Congress of the United States
House of Representatives
Washington, DC 20515

May 24, 2022

The Honorable Lina M. Khan
Chair
Federal Trade Commission
Washington, D.C. 20580

Dear Chair Khan:

We write to you today regarding the Federal Trade Commission's (FTC) Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and their Impact on Independent Pharmacies and Consumers, document identification FTC-2022-0015-0001. Please submit this letter on the public record as a formal comment submitted by United States Representatives Earl L. "Buddy" Carter and Diana Harshbarger.

We offer informed and unique perspectives on these issues from our professional pharmacist backgrounds, and believe a FTC 6(b) investigation and analysis of the roles the largest and market-dominating Pharmacy Benefit Managers ("PBMs") play in U.S. pharmaceutical supply chains could not be more timely or necessary.

Pharmacies are an integral pillar of health care throughout the United States, and often the sole provider of needed health care services in our rural and medically underserved communities. Addressing anticompetitive PBM practices is essential to help ensure that beneficiaries maintain access to pharmacies that provide critical prescription drugs and other essential services like chronic and complex disease management, wellness and prevention services, vaccines, certain testing, and disease education. Over the past two years, we witnessed how important that access is as the nation continues to rely on pharmacies to care for underserved and at-risk communities by ensuring access to COVID-19 testing, vaccination, and therapeutics. PBMs should not continue to threaten this important access.

Decades ago, the initial function of PBMs was to serve as third-party intermediaries between health plans, pharmaceutical manufacturers and pharmacies, to reduce administrative costs for insurers, validate a patient's eligibility, administer plan benefits, and negotiate costs between pharmacies and health plans. But PBMs have since morphed into one of the most profitable, most problematic, least regulated and least understood aspects of our healthcare delivery system. As shadowy middlemen, PBMs have exploited a lack of transparency — and insufficient legislative and regulatory oversight — to create market-dominating conflicts of interest that have significantly distorted competition, reduced choices and access to care for consumers, and ultimately increased the cost of drugs.

PBMs have grown into some of the largest, most profitable companies in our nation.[1] PBMs act as middlemen between pharmacies, drug manufacturing companies, and health insurance plans to administer prescription drug benefits.[2] Using their size, leverage, and negotiating power, PBMs play a large role in determining which prescription drugs are covered by insurance plans and how much they cost, while keeping themselves mostly hidden from the American public.[3]

Right now, medications leave the manufacturer at one price then skyrocket before they reach the pharmacy and the PBMs refuse to explain why. Patients deserve better.

PBMs increasingly employ a host of practices that result in higher prices for payers/consumers and eliminate opportunities to reduce overall costs, including anticompetitive practices, direct and indirect remuneration fees, and spread pricing.

PBMs wield enormous power as middlemen on a number of fronts, including:

1. Choosing what drugs are covered by health insurance;
2. Negotiating purchasing deals with drug makers;
3. Determining cost-sharing for consumers;
4. Deciding which pharmacies will be included in prescription plans; and
5. Deciding how much pharmacies are reimbursed for the drugs they sell.

These troubling marketplace dynamics can be illustrated by one sobering statistic in particular: in 2020, more than half of total spending on brand medicines in the U.S. went to drug supply chain middlemen like PBMs and other entities, overtaking the amount going to drug manufacturers for the first time, according to the Berkeley Research Group. Brand manufacturers retained just 37 percent of total spending on all prescription medicines (brand and generic medicines). The study revealed a steady decrease in the proportion of U.S. drug spending received by drugmakers from around 67% in 2013 to 49.5% in 2020. Over the same period, total gross expenditures on brand and generic medicines nearly doubled — from $268 billion to $517 billion.[4]

Vertical Integration:

As many experts have noted, PBMs are not really just PBMs anymore. PBMs are health insurance companies. PBMs are mail-order pharmacies. PBMs own prescribers and physician practices. PBMs own specialty pharmacies. In the case of a company like CVS Caremark, they

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[1] *See* PBM ACCOUNTABILITY PROJECT, UNDERSTANDING THE EVOLVING BUSINESS MODELS AND REVENUE OF PHARMACY BENEFIT MANAGERS 3 (2021), https://b11210f4-9a71-4e4c-a08f-cf43a83bc1df.usrfiles.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf [https://perma.cc/YWR6-HHLZ].

[2] *See id.*

[3] *See id.*

[4] [4] *"The Pharmaceutical Supply Chain, 2013 – 2020"*; by Andrew Browlee and Jordan Watson, Berkeley Research Group; January, 2022.

are a retail pharmacy. PBMs have been allowed to expand and consolidated into many interwoven and intricate corporate affiliations.[5]

PBMs' market concentration and power has enabled practices that have resulted in decreased competition and higher prices. PBMs have vertically integrated, creating healthcare conglomerates that control pricing with little competition.[6] The three largest PBMs are CVS Caremark, Express Scripts, and OptumRx. The big three PBMs control almost 80% of the market.[7]

Concentration of PBMs limits the choice of insurers and pharmacies and reduces competition within the PBM industry, keeping brand (and subsequently generic) prices high through rebates and spread pricing

PBMs' market concentration and power has enabled practices that have resulted in decreased access to prescription medicines. More than 30% of insured Americans have difficulty accessing prescription medications due to PBM and insurer rules and cost-sharing burdens.[8]

PBMs comprise the only entity in the drug supply chain that knows what everyone is paying and what everyone has as a cost-basis. Yet they operate in a black box with no transparency. PBMs use this lack of transparency to siphon-off significant dollars from the rest of the supply chain — resulting in much higher drug prices.

The chart below, from Drug Channels Institute, shows the extent of vertical integration involved. Note that the integration includes mergers with health providers too, not just insurers and pharmacies.[9] This integration presents opportunities for PBMs to lock competing pharmacies, insurers, or even providers out of the market. With less competition, PBMs can continue raising prices and steer away from other entities, again leading to increased drug costs.

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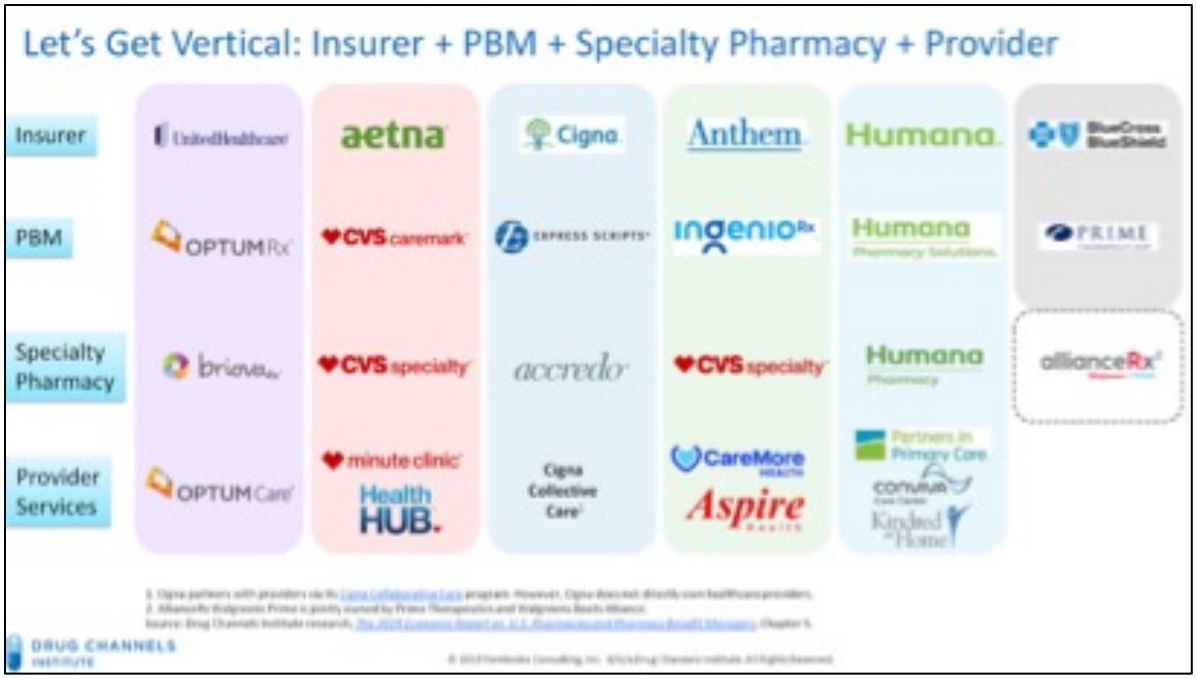
[5] "Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?" Drug Channels Institute; December 12, 2019.

[6] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, DRUG CHANNELS (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html [https://perma.cc/6JF6-BTYR**]**.

[7] *See* Matej Mikulic, *U.S. Prescription Market: Market Share of Pharmacy Benefit Managers 2020*, STATISTA (June 16, 2021), https://www.statista.com/statistics/239976/us-prescription-market-share-of-top-pharmacy-benefit-managers/ [https://perma.cc/2GUP-8EUM].

[8] Drug Channels News Roundup, August 2021: OptumRx's New GPO, Pharmacy DIR Fees, State Biosimilar Laws, UM Views, and a Newspaper Delivers, Drug Channels (August 25, 2021) https://www.drugchannels.net/2021/08/drug-channels-news-roundup-august-2021.html; Ipsos Public Poll Findings and Methodology (July 2021), https://www.ipsos.com/sites/default/files/ct/news/documents/2021-

[9] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, DRUG CHANNELS (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html [https://perma.cc/6JF6-BTYR**]**.



DIR Fees:

Direct and Indirect Remuneration (DIR) fees are not itemized and can be charged a year or more after medications are dispensed — a practice that has since also been termed as "clawbacks".[10] There is little transparency on how DIR fees are calculated, yet they are extracted by the PBM from each pharmacy dispensing claim.[11] Pharmacies may not even know if a transaction is profitable for months after it transpired, depending on the DIR fee assessed to the pharmacy by the PBM.[12]

Independent pharmacy owners can be suddenly hit with unplanned expenses from these "clawback" fees, which are sometimes so high that the business is no longer profitable.[13] These predatory practices make it very difficult for independent pharmacies to remain operational.

CMS states that that pharmacy DIR fees grew more than 107,400 percent between 2010 and 2020. Independent pharmacies rarely have negotiating power to stop these fees.[14] They are at the

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[10] *See Uncloaking Pharmacy Benefit Managers to Promote Market Competition*, BARCLAY DAMON (June 20, 2017), https://www.barclaydamon.com/blog/health-care/uncloaking-pharmacy-benefit-managers-to-promote-market-competition [https://perma.cc/U3E4-YAXK].

[11] See True North Political Solutions, White Paper: DIR Fees Simply Explained, PHARMACY TIMES (Oct. 25, 2017), https://www.pharmacytimes.com/view/white-paper-dir-fees-simply-explained [https://perma.cc/JKC3-GPL4].

[12] *See id.*

[13] Laurie Toich, *DIR Fees and Independent Pharmacies: What is the Impact?,* PHARMACY TIMES (Feb. 13, 2017), https://www.pharmacytimes.com/view/dir-fees-and-independent-pharmacies-what-is-the-impact [https://perma.cc/RG6W-N36L].

[14] *See, e.g.*, Letter from Earl L. "Buddy" Carter, U.S. Representative, House of Representatives et al. to Xavier Becerra, Sec'y, U.S. Dep't of Health and Human Servs. (Mar. 16, 2022), https://buddycarter.house.gov/uploadedfiles/dir_reform_letter_to_hhs_3.16.22.pdf [https://perma.cc/95NR-G9QT].

mercy of the PBMs because they rely on in-network status from the insurers the PBM might be merged with. As PBMs make more profit off these fees, the rest of the supply chain is forced to charge higher prices to ensure they can meet costs — hurting patients.[15]

Spread Pricing:

PBMs also utilize their power to pigeonhole independently owned pharmacies into predatory business contracts with a reimbursement structure termed "spread pricing."[16] According to the National Community Pharmacists Association, "spread pricing is the PBM practice of charging payers like Medicaid more than they pay the pharmacy for a medication, and then the PBM keeps the 'spread' or difference, as profit."[17]

For example, an independent pharmacy in Iowa serviced the local county jail and dispensed a generic bottle of antipsychotic pills for an inmate.[18] The PBM, CVS Caremark, billed the jail $198.22 for the medication but gave the pharmacy only $5.73.[19] CVS Caremark took $192.49 of profit on the generic medication, and the pharmacy reportedly lost money servicing the county jail for that year.[20]

PBMs use spread pricing tactics quite frequently to reimburse pharmacy claims below the cost of the dispensed drug. Pharmacy owners have little choice but to agree to these contracts, otherwise the PBM won't include them as an in-network pharmacy, likely putting the pharmacy out of business.[21]

Author Matt Stoller recently noted this no-win situation for independent community pharmacists: Pharmacists buy branded drugs at a rate based on something called the Average Wholesale Price (AWP), minus roughly 20%. To make a profit selling a branded drug, a pharmacist needs to be reimbursed at a higher rate than that amount. Under an Express Scripts contract, depending on the length of the prescription (more or less than 30 days), the pharmacists will get the average wholesale price minus 26.3% or minus 31.3%. Under this reimbursement scheme, for every branded drug dispensed through Express Scripts the independent pharmacy loses money and cannot raise prices to cover extra costs as prices are governed by the contracts with PBM.[22]

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[15] *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending [https://perma.cc/8C5F-NFQ3].

[16] Trevor J. Royce, Sheetal Kircher & Rena M. Conti, *Pharmacy Benefit Manager Reform: Lessons From Ohio*, 322 J. OF THE AM. MED. ASS'N 299, 299 (2019).

[17] *Spread Pricing 101*, NAT'L CMTY PHARMACISTS ASS'N, https://ncpa.org/spread-pricing-101 [https://perma.cc/2QTM-UGCN].

[18] *See* Robert Langreth, David Ingold & Jackie Gu, *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), https://www.bloomberg.com/graphics/2018-drug-spread-pricing/ [https://perma.cc/BB5C-MQLU].

[19] *Id*

[20] *Id*

[21] *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending [https://perma.cc/8C5F-NFQ3].

[22] Matt Stoller, "The Red Wedding for Rural Pharmacies" (March 28, 2022), available at https://mattstoller.substack.com/p/the-red-wedding-for-rural-pharmacies?s=r

Under these PBM contract arrangements, independent community pharmacies are often forced to sell prescriptions at significant losses. What choice do they have, but to pick the lesser of 2 evils?: either a) fill a prescription and lose money; or b) don't fill a prescription and lose a customer.

PBMs also "put their thumbs on the scale" against independent community pharmacies through other contract practices, such as:

- Forcing patients into mail-order delivery of prescriptions, away from community pharmacies, with PBMs often steering to their own corporate affiliations;
- Using abusive audit practices and penalizing pharmacies for minor, typographical errors on claims, forcing them to forego reimbursement due to small errors that posed no consequence to the claim.

For independent community pharmacists, this is akin to playing a high-stakes game without knowing the rules — or worse, a game in which there are no rules! Pharmacists often have no line of sight on the calculations PBMs use to reimburse. It is virtually non-transparent and many community pharmacists are at the mercy of the PBM. For patients, this has resulted in fewer health care choices and increased out-of-pocket costs. For community pharmacies, this lack of oversight holds them hostage to restrictive and inflexible, one-sided "take it or leave it" contracts making it virtually impossible to plan for the future and causing many of these small businesses to close their doors forever.[23]

Independent pharmacists face these difficult and distressing decisions every single day.

Fewer independent pharmacies, especially in rural areas without alternatives, not only weakens local economies and prevents skilled professionals from using their talents at a time we have a growing healthcare workforce shortage. It also significantly degrades our health-care safety net. And according to data from IQVIA, from December 2017 to December 2020, the United States lost more than 2,300 pharmacies.[24]

Conclusion:

The FTC has a unique mission and plays an important role in being a neutral and objective arbiter to protect consumers and competition in marketplaces. We believe this investigation is necessary to obtain an understanding of conflicts of interest, anti-competitive conduct and marketplace distortions that are causing prescription drug prices to increase continuously.

We further believe an FTC study on PBMs is critical in order to provide Congress and other policymakers a better understanding of the PBM industry, and to provide meaningful analysis

[23] https://ctexaminer.com/2020/11/10/why-pharmacy-benefit-managers-are-hurting-you-and-your-local-pharmacy/

[24] *"Independent Grocery Pharmacies Need DIR Fee Reform Now"*; National Grocers Association; June 11, 2021.

and recommendations for future legislation to lower prescription drug prices, better protect patients and safeguard competition.

This is why it is important that the FTC conduct a 6(b) study and review the ways in which PBMs are a root cause of high prescription drug costs and are inhibiting patients' access to lifesaving care. As we have always been fond of saying, sunlight is the best disinfectant. It's time to fix this broken system.

Thus, we ask the FTC to conduct a thorough investigation to analyze the practices of PBMs, without limitation. Thank you for your time and consideration of our views. We look forward to working with the FTC on this important issue. Please find attached Appendix A which describes in more detail the specific aspects we believe worthy of FTC's investigation and analysis.

Sincerely,

Earl L. "Buddy" Carter
Member of Congress

Diana Harshbarger, Pharm.D.
Member of Congress

Attachment: Appendix A

Appendix A

Recommended Issues & Scope for FTC 6(b) Study:

- The changes in market share — measured by number of covered lives, total sales, and number of dispensed drugs — during the past 10 years of at least the following PBMs: Express Scripts, CVS-Caremark, OptumRx, Prime Therapeutics, Humana, Ingenio Rx and "other PBMs"

- The changes in market share — measured by number of covered lives and total revenues — during the past 10 years of at least the following insurers: Cigna, Aetna, Humana, Anthem, Blue Cross Blue Shield Plans, and "other insurers"

- The changes in market share — measured by the number of pharmacies, the number of dispensed drugs and the total revenues — during the past 10 years of at least the following retail pharmacies: CVS, Walgreens, Kroger, Walmart, Costco, independents

- The types — and amounts — of manufacturer payments and other financial benefits negotiated by each of the three main rebate aggregators from each of the largest drug manufacturers, for (a) Medicare, (b) Medicaid (including supplemental rebates), (c) federal plans, and (d) other plans (including insurers) in the commercial marketplace. Also, the extent to which each of the above payments and other financial benefits are being passed through or retained (a) by each of the rebate aggregators, (b) each of the three related PBMs (Express Scripts, CVS-Caremark or OptumRx), (c) or by any other PBM that is contracting with one of the rebate aggregators or 3 large PBMs (like Prime Therapeutics, Humana, Navitus and Kroger Rx Plans)

- The extent to which PBMs pressure manufacturers to make larger payments to ensure the manufacturers' drugs are included on formularies, and/or preferred by being placed in better tiers, and/or favored via Prior Authorization, Step Therapy or Quantity Limit programs, and if such pressure is exerted, the extent to which it is exerted in connection with rebates and other payments that are passed through, or in connection with payments that aggregators or PBMs retain for themselves

- The extent to which manufacturers are increasing their drugs' list prices to position themselves to make greater payments to rebate aggregators and PBMs

- In connection with retail pharmacy dispensed drugs, the differences in PBMs' reimbursements to their own subsidiary or affiliated retail pharmacies, and PBMs' reimbursements to other pharmacies

- In connection with the contracts that the three largest PBMs (or their parent company insurers) execute with plans providing coverage in the commercial marketplace or plans providing coverage to federal employees: The extent to which PBMs require "exclusive" utilization of the PBM's own subsidiary mail order pharmacies for dispensing mail order drugs. Also, the differences in each PBM's (a) acquisition cost for drugs purchased for each of their mail order pharmacies, and (b) invoiced costs for the same drugs to plans. Also, to the extent the same drugs are dispensed from retail pharmacies, a comparison of the above two figures with (a) PBM's reimbursements for the same drugs to retail pharmacies, and (b) invoiced costs for the same drugs to plans when dispensed from retail pharmacies

- In connection with the contracts that the three largest PBMs (or their parent company insurers) execute with plans providing coverage in the commercial marketplace or plans providing coverage to federal government employees: The extent to which PBMs require "exclusive" utilization of the PBM's own subsidiary specialty drug pharmacies for dispensing specialty drugs. Also, the differences in each PBM's (a) acquisition cost for drugs purchased for each of their specialty drug pharmacies, and (b) invoiced costs for the same drugs to plans. Also, to the extent the same drugs are dispensed from retail pharmacies, a comparison of the above two figures with (a) PBM's reimbursements for the same drugs to retail pharmacies, and (b) invoiced costs for the same drugs to plans when those specialty drugs are dispensed from retail pharmacies

- The extent to which manufacturers of high-cost drugs are selecting only one – or a few – limited distribution drug pharmacies to dispense those drugs; which pharmacies are being selected; and what other quid pro quos accompany the selection

- The extent to which PBMs impose adhesion contracts ("take it or leave it" contracts) on retail and other pharmacies. Also, the extent to which retail pharmacies — or third-party mail or specialty drug pharmacies — are excluded from the PBM's pharmacy network by PBMs

- The extent to which the three largest PBMs engage in clawing back money from retail pharmacy after the PBMs' initial reimbursements to the pharmacies: How much is clawed back in total, and in relationship to the amount reimbursed? On what basis? With what impact on retail pharmacies?

- The extent to which PBMs harass independent pharmacies through audit or other practices (e.g., frequent batch audits, fishing for typographical or other minor errors on claims)

- The growth — or shrinkage — during the past 10 years of independent retail pharmacies, and to the extent independent retail pharmacies have closed, the extent to which they have been purchased by chain pharmacies, including specifically CVS pharmacies

- Each of the three largest PBM's Prior Authorization practices, including without limitation:
    - The number of drugs that each PBM creates Prior Authorization protocols for
    - The extent to which Prior Authorization programs reflect and "match" the clinical criteria referenced by the FDA when drugs are approved
    - The extent to which Prior Authorizations are a result of manufacturers' demands made in exchange for paying (a) rebates, or (b) other payments
    - The average prior authorization approval time
    - The impact on doctors and other healthcare providers attempting to deliver timely and appropriate care to patients
- Each of the three largest PBM's Step Therapy practices, including without limitation:
    - The number of drugs that each PBM creates Step Therapies for
    - The extent to which Step Therapies favor the initial use of lower-cost drugs over higher-cost drugs (or vice a versa)
    - The extent to which Step Therapies are a result of a manufacturer's demand made in exchange for paying (a) rebates, or (b) other payments
    - The impact on doctors and other healthcare providers attempting to deliver timely and appropriate care to patients
- Each of the three largest PBM's Quantity Limit practices, including without limitation:
    - The number of drugs with Quantity Limits
    - The extent to which restrictive Quantity Limits are imposed on higher-cost drugs that may not be fully used given their toxicity of other issues (like oncology drugs)
    - The extent to which larger Quantity Limits are a result of a manufacturer's demand made in exchange for paying (a) rebates, or (b) other payments
- The extent to which each of the three largest PBMs are engaging in "spread pricing" – meaning the price that PBMs invoice payers (including Medicare, Medicaid, FEHB and private payers) is more than the PBM pays for the drug, enabling the PBM to "pocket the difference". Spread pricing should be analyzed separately to assess:

- Each of the three PBM's *reimbursements* to non-affiliated retail pharmacies, as compared to each of their invoiced costs to each of the various payers

- CVS-Caremark's *reimbursements* to its *own subsidiary CVS retail pharmacies*, as compared to CVS-Caremark's invoiced costs to each of the various payers

- Each of the three PBM's *acquisition costs* for drugs dispensed from each of their *subsidiary mail order pharmacies*, as compared to each of their invoiced costs to each of the various payers

- Each of the three PBM's *acquisition costs* for drugs dispensed from each of their *specialty drug pharmacies*, as compared to each of their invoiced costs to each of the various payers

- Each of the three PBM's *reimbursement costs* to *third party limited distribution drug pharmacies*, as compared to each of their invoiced costs to each of the various players

- Each of the three PBM's *reimbursement costs* to *their own subsidiary specialty drug pharmacies when they are selected as a limited distribution drug pharmacy*, as compared to each of their invoiced costs to each of the various players

In addition to investigating the above matters, we strongly urge the FTC to provide statutory and/or regulatory policy recommendations to:

- Decrease the costs of prescription drugs for patients and payers

- Enhance competition (a) among PBMs, (b) among insurers, (c) among manufacturers, (d) among pharmacies

- Decrease anti-competitive conduct by each of the following: PBMs, insurers, rebate aggregators, manufacturers and pharmacies

- Increase transparency concerning the activities of PBMs, insurers, rebate aggregators, manufacturers and pharmacies

- Increase transparency related (a) prescription costs, and (b) prior authorization, step therapy and quantity limit programs