UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

August 19, 2014

Via Electronic Submission

Larry Good
Executive Secretary
ERISA Advisory Council
U.S. Department of Labor, Suite N–5623
200 Constitution Avenue NW, Washington, DC 20210

Dear Mr. Good:

The staffs of the Federal Trade Commission ("FTC or Commission") Office of Policy Planning, Bureau of Economics, and Bureau of Competition[1] appreciate the opportunity to highlight information from the FTC that may be useful to the Advisory Council on Employee Welfare and Pension Benefit Plans ("Council") as it considers issues related to PBM Compensation and Fee Disclosure.[2] Specifically, the purpose of this letter is to discuss prior FTC analyses that relate to the Council's general inquiry and address some of the recent questions directed to FTC staff. As explained below, FTC staff has examined competition among PBMs and the types of compensation and disclosure arrangements negotiated by PBMs and plan sponsors. In addition, the staff has analyzed proposed state regulations imposing PBM disclosure requirements and raised concerns that such mandates may prevent plan sponsors from negotiating the level of disclosure that they deem useful and raise plan sponsors' costs of providing pharmacy benefits.

A primary focus of the Council's inquiry is a determination "examining the current status of the need for and potential scope of compensation and fee disclosures by PBMs under Section 408(b)(2), whether such information is necessary for plan administrators to determine if reasonable compensation is being paid for PBM services under the statute, and how mandatory compensation and fee disclosures might impact the provision of prescription drug services to

[1] This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission ("Commission") or of any individual Commissioner. The Commission, however, has voted to authorize us to submit these comments. Commissioner Brill dissented on authorizing Commission staff to submit these comments, and she is writing separately to the Council to express her views.

[2] Emp. Benefits Sec. Admin., U.S. Dep't Labor, 171st Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting, 79 Fed. Reg. 28555 (May 16, 2014).

participants and beneficiaries of health care benefit plans and the costs of plan administration."[3] FTC staff has considered related disclosure questions within the context of our analysis of PBM markets and regulations.

Congress has charged the Commission with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[4] Pursuant to its statutory mandate, the FTC seeks to identify business practices and regulations that impede competition without offering countervailing benefits to consumers. For several decades, the FTC and its staff have investigated the competitive effects of restrictions on the business practices of health care providers,[5] issued reports and studies regarding various aspects of the pharmaceuticals industry,[6] and brought numerous enforcement actions against entities in that industry.[7]

Of particular relevance to the Council's current inquiry is the Commission's 2005 study of PBM industry practices. In response to a 2003 request from Congress, the FTC analyzed data on PBM pricing, generic substitution, therapeutic interchange, and repackaging practices, and examined whether PBM ownership of mail-order pharmacies served to promote competition and lower prescription drug prices for plan sponsors. The FTC found, among other things, that prices were generally lower at PBM owned mail-order pharmacies than at independent mail-order and retail pharmacies. To the extent that the plan sponsor's relationship with the PBM creates potential conflicts of interest, the study found that competition among PBMs affords plan sponsors the ability to safeguard their interests through the provisions they negotiate in their PBM contracts and plan designs.[8]

The Council asked whether the FTC has conducted further study of the PBM industry since 2005. Since 2005, FTC staff has analyzed a number of state legislative proposals involving

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[3] U.S. Dep't Labor, 2014 Issue Statement for the ERISA Advisory Council, PBM Compensation and Fee Disclosure, http://www.dol.gov/ebsa/publications/2014issuestatement1.html.

[4] Federal Trade Commission Act, 15 U.S.C. § 45.

[5] *See* FED. TRADE COMM'N, OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2013), http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf.

[6] *See, e.g.*, FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT: A REPORT OF THE FEDERAL TRADE COMMISSION (2011), http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf; Luke M. Olson & Brett W. Wendling, *Estimating the Effect of Entry on Generic Drug Prices Using Hatch-Waxman Exclusivity* (Fed. Trade Comm'n, Bureau of Econ. Working Paper No. 317, 2013), http://www.ftc.gov/sites/default/files/documents/reports/estimating-effect-entry-generic-drug-prices-using-hatch-waxman-exclusivity/wp317.pdf.

[7] *See* FED. TRADE COMM'N, OVERVIEW OF FTC ANTITRUST ACTIONS IN PHARMACEUTICAL SERVICES AND PRODUCTS (2013), http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/rxupdate.pdf.

[8] *See* FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 58 (2005), http://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf, (noting diverse audit rights and reporting under PBM contracts) [hereinafter PBM STUDY].

mandatory transparency requirements and their likely effect on competition.[9] These FTC staff comments have highlighted two particular types of concerns:

(1) mandatory disclosure requirements may hinder the ability of plans to negotiate an efficient level of disclosure with PBMs; and

(2) if such disclosures publicly reveal previously proprietary and private information about discounts negotiated with PBMs, disclosure may result in less aggressive pricing by, or even collusion among, pharmaceutical manufacturers.[10]

Additionally, in 2012, the FTC completed two investigations involving PBMs: (1) an investigation to determine whether some pricing and pharmacy reimbursement practices of CVS/Caremark constituted unfair methods of competition or unfair or deceptive acts or practices;[11] and (2) an investigation of a proposed merger between two PBMs, Express Scripts and Medco.[12] In connection with the Express Scripts/Medco merger, the Commission observed:

> The market for the provision of full-service PBM services to health care benefit plan sponsors is moderately concentrated and consists of at least ten significant competitors. Our staff's investigation revealed that competition for accounts is intense, has driven down prices, and has resulted in declining PBM profit margins—particularly in the large customer segment.[13]

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[9] *See, e.g.*, Letter from FTC staff to the Hon. James Seward Concerning N.Y. Senate Bill 58 on Pharmacy Benefit Managers (PBMs) (Mar. 2009), *available at* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf [hereinafter New York Comment]; Letter from FTC staff to the Hon. Nellie Pou Concerning N.J. A.B. A-310 to Regulate Contractual Relationships between PBMs and Health Benefit Plans (Apr. 17, 2007), *available at* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.nelie-pou-concerning-new-jersey.b.310-regulate-contractual-relationships-between-pharmacy-benefit-managers-and-health-benefit-plans/v060019.pdf.

[10] New York Comment, *id.* at 4.

[11] *See* In the Matter of CVS Caremark Corp., FTC File No. 112 3210 (Jan. 12, 2012) (consent order settling charges that CVSC misrepresented the prices of covered Medicare Part D prescription drugs), *available at* http://www.ftc.gov/enforcement/cases-proceedings/112-3210/cvs-caremark-corporation; In the Matter of CVS Caremark Corp., FTC File No. 091 0106, (closing letter sent Jan. 12, 2012), *available at* http://www.ftc.gov/sites/default/files/documents/closing_letters/cvs-caremark-corporation/120112cvsclosingletter.pdf.

[12] *See* Statement of the Fed. Trade Comm'n Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210 (Apr. 2012), *available at* http://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf. ("The transaction will reduce the number of significant competitors to nine (plus a fringe of several dozen smaller firms) and give the merged company a market share of just over 40%.") [hereinafter "Commission Statement"].

[13] Commission Statement , *id.* at 2; *but see* Dissenting Statement of Commissioner Julie Brill Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 110-0210 (Apr. 2012), *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/dissenting-statement-commissioner-julie-brill/120402medcobrillstatement.pdf.

Second, the Commission noted that the amount of transparency in the plan design is one dimension upon which PBMs compete for accounts:

> There are also several standalone PBMs that are substantially smaller than the Big Three but have had recent success winning significant employer business, including large employer accounts. These PBMs usually compete by trying to differentiate themselves from the Big Three and health plan-owned PBMs by emphasizing a transparent pricing model, providing more individualized account management support, and offering customized PBM offerings.[14]

Many of the economic principles and market characteristics that the FTC's 2005 study identified as important determinants of competition continued to be significant in 2012, notwithstanding evolution in the marketplace over this seven-year period. For example, when plan sponsors negotiate with PBMs, plan design is an important determinant of the pricing. Designs can vary significantly across plans in many dimensions depending on the coverage the plan sponsor wishes to provide and the costs it is willing to incur. One aspect of plan design highlighted in the 2005 study is the extent to which indirect payments from pharmaceutical manufacturers are to be passed through to the plan sponsor, which can vary considerably across plans.[15] Plan sponsors can also choose varying levels of disclosure. If a standard level of disclosure is imposed on all plans, thus denying plan sponsors the ability to negotiate their preferred level of disclosure, plans will be unable to use the level of disclosure as one element of a negotiating strategy. FTC staff notes that the agency has not undertaken any systematic examination of the PBM market since its ESI/Medco merger investigation in 2012. While staff is not aware of more recent evidence contradicting these observations, the Council may want to assess available evidence about the current state of the market.

Furthermore, rebates paid by drug manufacturers vary depending on certain characteristics of the plans. For instance, plans with relatively restrictive formularies often receive higher rebates.[16] When plan sponsors can choose among varying levels of disclosure – and other contract terms that may be associated with those levels of disclosure – then manufacturers can adjust the rebates they are willing to offer based on the plan design. If manufacturers tend to bid less aggressively when competitors and other plan sponsors can observe rebate levels and other terms, only sponsors seeking that level of transparency will pay the associated cost. A plan sponsor who values transparency may be willing to make this tradeoff. When the level of disclosure is mandatory, however, that tradeoff will be imposed on *all* plan sponsors, regardless of the value they place on transparency.[17]

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[14] Commission Statement , *supra note* 12, at 4.

[15] PBM STUDY, *supra note* 8, at 57-58. This section of the study also discusses a trend at that time toward plans specifying higher levels of rebate pass through than had been negotiated in the past. The Advisory Council posed a question to us about the connection between pass-through pricing and transparency. Higher levels of pass-through, even up to 100%, do not necessarily imply higher levels of information disclosure. To verify a PBM's performance of their contract, a plan sponsor entitled to 50% of the rebates generated by its claims would require exactly the same information as a plan sponsor entitled to 100% pass-through.

[16] PBM STUDY, *supra note* 8, at 51-52.

[17] New York Comment, *supra note* 9, at 4.

In sum, we encourage the ERISA Advisory Council to consider whether harm may result if plan sponsors are denied the ability to choose the level of transparency that best suits them, within the context of their overall plan design. If the Council determines that additional transparency may be desirable, we urge the Council to consider whether and how mandatory disclosure requirements might be tailored narrowly to present useful and meaningful information to plan administrators while mitigating the risk of competitive harm.

We appreciate your consideration of these issues, and we hope this information will be helpful in your deliberations.

Respectfully submitted,

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