MS CONTIN TAB 60MG CR	340516					91.8%	88.9%				
NEORAL CAP 100MG	780248	56.1%	60.6%	45.2%	31.9%	38.0%	37.8%	22.6%	22.5%		
NEORAL CAP 25MG	780246	48.4%	43.1%	43.1%	32.2%	34.4%	32.3%	23.3%	39.1%		
NITRO-DUR	853310			95.2%	82.9%	94.9%	94.6%				
NITRO-DUR	853320	64.0%	93.4%	96.4%	72.2%	94.7%	98.1%				
NITRO-DUR	853330			94.7%	52.9%						
NIZORAL	504580221			95.4%	96.1%	92.5%	98.1%				
NORDETTE-28 TAB	82533			89.2%	91.9%	87.4%	73.6%				
NORINYL 1+35	525440259			98.6%	98.4%	98.9%	99.4%				
NOR-QD TAB 0.35MG	525440235			92.5%	94.1%	91.2%	93.9%				
OCUPRESS	587680001					81.9%	81.8%				
ORTHO MICRONOR	621411			71.0%	93.1%	72.2%	61.9%				
ORTHO MICRONOR	621411			71.0%	89.6%	72.2%	61.9%				
ORTHO-CEPT TAB 28	621796	88.7%	87.1%	85.5%	82.0%	88.3%	78.4%			95.1%	89.9%
ORTHO-CYCLEN TAB 0.25/35	621901	74.0%	53.9%	67.8%	66.5%	67.0%	51.7%			73.3%	34.2%
ORTHO-NOVUM	621332			81.9%	90.0%	83.6%	74.0%				
ORTHO-NOVUM TAB 1/35-28	621761			84.4%	90.9%	87.3%	80.0%				
ORTHO-NOVUM TAB 7/7/7-28	621781			61.4%	60.5%	64.1%	51.5%	60.9%	52.5%	61.8%	28.9%
PAXIL TAB 10MG	293210	27.3%	21.1%	23.5%	25.0%	24.4%	25.1%				

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
PAXIL TAB 20MG	293211	26.6%	24.4%	23.7%	24.7%	23.8%	24.4%			21.5%	20.1%
PAXIL TAB 30MG	293212			25.2%	25.5%	23.8%	25.5%				
PAXIL TAB 40MG	293213	28.0%	23.6%	24.4%	24.6%	24.4%	27.3%			22.4%	25.0%
PEPCID TAB 20MG	60963			92.6%	94.6%	93.1%	93.5%				
PERCOCET	634810621	25.6%	66.7%								
PERCOCET TAB 5-325MG	634810623			49.6%	78.6%	20.6%	50.0%				
PHENERGAN SUP 25MG	80212	55.2%	60.0%								
PLAQUENIL TAB 200MG	241562	94.4%	93.5%					90.7%	93.5%		
PRILOSEC CAP 20MG CR	1860742	94.2%	76.3%	10.0%	81.8%	9.2%	81.1%			82.0%	82.4%
PROAMATINE TAB 5MG	540920004	9.8%	17.7%								
PROCARDIA XL TAB 60MG CR	692660	90.8%	91.4%	93.1%	92.8%	92.0%	87.4%			85.7%	77.5%
PROZAC CAP 10MG	7773104	93.6%	92.0%	90.6%	93.8%	87.4%	87.6%	87.8%	90.6%		
PROZAC TAB 10MG	24006										
PROZAC CAP 20MG	7773105	93.3%	91.4%	90.8%	91.8%	89.4%	87.9%	91.2%	90.3%	91.9%	94.4%
PROZAC CAP 40MG	7773107	92.7%	93.4%	91.1%	90.6%	89.3%	88.6%	91.4%	90.7%	91.6%	98.0%
PSORCON	660071					88.7%	85.7%				
RELAFEN	294851	95.0%	92.9%	92.6%	97.4%	90.5%	94.5%				
RELAFEN TAB 750MG	294852	96.7%	96.8%	92.3%	99.4%	91.9%	94.8%				
REMERON TAB 15MG	520105	77.5%	74.2%	63.1%	77.8%						
REMERON TAB 30MG	520107	75.6%	76.9%	72.5%	75.3%	71.0%	79.9%				

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
RETIN-A	620165			91.3%	83.9%	90.7%	86.7%				
RETIN-A	620275			80.3%	95.2%	83.8%	80.4%				
RITALIN	830003	81.2%	95.5%								
RYTHMOL	445022	97.6%	92.1%								
SANDIMMUNE CAP 100MG	780241	45.5%	44.0%								
SINEMET CR	560521	90.6%	95.5%	89.4%	96.1%	90.1%	88.1%				
SOMA TAB 350MG	372001	95.9%	94.8%	93.9%	93.1%	92.6%	92.3%				
SYNTHROID TAB 100MCG	481070									73.4%	83.5%
SYNTHROID TAB 112MCG	481080									61.8%	61.5%
SYNTHROID TAB 125MCG	481130									72.4%	78.5%
SYNTHROID TAB 150MCG	481090									70.1%	59.7%
SYNTHROID TAB 175MCG	481100									52.8%	45.8%
SYNTHROID TAB 200MCG	481140									63.3%	57.0%
SYNTHROID TAB 50MCG	481040									81.1%	64.6%
SYNTHROID TAB 75MCG	481050									80.1%	77.3%
SYNTHROID TAB 88MCG	481060									55.9%	84.7%
SYNTHROID TAB 100MCG	746624									18.6%	58.4%
SYNTHROID TAB 112MCG	749296									19.4%	83.7%
SYNTHROID TAB 125MCG	747068									18.3%	75.0%

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
SYNTHROID TAB 150MCG	747069									16.9%	65.2%
SYNTHROID TAB 200MCG	747148									14.1%	71.4%
SYNTHROID TAB 50MCG	744552									21.7%	71.7%
SYNTHROID TAB 75MCG	745182									21.1%	69.7%
SYNTHROID TAB 88 MCG	746594									22.0%	73.5%
TAMBOCOR TAB 100MG	890307	90.3%	76.9%	85.3%	79.5%	85.6%	75.9%			89.3%	66.7%
TEGRETOL TAB 200MG	830027	68.6%	68.9%	71.3%	72.6%	70.3%	59.0%	69.4%	53.4%	74.2%	76.7%
TENORMIN	3100105	98.4%	97.1%	98.3%	98.3%	97.5%	97.9%				
TIAZAC CAP 240MG/24	4562614			59.5%	37.8%	59.4%	57.8%				
TIAZAC CAP 360MG/24	4562616			62.6%	59.4%	61.5%	60.3%				
TRIPHASIL 28 TAB	82536	88.1%	77.0%	86.4%	83.8%	82.8%	68.4%	77.2%	73.4%		
ULTRAM TAB 50MG	450659	92.6%	89.0%	90.2%	86.4%	89.9%	92.5%	88.8%	90.4%		
VALIUM TAB 10MG	1400006	88.0%	89.4%	84.7%	83.3%	82.3%	82.0%				
VALIUM TAB 5MG	1400005	90.3%	86.3%	89.3%	92.1%	86.5%	89.9%				
VASERETIC	60720	100.0%	98.4%								
VASOTEC	60713	98.9%	99.9%								
VICODIN ES	741973	91.6%	87.2%							88.8%	25.0%
VICOPROFEN TAB	742277	23.9%	62.2%								
VIVELLE-DOT	780344							12.1%	4.2%		
VIVELLE-DOT	780346							6.6%	1.7%		
XANAX TAB 0.25MG	90029	96.2%	93.0%								

Drug	NDC	Company A		Company B		Company C		Company D		Company E	
		Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail	Owned Mail	Not-Owned Mail
XANAX TAB 0.5MG	90055	95.0%	94.2%	93.3%	94.3%	91.9%	91.5%	93.8%	92.7%	93.6%	98.3%
XANAX TAB 1MG	90090	93.4%	91.5%	90.1%	96.8%	89.8%	90.0%				
XANAX TAB 2MG	90094										
ZANAFLEX TAB 4MG	590750594	93.2%	86.8%	90.2%	94.3%	89.6%	87.9%			92.8%	90.9%
ZANTAC TAB 150MG	1730344	95.9%	93.9%	92.4%	94.5%	88.1%	93.1%	94.3%	96.1%	95.4%	99.0%
ZESTORETIC	3100142			95.2%	93.1%	95.7%	93.0%				
ZESTORETIC	3100145									98.0%	98.5%
ZESTRIL TAB 10MG	3100131	97.3%	95.4%	96.4%	95.2%	96.7%	96.2%	92.9%	91.6%	98.4%	99.6%
ZESTRIL TAB 20MG	3100132	97.5%	95.5%	96.7%	94.5%	97.3%	95.1%	93.3%	92.9%	98.7%	99.5%
ZESTRIL TAB 40MG	3100134	97.7%	95.4%	97.3%	94.1%	97.6%	95.7%			99.4%	99.6%
ZESTRIL TAB 5MG	3100130	97.1%	94.8%	96.3%	91.0%	96.3%	95.0%				
Total		**60**	**21**	**57**	**38**	**65**	**34**	**18**	**8**	**21**	**25**

TABLE F-IV-2(a). Top Selling Drug Products Examined By FTC Staff – 2002 Data
Comparison of Owned Mail vs. Not-Owned Retail

O M – owned mail; NO R –not-owned retail

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R &
ACTIGALL CAP 300MG	780319							93.4	84.8			92.8	90.1						
ADALAT CC	268841	92.7	81.8	89.9	79.6							96.1	92.1	90.5	78.1				
ADALAT CC	268851	91.6	74.4	88.5	71.4	94.6	79.1					95.4	88.9	86.7	71.2				
ADALAT CC 90 MG TABLET	268861					25.2	10.4												
ADDERALL	585210034					51.0	43.0												
ADDERALL TAB 20MG	585210033	48.1	44.3	50.7	41.3	48.5	46.1	61.5	46.1			64.3	70.9	34.1	51.3	59.2	40.3	50.9	51.8
ADDERALL TAB 5MG	585210031					48.4	45.4	59.7	46.7			64.9	67.4			53.7	40.6	50.7	51.4
ADDERALL TAB 10MG	585210032	47.5	44.9	48.7	42.9	51.0	45.8	61.7	47.2			63.0	70.5	40.2	55.0	58.1	40.5	62.4	48.9
ALESSE TAB -28	82576	72.6	62.0	69.9	60.4	81.7	57.7	76.1	68.2	70.4	55.3	71.3	61.3	67.3	60.2	73.3	60.0	79.4	62.7
ALESSE-21	80912					99.2	99.9			97.7	99.7								
ATIVAN	80065					91.0	90.5												
ATIVAN	80081					96.2	95.9												
ATIVAN TAB 1MG	80064					93.9	92.9	95.1	96.0	94.8	93.8	96.9	97.4						
AUGMENTIN SUS 400/5ML	296092																		

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
AUGMENTIN TAB 500MG	296080									2.4	24.1							34.4	23.5
AUGMENTIN TAB 875MG	296086	9.0	28.2	8.9	28.5					2.4	27.2							20.0	26.7
AVENTYL CAP 10MG	20817																		
AVENTYL CAP 25MG	20819																	99.5	99.4
AXID	23145					39.2	47.0												
AXID CAP 150MG	657260144	87.7	38.1	86.4	40.7	39.9	42.0			36.2	42.3	18.0	82.3			35.1	35.6	43.9	45.0
AXID 150MG PULVULE	23144					98.9	54.6			100.0	51.7								
AZULFIDINE	130102							11.3	22.8										
BACTRIM TAB 400-80MG	40050																	98.4	99.9
BACTRIM DS TAB 800-160	40117																	99.2	99.5
BETAPACE	504190106					91.9	71.4												
BETAPACE	504190107					83.9	74.3												
BETAPACE	504190109					90.7	82.2												
BETAPACE TAB 80MG	504190105					92.9	85.8	93.8	90.3	92.2	87.0	87.6	83.4						
BUSPAR	870818					91.5	73.3												
BUSPAR TAB 10MG	870819	82.9	75.6	83.2	76.8	89.7	75.4	93.6	90.3										

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
BUSPAR TAB 30MG	870824	84.4	80.2	84.5	77.6	82.5	79.7	77.3	81.4			92.6	90.3						
BUSPAR TAB 15MG	870822	87.7	88.7	88.6	88.5	93.5	87.3	92.5	91.0	93.5	89.8	93.9	94.7	86.0	89.3	91.7	93.2	93.9	94.9
CALAN SR	251901					95.8	93.7												
CALAN SR	251911					97.4	96.1												
CALAN SR TAB 240MG	251891					96.9	95.2			96.5	94.3								
CAPOTEN TAB 100MG	30485																	90.4	97.5
CAPOTEN TAB 12.5MG	30450																	97.4	95.8
CAPOTEN TAB 25MG	30452																	96.6	97.1
CAPOTEN TAB 50MG	30482																	97.8	97.8
CAPOZIDE TAB 25/15MG	30338																	80.9	97.8
CAPOZIDE TAB 25/25MG	30349																		
CAPOZIDE TAB 50/15MG	30384																	78.6	98.4
CAPOZIDE TAB 50/25MG	30390																		
CARDIZEM CD	881795					92.3	86.4												
CARDIZEM CD	881796					93.3	86.0			90.4	85.1	94.7	93.4						

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
CARDIZEM CD	881798					93.7	86.0			90.5	85.4								
CARDIZEM CD CAP 240MG/24	881797	92.0	88.9	89.1	86.2	93.0	86.8	94.3	88.8	90.6	85.1	95.1	93.1	90.9	86.2	89.3	84.8	94.3	87.3
CARDURA	492750					93.6	88.3												
CARDURA	492760					94.7	88.2												
CARDURA	492770					95.0	87.2												
CARDURA	492780					95.7	88.2												
CECLOR CAP 250MG	23061																	83.3	99.1
CEFTIN	659390387					76.2	71.0												
CEFTIN	659390394					83.3	71.2												
CEFTIN TAB 250MG	1730387					23.4	64.2					32.1	84.9					85.7	57.0
CEFTIN TAB 500MG	1730394					30.9	61.1					51.9	78.9					80.0	52.8
CLIMARA DIS 0.05MG	504190451	51.2	32.9	49.3	33.8	0.0	32.0	52.2	28.6			60.9	53.0			39.4	31.6	42.8	29.3
CLIMARA DIS 0.1MG	504190452	35.2	21.0	37.2	21.8	0.0	21.6					48.1	39.7			23.8	19.5	29.0	17.6
CORDARONE	84188							96.0	96.2	96.6	95.3								
CORGARD TAB 120MG	30208					82.0	83.5											78.9	77.9
CORGARD TAB 160MG	30246					90.2	87.1												

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
CORGARD TAB 20MG	30232					90.8	89.2											93.8	93.9
CORGARD TAB 40MG	30207					91.9	89.0											92.1	92.1
CORGARD TAB 80MG	30241					92.4	89.1											98.0	94.9
COUMADIN	560168	73.0	57.6	72.7	46.1			72.5	53.4										
COUMADIN	560173	72.2	51.6	71.4	45.0														
COUMADIN	560174	70.3	51.1	66.7	44.3														
COUMADIN	560188	74.7	58.7	73.5	47.5														
COUMADIN	560189	69.1	52.6	72.6	44.5														
COUMADIN TAB 2.5MG	560176	71.9	57.7	72.7	46.6			72.3	54.0			79.9	71.7			62.0	48.2	62.7	48.8
COUMADIN TAB 5MG	560172	69.2	55.4	69.9	46.2			71.6	53.1			80.3	71.4	75.6	53.7	81.2	72.8	77.0	71.2
COUMADIN TAB 1MG	560169	76.4	61.7	75.8	52.0			75.4	59.6			71.3	75.7						
COUMADIN TAB 2MG	560170	71.9	57.9	71.6	48.0			72.7	54.8			80.3	72.5			65.5	50.5	62.9	47.7
CREON 20	321220															53.1	89.0	87.4	86.0
DARVOCET-N TAB 50	20351															10.6	46.2		
DARVOCET-N 100 TABLET	20363	89.3	92.7	89.0	93.8			94.4	96.6	93.8	95.2	95.0	97.9	93.0	96.0	90.9	95.1	90.8	95.9
DEMADEX	40262					24.6	6.6												
DEMADEX	40263					50.2	27.4												
DEMADEX	40265					49.6	21.9												
DEMADEX TAB 20MG	40264	45.8	32.2	50.2	33.8	49.8	34.7					81.5	63.2						
DESOGEN 28 DAY TABLET	520261	86.5	74.8	82.5	70.0	51.7	74.1	90.0	78.9			85.7	75.5						
DESYREL	870775					98.2	99.0												
DESYREL	870776					99.2	99.2												

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R &
DESYREL	870778					91.8	94.3												
DESYREL	870796					83.0	57.1												
DEXEDRINE	73512					49.0	22.4												
DEXEDRINE	73514					54.0	29.3												
DEXEDRINE CAP 10MG	73513					51.1	27.9											49.4	63.5
DILANTIN CAP 100MG	710362	60.9	37.4	58.7	29.6			60.2	34.1			36.4	29.8	58.9	35.2	52.3	32.4	46.4	31.0
DYAZIDE	73650											96.4	95.9	93.2	91.6				
DYNACIN CAP 100MG	992070498					95.4	93.8			93.8	93.9	97.5	97.0						
DYNACIN CAP 75MG	992070499	19.6	55.6	21.2	55.3	75.0	59.3					73.7	76.1						
ELOCON	850370	37.3	49.9	35.7	51.1														
ESTRACE	870021					92.7	85.7												
ESTRACE	870755					91.8	84.4	90.8	87.5										
ESTRACE	870756					81.0	83.6												
ESTRADERM	832310													16.0	1.2				
ESTRADERM	832320													6.3	2.0				
FIORICET	780084							90.5	87.1			1.1	84.3						
FLORINEF ACETATE	30429							34.1	29.1										
GLUCOPHAGE TAB 1000MG	876071	83.2	74.3	81.8	70.9	87.1	76.8	86.7	78.6	85.7	77.0	88.6	87.7			73.6	75.3	85.7	93.3
GLUCOPHAGE TAB 500MG	876060	82.6	73.0	81.2	71.2	87.0	77.2	87.2	78.7	86.0	77.2	91.1	88.9			72.7	72.9	86.1	79.9

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
GLUCOPHAGE TAB 850MG	876070	82.7	69.4	80.5	67.6	84.0	75.5			86.3	75.2	90.0	87.7	90.0	86.0	70.2	69.8	85.6	93.2
GOLYTELY	522680100	95.5	88.4	99.1	89.9														
HALDOL DECAN INJ 100MG/ML	450254																		
HYDREA CAP 500MG	30830																	92.4	88.7
HYTRIN CAP 5MG	743807							94.2	91.7	93.9	87.6	96.0	95.3						
IMDUR	851153	1.6	74.1			94.4	68.8												
IMDUR	853306	93.8	95.5	92.1	94.0	95.3	93.8			93.9	94.1								
IMDUR	854110	93.5	94.3	93.1	92.5	95.0	92.0												
K-DUR	850263					96.0	87.0												
K-DUR TAB 20MEQ CR	850787	91.8	87.0	89.9	86.9	95.8	87.6			89.8	87.5	95.2	93.2	89.5	83.6	89.0	84.9	93.4	88.9
KEFLEX	7770871									97.1	99.2								
KENALOG CRE 0.1%	30506																	99.0	99.9
KENALOG OIN 0.1%	30508																	99.2	99.6
KENALOG/ORAB PST 0.1%	30496																	90.6	95.9
KLONOPIN TAB 0.5MG	40068					93.6	93.7	94.6	95.6			95.1	96.5			91.1	93.4	92.5	94.4
KLONOPIN TAB 1MG	40058					92.6	92.5	93.2	94.9							91.3	92.8	93.7	95.3
KLONOPIN TAB 2MG	40098					91.5	91.8									91.0	92.1	85.5	94.6
LAC-HYDRIN CRE 12%	725730																	17.0	8.0

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
LAC-HYDRIN LOT 12%	725712																	29.9	12.3
LANOXIN	1730242	88.7	61.6	88.9	48.7														
LANOXIN TAB 0.25MG	1730249	86.7	55.0	86.4	45.8			66.1	50.0										
LEVLITE-28	504190408									86.5	85.8	83.1	84.3						
LO/OVRAL	80078					96.0	98.0			95.4	97.7								
LO/OVRAL TAB -28	82514	79.9	69.0	76.5	62.9	80.9	62.2	80.2	69.2	78.7	61.0	73.9	63.7	75.8	65.6			81.1	69.8
LOESTRIN FE TAB 1.5/30	710917	70.8	50.9	68.2	47.8	47.9	50.5	71.7	51.5			62.0	55.3			64.2	50.7	75.4	82.3
LOESTRIN FE TAB 1/20	710913	74.1	44.9	70.4	42.7	46.9	43.3					57.5	53.7			53.5	45.9	65.7	80.0
LOPRESSOR	280051					96.6	95.3	96.9	96.9										
LOPRESSOR	280071					95.5	94.6												
LORTAB	504740902									99.3	99.3								
LUPRON 6-PK INJ 5MG/ML	3003612											2.5	58.6						
LUVOX	324202					93.8	86.1												
LUVOX	324205					95.5	85.7												
LUVOX TAB 100MG	324210					93.6	87.5					84.9	91.6						
MEGACE ORAL SUS 40MG/ML	150508											90.5	86.4						

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
MEVACOR	60730					93.2	87.3												
MEVACOR TAB 20MG	60731					88.5	82.8					93.1	96.3						
MEVACOR TAB 40MG	60732					88.2	87.3					94.0	97.8						
MINOCIN	55344									97.2	98.0								
MIRCETTE 28 DAY TABLET	520281	43.9	30.4	44.9	29.0	0.3	29.3	47.7	33.8			80.6	74.6	63.4	46.3	68.1	56.5	73.0	61.5
MODICON	621714	86.2	74.8	82.0	69.7														
MS CONTIN	340513			12.5	53.0	42.3	27.4												
MS CONTIN	340514	51.8	69.5	58.3	67.5	88.9	69.7												
MS CONTIN	340515	83.0	70.6	89.2	69.7	85.9	71.4												
MS CONTIN	340516	63.5	65.6	56.3	65.5	73.3	66.1	81.8	69.5										
MS CONTIN TAB 100MG CR	340517	18.8	50.3	23.1	51.5	36.6	49.8	14.9	56.9			6.5	40.8					12.5	50.4
MYCOLOG II CRE	30566																	79.8	98.5
MYCOLOG II OIN	30466																	76.2	96.5
MYCOSTATIN POW 100000	30593																	93.9	94.9
NEORAL CAP 100MG	780248	43.2	31.7	33.5	31.5	48.9	37.2	47.3	33.9			13.3	36.5	19.3	36.2	38.7	32.0	48.0	36.8
NEORAL CAP 25MG	780246	41.8	28.1	29.8	27.8	45.8	33.6	44.3	30.2			11.2	31.0	20.2	32.0	34.4	24.9	43.6	18.8
NITRO-DUR	853310	91.6	84.1	88.6	85.8														
NITRO-DUR	853320	93.1	85.4	89.8	85.6			55.6	88.4										
NITRO-DUR	853330	91.2	83.0	89.7	83.7														
NIZORAL	504580221	86.6	93.0	83.2	92.7														
NOLVADEX TAB 20MG	3100604											0.8	0.1						

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
NORCO	525440539											93.7	95.2						
NORDETTE-28 TAB	82533	85.8	80.5	84.7	74.7							67.7	68.2						
NORINYL 1+35	525440259	98.4	97.3	98.4	98.4														
NOR-QD TAB 0.35MG	525440235																	7.3	4.0
OCUPRESS	587680001	74.5	57.2	71.0	52.3														
ORTHO MICRON TAB DIALPAK	621411											34.3	15.7						
ORTHO-CEPT TAB 28	621796	87.1	79.3	85.2	76.6	7.8	71.3	84.2	76.2			89.5	81.8	82.9	80.7	86.4	77.8	90.7	84.7
ORTHO-CYCLEN TAB 0.25/35	621901	13.6	7.4	13.2	6.9	0.0	7.1	13.8	7.0	3.2	6.9	71.1	42.9			10.9	6.8	17.8	9.3
ORTHO-NOVUM	621332	83.6	70.4	77.4	68.9	23.3	72.3												
ORTHO-NOVUM	621771					82.8	43.5												
ORTHO-NOVUM 1/35-28	621761	86.6	82.5	82.3	83.3	40.2	79.3					93.2	92.5	85.4	86.0			90.6	86.9
PARLODEL TAB 2.5MG	780017											21.2	39.4						
PEPCID TAB 20MG	60963	87.2	91.9	86.3	91.1	91.0	91.4			92.0	91.3	93.8	95.9	90.8	92.6				
PEPCID TAB 40MG	60964					90.5	89.1												

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
PERCOCET TAB 10-650MG	634810622							16.8	77.2			78.1	87.4						
PERCOCET TAB 5-325MG	634810623							88.6	95.5			91.3	96.8						
PHENERGAN SUP 25MG	80212																	50.0	41.9
PLAQUENIL	241562							94.1	93.9			95.6	96.1	90.8	91.7				
PRILOSEC CAP 20MG CR	1860742			0.0	2.4			0.0	2.3	0.0	2.3							4.0	2.6
PRINIVIL	60015					48.6	51.6												
PRINIVIL TAB 10MG	60106					48.6	51.9			48.3	51.6	47.6	54.5	92.3	84.4				
PRINIVIL TAB 20MG	60207					49.1	51.4			46.3	51.0	47.7	54.0	91.9	83.9				
PRINIVIL TAB 40MG	60237					50.5	53.1			50.8	52.8	50.3	54.0						
PRINIVIL TAB 5MG	60019					48.2	51.6			48.1	52.1	46.4	55.4						
PRINZIDE TAB 10/12.5	60145					47.6	51.6					46.9	59.1						
PRINZIDE TAB 20-12.5	60140					49.5	50.0			42.2	49.0	47.5	56.4						
PRINZIDE TAB 20-25MG	60142					49.1	50.4			47.1	48.6	47.7	56.4						
PROCARDIA XL	692650					89.2	77.9												
PROCARDIA XL TAB 60MG CR	692660	89.0	80.6	87.3	80.7	89.7	80.1	90.0	81.2	90.1	80.2	92.4	88.0			75.8	76.3	84.4	79.4

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
PROVENTIL AER 90MCG RF	850614																	86.6	97.3
PROVERA	90050					84.8	91.0												
PROVERA	90064					87.3	88.1												
PROZAC CAP 10MG	7773104	86.3	82.2	84.5	84.0	90.4	86.3	91.8	91.7			92.4	92.5	84.5	87.4				
PROZAC CAP 20MG	7773105	86.7	80.8	85.7	82.9	91.1	86.0	91.7	89.7	90.8	85.1	92.6	92.1	86.4	87.6	84.2	85.6	88.9	89.2
PROZAC CAP 40MG	7773107	87.7	86.7	85.0	86.1	90.3	87.7	89.7	89.7	90.0	86.8	92.8	93.0	87.8	89.1	86.4	85.4	86.7	91.4
PROZAC TAB 10MG	24006					88.4	87.9					90.2	93.3			83.8	86.0	88.6	85.1
PSORCON	660071	81.1	82.4	79.5	81.6														
RELAFEN TAB 500MG	294851	87.9	86.6	85.0	88.3	91.4	84.3	92.3	89.0										
RELAFEN TAB 750MG	294852	87.0	86.1	84.5	87.5	92.4	83.9	93.3	88.9			84.4	94.2						
RETIN-A	620165	85.4	90.4	84.5	88.6														
RETIN-A	620175	78.0	77.9	75.1	75.6														
RETIN-A	620275	76.1	73.9	73.2	71.5														
RITALIN	830003					73.3	79.2	78.6	84.8										
RITALIN	830007					75.2	79.4												
RITALIN	830016					74.8	78.8												
RITALIN	830034					70.8	76.5												
RYTHMOL	445022					88.0	63.3	88.2	68.5										
RYTHMOL	445023					50.7	35.6												
RYTHMOL	445024					85.6	63.0												

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
SANDIMMUNE CAP 100MG	780241							21.5	6.0			4.2	13.7					95.1	96.5
SINEMET	560647					92.7	92.2												
SINEMET	560650					93.2	92.4												
SINEMET	560654					90.4	89.5												
SINEMET CR	560601					86.1	71.9												
SINEMET CR TAB 50/200	560521	84.3	75.0	83.9	71.9	87.2	74.9	88.0	79.3			89.1	88.5	87.4	72.8				
SOMA	372103					91.8	96.1												
SOMA TAB 350MG	372001	93.5	97.4	91.7	97.1			95.5	97.4	94.2	96.5	96.9	98.8			93.0	96.7	92.9	98.9
SPECTAZOLE CRE 1%	625460											25.0	31.9						
STADOL NS SOL 10MG/ML	875650					33.8	55.3	38.9	61.7			88.6	79.8						
SYNTHROID TAB 100MCG	481070															14.0	32.3	35.4	25.9
SYNTHROID TAB 112MCG	481080															14.0	28.1	36.9	22.7
SYNTHROID TAB 125MCG	481130															13.9	28.9	31.5	22.8
SYNTHROID TAB 150MCG	481090															12.2	30.2	33.9	24.6
SYNTHROID TAB 175MCG	481100															12.0	27.7	35.1	24.6

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
SYNTHROID TAB 200MCG	481140															10.4	27.0	31.2	21.2
SYNTHROID TAB 25MCG	481020															18.8	36.3	37.9	25.9
SYNTHROID TAB 50MCG	481040															17.2	34.9	37.8	26.0
SYNTHROID TAB 75MCG	481050															16.6	33.9	36.3	27.6
SYNTHROID TAB 88MCG	481060															14.5	30.4	35.6	21.6
TAMBOCOR	890314					51.3	26.3												
TAMBOCOR TAB 100MG	890307	45.1	21.6	45.7	21.0	48.3	26.3	50.9	21.8			26.1	47.5			48.9	29.2	58.8	39.4
TAMBOCOR TAB 50MG	890305					48.4	23.3					32.0	38.2						
TEGRETOL	830019					50.0	37.5												
TEGRETOL	830052					75.2	70.9												
TEGRETOL TAB 200MG	830027	70.0	70.8	69.9	65.0	68.8	69.1	67.6	67.8			78.8	77.9			70.3	67.5	64.5	67.1
TENORMIN	3100101					97.9	97.9												
TENORMIN	3100107					98.2	97.7												
TENORMIN TAB 50MG	3100105	97.7	97.9	96.9	97.2	97.7	96.8	98.2	98.1	97.8	96.7								

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
TICLID TAB 250MG	40018																	95.0	82.6
TRI-LEVLEN 21	504190432									100.0	100.0								
TRI-LEVLEN 28	504190433									95.1	86.9								
TRIPHASIL 28 TAB	82536	82.4	72.8	79.2	66.8	64.5	61.4	81.9	71.3	80.7	58.7	78.5	63.8	72.5	60.8			78.1	69.2
TRIPHASIL-21	82535									98.9	99.8								
ULTRAM TAB 50MG	450659	44.1	35.9	49.5	35.6	45.0	41.3	34.9	40.8	41.9	40.3	91.4	91.5	75.9	81.9	37.9	39.2	47.7	42.4
VALIUM	1400004					91.4	92.5												
VALIUM TAB 10MG	1400006	82.5	89.9	82.7	88.4	85.0	87.5	87.4	90.5			91.3	92.6						
VALIUM TAB 5MG	1400005	87.6	91.9	86.9	90.2	87.8	89.0	90.4	92.6			93.4	92.9						
VASERETIC	60720							90.8	68.3										
VASOTEC	60014					80.5	87.4												
VASOTEC	60712					73.4	87.6												
VASOTEC	644550141					99.7	99.9												
VASOTEC	644550143					99.8	99.6												
VASOTEC TAB 10MG	60713					92.9	88.8	92.8	92.0	92.9	89.1	94.6	95.4						
VASOTEC TAB 20MG	60714					92.9	91.0	92.9	93.5	93.5	90.1	95.6	96.7						
VENTOLIN	1730321									97.8	93.3								
VICODIN	440727									98.5	98.2								
VICODIN	741949									97.9	99.2								
VICODIN ES	741973							96.7	98.5										
VICODIN ES TAB 7.5-750	440728							94.1	95.2			93.0	97.1			90.6	93.3	91.1	93.7

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
VIVELLE-DOT	780344													17.5	0.8				
VIVELLE-DOT	780346													5.2	1.1				
XANAX	90094					87.0	91.1					90.8	95.5						
XANAX TAB 0.25MG	90029							96.1	96.7			96.8	97.3						
XANAX TAB 0.5MG	90055	92.5	94.9	90.1	94.2	0.9	93.3	94.5	96.1	94.5	93.5	95.9	97.2	93.1	94.5	91.7	94.2	91.8	96.2
XANAX TAB 1MG	90090	89.0	94.4	88.5	93.1			93.4	94.7			95.4	96.2			90.0	93.1	91.8	96.0
ZANAFLEX TAB 2MG	590750592					46.8	35.9					49.2	91.4						
ZANAFLEX TAB 4MG	590750594	45.3	38.3	49.4	38.7	45.6	40.6	40.9	39.1	41.8	40.2	52.5	92.5			45.7	45.8	52.5	46.1
ZANTAC	1730393					93.9	96.2												
ZANTAC TAB 150MG	1730344	93.3	95.6	90.5	93.3	94.4	93.6	95.6	96.7	93.0	93.1	96.9	98.1	95.0	96.0	92.8	96.1	95.1	97.3
ZESTORETIC	3100141					86.1	64.2												
ZESTORETIC	3100145					88.9	66.9			88.9	59.4					64.6	68.5	74.1	69.8
ZESTORETIC TAB 20-12.5	3100142	47.0	33.8	52.8	34.6	88.2	67.1			86.9	58.9	93.9	73.3	44.3	39.5	60.4	62.2	70.0	65.6
ZESTRIL	3100133					49.2	41.4												
ZESTRIL	3100135					88.7	71.5												
ZESTRIL TAB 10MG	3100131	46.0	38.7	50.8	38.8	89.9	71.4	48.0	53.0	86.9	63.8	95.4	76.9	47.4	42.6	65.0	70.6	75.6	73.8
ZESTRIL TAB 20MG	3100132	46.8	38.7	51.6	38.5	89.5	71.7	49.1	53.5	85.5	65.4	96.0	78.3	46.8	42.7	67.6	73.6	76.6	76.0

Drug	NDC9	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR &
ZESTRIL TAB 40MG	3100134	49.3	41.4	53.1	41.7	90.1	74.6	49.6	53.4	87.1	66.9	96.7	81.5	48.8	44.0	84.1	87.7	89.5	89.2
ZESTRIL TAB 5MG	3100130	46.0	37.6	50.4	37.6	89.1	69.8	47.6	52.1	86.3	61.1	94.9	74.8	45.9	41.4	79.8	82.1	87.3	84.8
ZIAC	53234					88.5	83.3												
ZIAC	53235					90.5	85.4												
ZIAC	53238					87.1	81.1												
Total		**66**	**23**	**64**	**27**	**118**	**51**	**48**	**30**	**38**	**23**	**46**	**55**	**25**	**15**	**23**	**36**	**58**	**38**

TABLE F-IV-2(b). Top Selling Drug Products Examined By FTC Staff – 2003 Data
Comparison of Owned Mail vs. Not-Owned Retail

O M – owned mail; NO R –not-owned retail

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %
ACCUTANE CAP 20MG	40169							11.8	46.6										
ACCUTANE CAP 40MG	40156											17.5	58.0					90.0	52.7
ADALAT CC	268841	95.2	91.5	94.1	87.8														
ADALAT CC	268851	94.0	88.2	91.0	83.9	96.4	85.6					97.4	94.3	92.9	84.4				
ADALAT CC	268861					93.9	68.6												
ADDERALL	540920371					97.6	96.9												
ADDERALL	540920372					82.4	72.1												
ADDERALL	540920374					25.0	75.8												
ADDERALL	540920375					65.1	69.7												
ADDERALL	540920377					91.7	91.6												
ADDERALL	585210034					81.1	79.4												
ADDERALL	585210075					32.9	25.4												
ADDERALL	585210125					13.3	25.9												
ADDERALL	585210150					31.8	32.7												
ADDERALL TAB 10MG	540920373					96.3	94.4					95.1	97.1						
ADDERALL TAB 10MG	585210032	80.3	79.8	79.8	76.5	81.7	81.2	87.8	85.9			84.6	88.5	48.9	75.0	79.8	78.2	85.7	89.0
ADDERALL TAB 20MG	540920376					92.4	93.0					94.6	96.6						
ADDERALL TAB 20MG	585210033	77.8	77.3	76.1	74.7	80.8	79.5	88.3	83.6			85.0	88.4	48.3	73.7	77.7	78.3	73.9	90.7

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
ADDERALL TAB 5MG	585210031					75.5	80.7	86.7	85.8			89.6	88.3						
ALESSE TAB -28	82576	81.1	75.2	76.4	72.5	87.3	73.0	87.8	81.3	82.6	71.4	81.7	75.5	73.0	74.6	82.0	75.4	82.8	78.8
AMOXIL SUS 400/5ML	296049																		
ANEXSIA	4065361									100.0	100.0								
ATIVAN	80065					93.1	92.6												
ATIVAN	80081					96.7	96.9												
ATIVAN TAB 1MG	80064					94.9	94.8	95.3	96.7	95.9	94.9	96.4	97.8						
AUGMENTIN TAB 500MG	296080					94.1	96.0			87.2	96.3	61.9	97.7						
AUGMENTIN SUS 400/5ML	296092					71.4	90.7												
AUGMENTIN TAB 875MG	296086	85.1	96.6	78.9	96.4	94.4	96.8			88.8	97.0	14.8	98.1						
AVENTYL CAP 25MG	20819																		
AXID	23145					95.6	93.2												
AXID	657260145					94.6	89.4												
AXID CAP 150MG	657260144	83.4	86.2	89.7	85.1	90.6	87.9					88.3	86.1					91.3	89.0
AZULFIDINE	130102							64.3	57.5										
BACTROBAN OIN 2%	291525																	7.5	6.7

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
BENZAMYCIN GEL	660510											12.4	63.6					86.5	89.6
BETAPACE	504190105					95.4	91.7	94.8	94.9										
BETAPACE	504190106					93.6	82.7												
BETAPACE	504190107					92.5	94.5												
BETAPACE	504190109					93.1	89.7												
BUSPAR	870818					96.3	93.4												
BUSPAR	870819	91.7	93.7	92.7	92.2	95.1	92.0	94.2	95.6										
BUSPAR	870824	91.2	92.0	86.8	89.0	94.7	90.1	95.2	94.6			95.9	95.6						
BUSPAR TAB 15MG	870822	92.6	95.3	92.9	93.9	95.8	93.4	95.8	96.3			96.0	97.2	92.6	94.6	96.9	97.2	96.3	98.0
CALAN SR	251901					96.4	95.7												
CALAN SR	251911					98.2	97.0												
CALAN SR TAB 240MG	251891					97.5	95.9			97.4	95.6								
CAPOZIDE TAB 25/15MG	30338																		
CAPOZIDE TAB 50/25MG	30390																		
CARDIZEM CD	881795					94.3	90.4												
CARDIZEM CD	881796					95.2	89.8			93.2	89.8								
CARDIZEM CD	881798					94.9	89.9			93.1	90.3								
CARDIZEM CD CAP 240MG/24	881797	94.4	92.5	93.0	89.6	94.7	90.2	94.7	92.6	93.4	89.8	95.4	94.5	91.9	90.6				
CARDURA	492750					96.2	91.8												
CARDURA	492760					96.5	92.4												
CARDURA	492770					96.5	91.1												
CARDURA	492780					97.0	92.0												

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %
CEFTIN	659390387					98.5	98.9												
CEFTIN TAB 250MG	1730387					96.3	96.4			85.1	96.4	93.9	97.2						
CEFTIN TAB 500MG	1730394					88.5	95.5					90.0	96.8					40.0	95.4
CLARITIN	850458	0.1	22.1																
CLIMARA DIS 0.05MG	504190451	51.9	39.5	53.0	40.9	0.0	37.7	54.9	35.6			61.6	60.4			47.1	37.0	46.6	41.1
CLIMARA DIS 0.1MG	504190452	36.7	26.5	39.0	27.9	0.0	26.4					51.7	47.3			34.3	23.7	32.7	28.2
CORDARONE	84188							97.2	97.8	98.0	97.0								
CORGARD TAB 120MG	30208																		
COUMADIN	560168	75.4	69.0	75.7	55.4			74.1	65.5										
COUMADIN	560173	77.1	63.2	73.3	54.4														
COUMADIN	560174	74.9	61.8	70.2	51.0														
COUMADIN	560188	78.9	70.5	77.5	55.7														
COUMADIN	560189	74.1	65.4	77.2	52.9														
COUMADIN TAB 1MG	560169	79.0	71.7	77.6	60.8			76.6	70.8			84.7	83.1	73.2	66.7				
COUMADIN TAB 2.5MG	560176	76.0	68.0	73.3	54.9			71.6	64.4			81.4	77.5						
COUMADIN TAB 2MG	560170	75.9	69.1	77.0	56.6			75.1	66.1			81.0	78.4						
COUMADIN TAB 5MG	560172	73.7	65.6	73.0	54.0			73.6	64.5			82.3	78.1	74.0	61.6	85.0	80.0	83.1	83.0
CREON 20	321220															53.5	90.0	86.1	90.5
DARVOCET-N TAB 100	20363	90.3	95.0	90.0	94.8			95.0	97.4	95.4	96.3	95.3	98.2	93.8	96.9	94.0	96.8	93.2	97.9

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
DEMADEX	40264	89.8	80.3	88.5	81.1							88.3	80.6						
DESOGEN	520261	90.0	84.3	87.9	79.9			92.0	85.4			89.1	82.9						
DEXEDRINE CAP 10MG	73513																		
DILANTIN CAP 100MG	710362	61.4	45.5	58.2	35.7			61.3	42.0			55.7	38.3	61.5	42.4	60.2	39.0	58.6	56.3
DIPROLENE AF CRE 0.05%	850517											25.0	91.6						
DYNACIN	992070497					97.5	97.5												
DYNACIN CAP 100MG	992070498					97.3	95.8			96.5	95.7	98.6	97.7						
DYNACIN CAP 75MG	992070499	75.8	73.6	70.2	71.2	83.4	75.6					82.3	85.3						
ELOCON	850370	83.0	82.7	78.5	81.6														
ESTRACE	870021					96.5	91.1												
ESTRACE	870755					94.2	89.1	92.7	90.6										
ESTRACE	870756					92.1	88.3												
ESTRACE	4300021					98.4	98.4												
ESTRADERM	832310													16.5	19.8				
ESTRADERM	832320													10.8	16.1				
FIORICET	780243					54.3	65.0												
FIORICET TAB	780084					90.6	88.7	89.1	91.5			75.8	89.7						
FLORINEF ACETATE	30429							85.1	73.1										
GLUCOPHAGE TAB 1000MG	876071	96.0	93.2	93.3	88.1	96.6	93.6	96.5	95.5	96.8	93.9	95.5	95.7			94.6	93.7	95.4	98.9
GLUCOPHAGE TAB 500MG	876060	95.6	93.4	93.2	90.0	96.6	93.6	96.4	95.1	96.6	93.8	96.8	97.0			93.5	92.6	95.5	96.2

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
GLUCOPHAGE TAB 850MG	876070	95.1	91.9	92.1	88.3	95.9	92.4					96.6	96.7	93.5	93.2	93.1	91.2	94.0	97.0
GLUCOPHAGE TAB XR 500MG	876063	5.9	3.5	6.1	3.3	7.1	3.8			5.9	3.8	94.1	98.8						
GLUCOTROL XL TAB 10MG	491560	7.4	4.4	7.1	4.6	9.2	5.1					89.1	69.9			48.3	43.4	53.9	58.0
GLUCOTROL XL TAB 5MG	491550					9.2	4.9												
GOLYTELY	522680100	97.9	90.3																
HYDREA CAP 500MG	30830																		
HYTRIN	743805					16.6	95.3												
HYTRIN	743806					16.8	93.7												
HYTRIN	743807					16.7	91.9	93.8	94.7			97.6	96.3						
HYTRIN	743808					17.2	92.7												
IMDUR	851153					96.6	82.5												
IMDUR	853306	95.9	97.1	95.2	95.5	96.8	95.7												
IMDUR	854110	95.1	96.3	94.8	94.2	96.4	94.2												
IMURAN TAB 50MG	654830590											96.0	97.3						
ISOPTIN S.R.	441826									99.9	99.7								
ISOPTIN S.R.	741625									99.6	99.4								
K-DUR TAB 20MEQ CR	850787	95.9	95.1	94.9	94.3					95.6	94.6	97.4	97.1						
KEFLEX	7770871									97.7	99.4								

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
KENALOG LOT 0.1%	30502																		
KLONOPIN TAB 0.5MG	40068					94.6	94.9	94.8	96.4			96.1	97.0	91.3	94.6				
KLONOPIN TAB 1MG	40058					94.4	94.5	93.9	96.0										
KLONOPIN TAB 2MG	40098					93.5	94.4												
LAC-HYDRIN CRE 12%	725730											0.6	56.6					69.7	55.8
LAC-HYDRIN LOT 12%	725712											4.7	65.8						
LANOXIN	1730242	92.1	73.8	93.2	59.7	94.0	63.5												
LANOXIN TAB 0.25MG	1730249	90.6	67.0	91.6	56.1	92.4	58.8	72.2	61.4										
LEVLITE-28	504190408									91.1	93.4								
LO/OVRAL TAB -28	82514	84.2	79.6	82.1	76.2	87.1	75.4	86.5	81.1	83.6	73.3	82.0	75.2	78.4	77.7			85.8	81.3
LO/OVRAL-21	80078					96.9	98.7			95.3	98.7								
LOESTRIN	710915					26.1	17.0												
LOESTRIN	710916					25.8	15.2												
LOESTRIN FE TAB 1.5/30	710917	77.1	68.7	75.1	65.3	85.7	67.8	84.8	74.5			79.3	70.5					81.2	91.1
LOESTRIN FE TAB 1/20	710913	79.5	65.4	75.0	61.8	85.7	65.9					76.2	66.5					79.1	89.1
LOPID	710737									97.6	98.2								
LOPRESSOR	280071					96.8	95.7												
LOPRESSOR TAB 50MG PP	280051					97.3	96.5	97.2	97.6										

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
LORTAB	504740902									99.3	99.5								
LUPRON 6-PK INJ 5MG/ML	3003612											2.3	66.6						
METADATE ER	530140593	4.4	24.9	18.9	27.7														
MEVACOR	60732									97.3	95.1	98.0	99.1						
MICRONASE	90171									99.0	97.0								
MINOCIN	55344									98.3	98.8								
MIRCETTE TAB 28	520281	68.0	60.4	65.5	59.4	3.1	59.1	77.7	64.8			79.3	70.9	65.2	64.2	87.4	79.3	87.0	83.1
MODICON	621714	79.0	74.5	78.9	72.4														
MS CONTIN	340514	92.2	83.9	87.2	78.9	90.1	82.0												
MS CONTIN TAB 100MG CR	340517	86.7	68.6	51.7	66.6	62.1	74.4	41.8	73.7			66.7	63.5						
MS CONTIN TAB 200MG CR	340513	57.1	51.4	56.7	52.3	54.7	55.1												
MS CONTIN TAB 30MG CR	340515	88.6	84.8	90.3	80.6	87.7	82.7												
MS CONTIN TAB 60MG CR	340516	90.6	80.3	91.8	75.6	78.9	79.4	79.3	80.4										
MYCOSTATIN TAB 500000	30580																		
NAPROSYN SUS 125/5ML	40028																		

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
NEORAL CAP 100MG	780248	45.2	39.7	38.0	37.3	52.4	47.6	56.1	48.8			14.9	41.6	22.6	41.6	48.9	39.6	40.4	56.2
NEORAL CAP 25MG	780246	43.1	34.4	34.4	33.5	49.7	40.9	48.4	44.2			14.3	36.7	23.3	38.1	42.4	31.5	43.8	45.5
NITRO-DUR	853305	95.7	85.2	94.3	80.3														
NITRO-DUR	853310	95.2	90.8	94.9	88.7														
NITRO-DUR	853320	96.4	90.6	94.7	88.3			64.0	91.5										
NITRO-DUR	853330	94.7	89.0	95.2	86.5														
NIZORAL	504580221	95.4	98.2	92.5	98.0														
NOLVADEX	3100600									81.4	95.3								
NOLVADEX TAB 20MG	3100604									82.9	95.5	98.9	97.7						
NORCO	525440539											96.0	97.0						
NORDETTE-28 TAB	82533	89.2	85.6	87.4	80.8							85.4	78.2						
NORINYL 1+35	525440259	98.6	98.4	98.9	98.7														
NOR-QD TAB 0.35MG	525440235	92.5	79.3	91.2	81.7													89.7	79.9
OCUPRESS	587680001	79.0	68.2	81.9	60.9														
ORTHO MICRONOR	621411	71.0	63.3	72.2	61.7	3.0	55.3					86.1	73.8					84.0	78.3
ORTHO TRI-CYCLEN	621902									100.0	29.8								
ORTHO-CEPT-28	621796	85.5	82.8	88.3	83.4	12.2	71.3	88.7	83.1			91.9	87.4	86.4	89.2	95.1	90.1	92.9	90.3
ORTHO-CYCLEN TAB 0.25/35	621901	67.8	50.1	67.0	50.6	1.4	41.8	74.0	53.0			70.9	56.6			73.3	57.1	71.6	62.1
ORTHO-NOVUM	621332	81.9	75.2	83.6	75.0	30.2	71.7												
ORTHO-NOVUM	621771					75.0	26.5												

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
ORTHO-NOVUM 1/35-28	621761	84.4	82.1	87.3	85.1	41.5	72.6					95.8	94.3	87.7	91.0			90.6	90.9
ORTHO-NOVUM 7/7/7-28	621781	61.4	46.1	64.1	47.7	0.8	35.4					69.3	50.1	60.9	48.7	61.8	53.8	70.1	63.0
PAXIL TAB 10MG	293210	23.5	18.2	24.4	17.9	26.6	20.0	27.3	21.6			85.6	74.4						
PAXIL TAB 20MG	293211	23.7	18.0	23.8	18.6	26.7	20.6	26.6	20.9			87.4	76.6			21.5	18.9	26.7	23.0
PAXIL TAB 30MG	293212	25.2	17.9	23.8	18.6	27.0	20.6					85.9	76.5						
PAXIL TAB 40MG	293213	24.4	19.3	24.4	20.0	27.4	22.0	28.0	22.2			88.5	77.5			22.4	20.8	28.7	23.7
PEPCID TAB 20MG	60963	92.6	95.7	93.1	94.5	94.2	95.4					96.1	97.7						
PEPCID TAB 40MG	60964					93.6	94.3												
PERCOCET	634810621							25.6	89.9										
PERCOCET	634810622							43.7	87.6			89.1	92.7						
PERCOCET TAB 10-325MG	634810629																	11.5	12.6
PERCOCET TAB 5-325MG	634810623	49.6	95.5	20.6	92.3			89.1	96.2			93.0	97.3						
PHENERGAN SUP 25MG	80212							55.2	92.5			15.0	93.6						
PLAQUENIL TAB 200MG	241562							94.4	95.1			95.7	96.4	90.7	93.2				
PRILOSEC CAP 10MG CR	1860606					26.9	12.0					49.7	44.4						

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
PRILOSEC CAP 20MG CR	1860742	10.0	77.6	9.2	76.6	51.0	80.6	94.2	80.4	88.4	75.4	95.7	97.2			82.0	80.7	85.3	81.3
PRINIVIL	60015					98.6	96.1												
PRINIVIL	60019					98.4	96.7												
PRINIVIL	60106					98.7	97.0			97.9	96.5	98.6	98.3						
PRINIVIL	60207					98.5	96.7			97.6	96.2	98.3	98.3						
PRINIVIL	60237					98.9	97.1			97.8	96.4								
PROAMATINE TAB 5MG	540920004							9.8	11.1										
PROCARDIA XL	692650					92.5	84.4												
PROCARDIA XL TAB 60MG CR	692660	93.1	87.9	92.0	86.3	92.9	85.7	90.8	89.3	93.9	86.5	93.9	91.7			85.7	87.9	87.1	92.7
PROVENTIL	851806									98.7	99.9								
PROVENTIL AER 90MCG RF	850614																	89.5	98.9
PROZAC CAP 10MG	7773104	90.6	89.6	87.4	88.8	93.8	93.0	93.6	95.6			93.6	95.2	87.8	92.8	92.6	94.5	90.5	98.8
PROZAC TAB 10MG	24006					91.6	92.7					93.8	95.6						
PROZAC CAP 20MG	7773105	90.8	88.3	89.4	86.7	93.3	91.6	93.3	94.2	93.7	90.5	94.7	94.5	91.2	92.1	91.9	92.5	92.1	95.4
PROZAC CAP 40MG	7773107	91.1	92.8	89.3	90.7	93.0	93.1	92.7	93.9	92.9	92.1	94.6	95.2	91.4	93.6	91.6	92.0	92.2	93.7
PSORCON	660071	84.3	88.1	88.7	87.3														
RELAFEN	294851	92.6	93.8	90.5	94.2			95.0	95.9										
RELAFEN TAB 750MG	294852	92.3	93.7	91.9	94.4			96.7	96.6			93.0	97.7						
REMERON	520109					42.7	35.2												
REMERON TAB 15MG	520105	63.1	25.3	57.0	23.7	85.6	69.8	77.5	73.9			79.7	81.1						

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %
REMERON TAB 30MG	520107	72.5	68.3	71.0	67.2	84.8	70.6	75.6	72.4			80.6	81.1						
RETIN-A	620165	91.3	93.3	90.7	92.0														
RETIN-A	620175	85.1	86.5	84.9	83.8														
RETIN-A	620275	80.3	81.4	83.8	78.4														
RITALIN	830003					81.8	85.3	81.2	87.5										
RITALIN	830007					81.9	86.4												
RITALIN	830016					80.3	85.8												
RITALIN	830034					76.4	81.8												
RYTHMOL	445022							97.6	90.8										
SANDIMMUNE CAP 100MG	780241							45.5	36.3			25.5	30.7					62.3	54.6
SANDIMMUNE CAP 25MG	780240											24.8	31.5						
SERZONE	870031					19.0	8.9												
SERZONE	870032					18.2	12.7												
SERZONE	870041					20.3	12.2												
SERZONE TAB 150MG	870039					18.4	12.3					89.0	69.4						
SERZONE TAB 200MG	870033					19.1	13.1					90.8	76.0						
SINEMET CR	560521	89.4	88.6	90.1	86.0	92.5	88.2	90.6	89.6										
SINEMET CR	560601					89.9	85.7												
SOMA	372103					89.3	97.4												
SOMA TAB 350MG	372001	93.9	98.1	92.6	97.6			95.9	98.0	95.3	97.3	96.7	98.9					95.7	99.4

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
STADOL NS SOL 10MG/ML	875650							87.8	82.4			88.0	90.6			69.1	73.9	87.3	89.9
SYNTHROID TAB 100MCG	481070															73.4	54.7	71.9	54.8
SYNTHROID TAB 112MCG	481080															61.8	53.8	65.7	52.1
SYNTHROID TAB 125MCG	481130															72.4	53.0	73.4	53.4
SYNTHROID TAB 150MCG	481090															70.1	51.8	70.5	53.0
SYNTHROID TAB 175MCG	481100															52.8	49.0	61.4	50.2
SYNTHROID TAB 200MCG	481140															63.3	47.0	67.1	45.9
SYNTHROID TAB 25MCG	481020																		
SYNTHROID TAB 50MCG	481040															81.1	60.7	74.9	60.9
SYNTHROID TAB 75MCG	481050															80.1	58.4	75.8	59.4
SYNTHROID TAB 88MCG	481060															55.9	56.6	82.6	53.9
SYNTHROID TAB 100MCG	746624									29.0	41.2	28.2	46.3			18.6	47.1	34.6	41.6

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %
SYNTHROID TAB 112MCG	749296											35.5	43.2			19.4	44.2	37.1	43.4
SYNTHROID TAB 125MCG	747068									26.3	39.2	36.7	45.4			18.3	43.2	33.5	40.1
SYNTHROID TAB 150MCG	747069											34.0	45.4			16.9	46.7	35.0	42.1
SYNTHROID TAB 175MCG	747070											28.5	44.7						
SYNTHROID TAB 200MCG	747148											29.0	44.3			14.1	45.3	31.4	40.7
SYNTHROID TAB 50MCG	744552									31.6	40.8	31.9	45.5			21.7	46.7	37.1	41.6
SYNTHROID TAB 75MCG	745182									29.5	41.3	30.0	46.8			21.1	46.3	35.7	43.0
SYNTHROID TAB 88 MCG	746594											32.8	42.4			22.0	42.2	32.8	38.5
TAMBOCOR	890305					90.8	71.0					82.5	57.2						
TAMBOCOR	890314					91.3	70.2												
TAMBOCOR TAB 100MG	890307	85.3	68.4	85.6	65.9	90.8	73.9	90.3	75.9			87.1	55.1			89.3	77.2	88.2	83.7
TAMOXIFEN TAB 10MG	5550446											99.1	99.3						
TEGRETOL	830019					63.7	45.1												

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
TEGRETOL	830052					78.5	74.6												
TEGRETOL TAB 200MG	830027	71.3	74.0	70.3	66.9	72.4	71.7	68.6	71.8			81.1	80.8	69.4	75.2	74.2	72.4	66.6	81.9
TENORMIN	3100101					98.6	98.4												
TENORMIN	3100105	98.3	98.4	97.5	97.6	98.3	97.6	98.4	98.4	98.4	97.5								
TENORMIN	3100107					98.7	98.3			98.7	98.3								
TIAZAC	4562612					62.8	37.3												
TIAZAC	4562613					64.5	37.1												
TIAZAC CAP 240MG/24	4562614	59.5	37.1	59.4	39.6	64.1	38.5					88.5	58.0						
TIAZAC CAP 300MG/24	4562615					64.4	37.1												
TIAZAC CAP 360MG/24	4562616	62.6	36.8	61.5	39.8	65.3	39.7					83.8	59.1						
TRI-LEVLEN 21	504190432									100.0	100.0								
TRI-LEVLEN 28	504190433									96.1	91.8								
TRIPHASIL 28 TAB	82536	86.4	81.3	82.8	75.4	69.6	73.0	88.1	82.6	85.9	71.4	100.0	99.9	77.2	74.7			86.4	79.8
TRIPHASIL-21	82535									99.0	99.9								
ULTRAM TAB 50MG	450659	90.2	90.1	89.9	88.6	94.4	91.5	92.6	93.8	93.8	91.9	93.0	95.6	88.8	92.3	89.9	92.4	91.3	95.0
VALIUM	1400004					93.1	93.7												
VALIUM TAB 10MG	1400006	84.7	91.6	82.3	89.1	86.6	89.6	88.0	91.1			90.5	93.5						
VALIUM TAB 5MG	1400005	89.3	93.4	86.5	90.6	89.7	91.0	90.3	93.5			92.8	93.7			90.0	92.5	91.2	95.1
VANACET	588090838									100.0	100.0								
VASERETIC	60720							100.0	97.0										

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %	O M %	NO R %
VASOTEC	60014					99.1	95.6												
VASOTEC	60712					99.4	96.4												
VASOTEC	60713					99.4	96.7	98.9	98.0			99.1	98.9						
VASOTEC	60714					99.7	97.6	99.5	98.6	99.9	97.6	99.5	99.1						
VASOTEC	644550140					97.2	97.8												
VASOTEC	644550141					95.6	96.2												
VASOTEC	644550142					95.4	94.8												
VASOTEC	644550143					95.0	95.8			95.9	96.4								
VICODIN	440727									100.0	99.9								
VICODIN	741949									97.5	98.1	97.3	98.8						
VICODIN ES	741973							91.6	95.4			92.5	97.0			88.8	95.0	89.3	95.6
VICODIN ES TAB 7.5-750	440728																		
VICOPROFEN	742277					61.9	53.3	23.9	56.5			87.8	78.6						
VIVELLE-DOT	780344													12.1	8.3				
VIVELLE-DOT	780346													6.6	5.0				
XANAX TAB 0.25MG	90029					95.4	95.5	96.2	97.3			96.3	97.5						
XANAX TAB 0.5MG	90055	93.3	96.0	91.9	94.5	93.9	94.9	95.0	96.7	84.2	94.8	96.0	97.5	93.8	95.6	93.6	95.8	93.7	97.9
XANAX TAB 1MG	90090	90.1	95.3	89.8	93.5	91.8	93.0	93.4	95.6			94.9	96.6			93.5	94.7	94.2	98.2
XANAX TAB 2MG	90094					89.0	92.4					96.0	95.9						
ZANAFLEX TAB 4MG	590750594	90.2	92.1	89.6	92.2			93.2	94.0	95.0	93.2	86.5	94.7					94.7	94.3
ZANTAC	1730393					96.3	97.3												

Drug	NDC	Company F		Company G		Company H		Company I		Company J		Company K		Company L		Company M		Company N	
		O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %	O M %	NOR %
ZANTAC TAB 150MG	1730344	92.4	97.3	88.1	94.6	95.8	95.1	95.9	97.5	95.2	95.1	97.2	98.4	94.3	97.4	95.4	97.5	96.0	99.0
ZESTORETIC	3100142	95.2	92.0	95.7	90.8											97.4	97.0	97.7	97.7
ZESTORETIC	3100145															98.0	97.8	98.5	97.5
ZESTRIL	380130																		
ZESTRIL	380131																		
ZESTRIL	380132																		
ZESTRIL	380134																		
ZESTRIL	3100133					96.8	91.9												
ZESTRIL	3100135					98.4	96.8												
ZESTRIL TAB 10MG	3100131	96.4	95.6	96.7	94.3	98.3	97.0	97.3	96.5	98.7	96.5	98.7	98.4	92.9	95.1	98.4	98.5	98.8	98.9
ZESTRIL TAB 20MG	3100132	96.7	95.4	97.3	93.9	98.2	97.0	97.5	96.3	98.7	96.4	98.7	98.2	93.3	95.2	98.7	98.5	98.8	99.0
ZESTRIL TAB 40MG	3100134	97.3	96.0	97.6	94.8	98.6	97.2	97.7	96.5	98.9	96.8					99.4	99.4	99.5	99.6
ZESTRIL TAB 5MG	3100130	96.3	95.2	96.3	93.2	98.1	96.6	97.1	96.1							99.2	99.2	99.5	99.5
ZIAC	53234					95.8	92.1												
ZIAC	53235					96.6	93.6												
ZIAC	53238					95.7	92.3												
ZIAC	512850040					99.7	99.3												
ZIAC	512850047					98.4	97.5												
ZIAC	512850048					98.8	98.4												
ZIAC	512850049					99.2	98.3												
ZIAC	512850050					99.3	99.2												
Totals		**77**	**30**	**78**	**27**	**125**	**57**	**47**	**43**	**37**	**24**	**54**	**65**	**12**	**22**	**32**	**27**	**35**	**44**

APPENDIX G. THERAPEUTIC INTERCHANGE COMPANY DATA

TABLE G-V-1. Therapeutic Categories Examined By FTC Staff in Which Study Participants Engaged in Therapeutic Interchange.

Company	PBM Category	Therapeutic Category
A	Large PBM	Cardiac, Antihistamines, Antiulcer
B	Large PBM	Cardiac, Antihistamines, Anti-inflammatory, Lipid Lowering, Antidepressant, Osteoporosis, Autonomic
C	Large PBM	Cardiac, Antihistamines, Anti-inflammatory, Lipid Lowering, Antidepressant, Osteoporosis, Autonomic
D	Large PBM	Cardiac, Antihistamines, Anti-inflammatory, Lipid Lowering, Antiulcer, Antidepressant
E	Large PBM	Cardiac, Antihistamines, Anti-inflammatory, Lipid Lowering, Antiulcer, Antidepressant, Osteoporosis, Autonomic, Antiinfectives, Antidiabetic
F	Retailer-Owned PBM	Cardiac, Anti-inflammatory, Lipid Lowering, Antidepressant
G	Retailer-Owned PBM	Cardiac, Antihistamines, Anti-inflammatory, Lipid Lowering, Antiulcer

TABLE G-V-2(a). Company Data on Possible Effect of Therapeutic Interchange – Owned Mail 2002

2002 Owned Mail		No. of Preferred Drugs	Corresponding No. of Unique NDC Pairs	No. of NDC Pairs in which TI had:			% of NDC Pairs w/ Total Savings	Magnitude of Savings (Loss) Compared to Total Price of Prescribed Drug (No. of NDC Pairs)					
Co.	PBM Category			Member Sav.	Plan Sav.	Total Sav.		Savings<5%	Savings 5-20%	Savings> 20%	Losses <5%	Losses 5-20%	Losses>20%
A	Large PBM	8	102	69	38	46	45.1%	11	19	22	8	8	34
B	Large PBM	28	155	135	81	102	65.8%	23	36	43	8	36	9
C	Large PBM	28	151	133	61	75	49.7%	19	25	32	22	32	21
D	Large PBM	18	120	110	90	104	86.7%	11	52	39	7	7	4
E	Large PBM	79	841	682	369	415	49.3%	76	225	114	77	158	191
F*	Retailer-PBM	11	53	45	29	41	77.4%	11	14	16	7	2	3
G* **	Retailer-PBM	20	221	127	116	120	54.3%	27	54	40	17	41	42

* These companies could not provide information about how much of their pharmaceutical payments they passed on to their plan sponsor clients. As a result, the data may understate the savings their clients could obtain through TIs.

** This company's data were provided on a per prescription, rather than per day basis.

TABLE G-V-2(b). Company Data on Possible Effect of Therapeutic Interchange – Retail 2002***

2002 Retail***		No. of Preferred Drugs	Corresponding No. of Unique NDC Pairs	No. of NDC Pairs in which TI had:			% of NDC Pairs w/ Total Savings	Magnitude of Savings (Loss) compared to Total Price of Prescribed Drug (No. of NDC Pairs)					
Co.	PBM Category			Member Sav.	Plan Sav.	Total Sav.		Savings<5%	Savings 5-20%	Savings >20%	Losses <5%	Losses 5-20%	Losses>20%
A	Large PBM	9	150	103	46	67	44.7%	17	20	28	15	17	53
B	Large PBM	29	844	549	396	473	56.0%	67	166	244	53	123	191
C	Large PBM	28	747	505	377	415	55.6%	51	131	233	33	103	196
D	Large PBM	18	127	117	98	108	85.0%	9	67	32	5	9	5
E	Large PBM	56	317	241	152	182	57.4%	24	95	63	26	59	51
F*	Retailer-PBM	13	147	141	68	118	80.3%	27	62	29	17	9	3
G* **	Retailer-PBM	20	464	285	245	259	55.8%	51	114	94	56	91	58

* These companies could not provide information about how much of their pharmaceutical payments they passed on to their plan sponsor clients. As a result, the data may understate the savings their clients could obtain through TIs.

** This company's data were provided on a per prescription, rather than per day basis.

***"Retail" includes transactions that occurred in both owned and not-owned retail pharmacies. Only two companies owned retail pharmacies.

TABLE G-V-2(c). Company Data on Possible Effect of Therapeutic Interchange – Owned Mail 2003

2003 Owned Mail		No. of Preferred Drugs	Corresponding No. of Unique NDC Pairs	No. of NDC Pairs in which TI had:			% of NDC Pairs w/ Total Savings	Magnitude of Savings (Loss) Compared to Total Price of Prescribed Drug (No. of NDC Pairs)					
Co.	PBM Category			Member Sav.	Plan Sav.	Total Sav.		Savings<5%	Savings 5-20%	Savings >20%	Losses <5%	Losses 5-20%	Losses>20%
A	Large PBM	8	87	68	34	43	49.4%	10	12	21	9	9	26
B	Large PBM	28	148	133	86	100	67.6%	10	38	52	12	21	15
C	Large PBM	28	161	142	142	115	71.4%	15	44	55	14	17	16
D	Large PBM	12	71	69	55	62	87.3%	6	27	29	3	5	1
E	Large PBM	60	439	326	221	229	52.2%	36	135	58	37	95	78
F*	Retailer-PBM	10	44	32	27	37	84.1%	8	13	16	2	4	1
G**	Retailer-PBM	20	226	126	121	124	54.9%	34	62	28	19	54	29

* These companies could not provide information about how much of their pharmaceutical payments they passed on to their plan sponsor clients. As a result, the data may understate the savings their clients could obtain through TIs.

** This company's data were provided on a per prescription, rather than per day basis.

TABLE G-V-2(d). Company Data on Possible Effect of Therapeutic Interchange – Retail 2003***

2003 Retail***		No. of Preferred Drugs	Corresponding No. of Unique NDC Pairs	No. of NDC Pairs in which TI had:			% of NDC Pairs w/ Total Savings	Magnitude of Savings (Loss) Compared to Total Price of Prescribed Drug (No. of NDC Pairs)					
Company	PBM Category			Member Sav.	Plan Sav.	Total Sav.		Savings<5%	Savings 5-20%	Savings >20%	Losses <5%	Losses 5-20%	Losses>20%
A	Large PBM	9	141	87	56	63	44.7%	14	15	34	9	25	44
B	Large PBM	28	878	592	466	526	59.9%	61	174	293	54	98	198
C	Large PBM	28	903	657	453	547	60.6%	56	152	338	28	115	214
D	Large PBM	12	77	69	58	63	81.8%	3	40	20	6	2	6
E	Large PBM	54	197	125	96	103	52.3%	21	43	39	23	42	29
F*	Retailer-PBM	12	122	106	58	95	77.9%	19	41	35	5	16	6
G* **	Retailer-PBM	20	464	276	221	247	53.2%	57	121	69	54	95	68

* These companies could not provide information about how much of their pharmaceutical payments they passed on to their plan sponsor clients. As a result, the data may understate the savings their clients could obtain through TIs.

** This company's data were provided on a per prescription, rather than per day basis.

***"Retail" includes transactions that occurred in both owned and not-owned retail pharmacies. Only two companies owned retail pharmacies.

GLOSSARY OF TERMS AND ACRONYMS

TERM	DEFINITION
A/B rated generic product	AB-rated generic products are considered by the FDA to be therapeutically equivalent to the brand product. The generic manufacturer must demonstrate that the brand and generic are bioequivalent.
Administrative fees	This term refers to the payments pharmaceutical manufacturers make to PBMs to administer formulary access programs on behalf of the manufacturer. This payment is one of the four types of payments included within the term "total payments."
Allowance or Allowance Level	This term refers to the percentage level of "pharmaceutical payments." *See* definition below. Industry members may refer to this term as the "rebate level."
AWP	Average Wholesale Price. AWP is not the actual price that wholesalers or pharmaceutical manufacturers charge or the amount retail pharmacies pay to acquire drugs; rather it is more like a sticker price in the automobile industry.
Brand-to-brand therapeutic interchange	This is a type of therapeutic interchange that involves brand drug-to-brand drug interchanges. The interchange usually involves switching a patient from a prescribed drug that is not on a plan sponsor's formulary to a chemically distinct drug in the same therapeutic class that is on the formulary. For example, a patient presents a prescription for the cholesterol-lowering drug Crestor, but the pharmacy, after obtaining physician approval, fills the prescription with Lipitor instead. *See* TI definition below.
Brand-to-generic therapeutic interchange	This is a type of therapeutic interchange involves switching a patient from a prescribed single-source brand drug to a therapeutically equivalent, but chemically distinct, generic drug. For example, with the prescribing physician's approval, generic Prozac is dispensed for a prescription for brand drug Zoloft. *See* TI definition below.
CD	Company document.
CMS	Centers for Medicare and Medicaid Services. A federal agency within the Department of Health and Human Services, CMS is responsible for administering the Medicare, Medicaid, State Children's Health Insurance, Health Insurance Portability and Accountability Act, Clinical Laboratory Improvement Amendments, and several other health-related programs.
DAW	Dispense as written. The physician, when writing a prescription, limits the ability of a pharmacist to substitute a generic drug product for a brand drug. DAW prescriptions override state

TERM	DEFINITION
	generic substitution laws.
DUR	Drug Utilization Review. DUR is a program that reviews how outpatient drugs are prescribed. DUR can assess provider prescribing habits and dollars saved by avoidance of problems such as drug-drug interactions, drug-disease interactions, therapeutic duplication and over-prescribing by providers. DUR can also identify pharmacists with low GDR or GSR.
Formulary payment	A payment from a pharmaceutical manufacturer to a PBM, specified as a percentage of the drug's price and the quantity dispensed, based on the listing and status of the manufacturer's drug on the formulary. Formulary payments are sometimes referred to as access payments. Formulary payments are a way for manufacturers to ensure that patients have access to their drugs, regardless of whether a PBM's formulary structure or interventions actively encourage utilization of the manufacturer's drug. This payment is one of the four types of payments included within the term "total payments." *See* definition below.
G	Generic drugs. *See* definition below. One of the three drug categories for which the FTC collected 2002-2003 price information.
GDR	Generic Dispensing Rates. GDRs measure the percentage of generic prescriptions dispensed compared to *all* brand and generic prescriptions dispensed. A PBM could have a different GDR for each therapeutic class and dispensing channel. This is a less reliable measure to examine generic drug usage. The more reliable measure is GSR. *See* definition below.
Generic drug	This term refers to drugs that 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 the corresponding brand drug.
Generic substitution	This term refers to the act of substituting a generic drug for a brand drug. The generic drug is a bioequivalent to the brand drug. *See* definition above for generic drug.
GSR	Generic Substitution Rates. Generic substitution rates (GSR) measure how frequently pharmacies dispense generic drugs *when a generic drug is available*. There are multiple bases on which to measure GSRs. For example, GSRs can be calculated for a brand drug by dispensing channel, for a brand drug in all dispensing channels, or for all drugs in a particular dispensing channel.

TERM	DEFINITION
Large PBMs	This group included five participants that owned a mail-order pharmacy during the study period. Three of these participants provided data related to serving plan sponsors with not owned mail-order facilities.
MAC	Maximum Allowable Cost. MAC prices are a schedule of pricing for generically equivalent drugs based on the AWPs (*see* definition above) of competing generic drug manufacturers. The federal government issues a MAC price for generic products that have 3 or more manufacturers or distributors. Each PBM can have its own MAC lists and some PBMs maintain multiple MAC lists.
Mail-Order Pharmacy or Mail Pharmacy	A pharmacy that dispenses drugs through the mail rather than through a retail store front.
Market-share payment	This term refers to the payments made by pharmaceutical manufacturers to PBMs based on the "market share" of the manufacturer's drug among drugs in the same class dispensed to the PBM's clients. This payment is often specified as a percentage of the drug's cost (*e.g.*, a market-share allowance level of 10% means the manufacturer will pay the PBM 10% of a measure of the drug's cost multiplied by the quantity dispensed). This payment is one of the four types of payments included within the term "total payments."
Member Price(s)	This term includes co-payment, deductible, and any co-insurance amounts that a member pays.
Members	Throughout this Report this term refers to a plan's enrollees.
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pub. L. No. 108-173. Within the MMA, Congress requested that the FTC assess the differences in payment amounts incurred by plans and their members for prescription drugs dispensed by mail pharmacies owned by PBMs compared to both non-owned mail-order pharmacies and community retail pharmacies.
MSB	Multi-Source Brand. This term refers to brand name drug products that have at least one generic alternative. This is one of the three drug categories (*see* G and SSB for other drug categories) for which the FTC collected 2002-2003 price information.
NDC	National Drug Code. The NDC serves as a universal product identifier for human drugs.
Not-Owned Mail-Order Pharmacy	This term refers to a mail-order pharmacy that is not owned by a PBM.
OTC	Over-The-Counter drug products. A prescription is not required to purchase these drugs.

TERM	DEFINITION
Owned Mail-Order Pharmacy (or owned mail pharmacy)	This term refers to a mail-order pharmacy that is owned by a PBM.
P&T committee	Pharmacy and Therapeutics committee. PBMs create committees of pharmacists and physicians from different specialties to design the PBM's formulary. Most P&T committees evaluate the drugs in particular therapeutic categories for clinical effectiveness and safety. In addition to evaluating all drugs currently on a PBM's national formulary, most P&T committees evaluate therapeutic class reviews and new drug monographs compiled from various public and private sources.
PBA	Pharmacy Benefit Administrator. Health plans may use PBAs that focus only on retail network administration and claims administration. PBAs do not represent their clients in financial negotiations with pharmaceutical manufacturers.
PBM	Pharmacy Benefit Manager. Health plans may hire PBMs to manage pharmacy benefits on their behalf. PBMs may assemble networks of retail and mail pharmacies so that the health plan members can fill prescriptions easily and in multiple locations. PBMs also negotiate rebates with pharmaceutical manufacturers that may lower the price that health plans and members pay for prescription drugs.
PBM formulary	A list of approved drugs for which the plan will reimburse its members. The formulary provides one method for controlling drug costs for consumers that have insurance coverage and a low sensitivity to the prices of prescription drugs.
PBM's client	Throughout the Report, this term refers to "health plan sponsors," "plan sponsors," and "plans" (*i.e.*, health insurance plans). This may include Health Maintenance Organizations (HMOs), self-insured employers, labor union plans, and other entities.
PDP	Prescription Drug Plan. The term used by the MMA (*see* definition above) for prescription drug insurance for Medicare enrollees beginning in 2006.
Pharmaceutical payment	This term refers to the payments made by pharmaceutical manufacturers to PBMs to have their drugs listed in a preferred spot on the formulary and as an incentive to the PBM to increase a drug's market share. The 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

TERM	DEFINITION
	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" (*see* definition above) will be used to describe the percentage level.
Plan Price(s)	This term includes the following costs that a health plan pays: ingredient costs (that portion of the dispensed drug for which the plan pays), dispensing fees, and any pharmaceutical rebates shared with the plan that reduce the prices plan sponsors pay.
Prior authorization	This term refers to the requirement that a physician or patient receive prior approval from a PBM before certain drugs will be reimbursed by insurance.
Rebate	*See* definition for pharmaceutical payment.
Rebate level	*See* definition for allowances.
Not-Owned Retail	Retail pharmacy with a store front that is not owned by a PBM.
Retailer-Owned PBMs	Retail pharmacy with a store front that is owned by a PBM. This group included four participants all of which 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 independently owned mail-order pharmacies as well.
Small or Insurer-Owned PBM	This group included six participants. Five of these six participants used independently owned mail-order pharmacies because they did not own one during the study period. One participant owned a mail pharmacy during the study time period and one PBM acquired an interest in a mail-order pharmacy in 2003.
SSB	Single-Source Brand. This term refers to brand name drug products that do not have a generic alternative. This is one of the three drug categories (*see* G and MSB for other drug categories) for which the FTC collected 2002-2003 price information.
Stand-Alone Retail Pharmacies	This group included six participants. 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.
Step-therapy	This term refers to health plan designs that will pay for certain more expensive drugs only if a physician first prescribes one or two less expensive prescription or over-the-counter drugs prior to prescribing a more expensive single-source drug from the same therapeutic category.
TI	Therapeutic Interchange. TI refers to situations in which a PBM interchanges a preferred drug for the prescribed drug. TI typically involves switching a patient from a prescribed drug that is not on a plan sponsor's formulary to a chemically distinct drug

TERM	DEFINITION
	in the same therapeutic class that is on the formulary. There are two types of interchanges. The first type involves brand drug-to-brand drug interchanges ("brand-to-brand"). *See* definition above. The second type refers to interchange of a generic version of a therapeutically similar brand drug for the prescribed brand drug ("brand-to-generic"). *See* definition above.
Total price	This term is the sum of "member price" and "plan price." See definitions above.
Total payments	This term includes four types of payments made to PBMs. The four payments include: formulary payment, market-share payment, administrative fees, and payments to provide other services, including therapeutic and compliance programs.

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