
From: David Balto [mailto:david.balto@yahoo.com]

Sent: Friday, December 10, 2010 1:15 PM

To: EBSA, E-ORI - EBSA; Borzi, Phyllis - EBSA; Hauser, Timothy - SOL; Doyle, Robert - EBSA

Cc: Ashley Fidel

Subject: EBSA Testimony Supplement

Hi Phyllis, Tim, and Bob,

Thanks so much for the opportunity to testify earlier this week. I thought the hearing was very productive and got to the heart of PBM transparency issues. I am writing to submit the attached supplementary comments for the record. In my additional comments, I make the following points:

- **Transparency is not harmful.** The argument against pricing or rebate transparency rests on the theory that these prices would be widely disclosed to manufacturers and hurt a PBM's ability to negotiate for rebates and discounts. In my experience as an antitrust enforcer, I can recall no occasion where disclosure has led to tacit collusion. Marketplace realities and examples of transparent PBM contracts show that these theoretical concerns bear little fruit.
- **Plan fiduciaries need access to more disclosure from PBMs to assess the reasonableness of PBM compensation and conflicts of interest.** In order for plan sponsors to fulfill their fiduciary role, they need access to all instances where PBMs receive payments from drug manufacturers, retail pharmacies, and data managers. Understanding these financial relationships enables plan fiduciaries to improve their bargaining position and achieve better benefits for their plan participants.
- **The FTC/DOJ study and FTC letters on the PBM industry are not a basis to reject the proposed regulation.** While the 2004 FTC/DOJ study took more than two years to complete, the report only includes a handful of pages on the PBM industry and two paragraphs on PBM transparency. In addition, the FTC letters objecting to proposed state transparency legislation rely on a singular economic study and no evidence from enforcement actions. The analysis advanced by the FTC/DOJ study and FTC letters lack empirical evidence that would practically suggest that transparency increases the risk of collusion.
- **Major consumer groups have supported greater PBM transparency.** Consumer groups such as AARP, Consumer Federation of American, and the National Legislative Association on Prescription Drug Prices have advocated for legislative efforts to increase PBM transparency. In addition,

the American Antitrust Institute believes the FTC's advocacy has been "ill-advised."

Again, thank you for the opportunity to offer my comments. Please let me know if I can be of further assistance.

Many thanks,

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December 8, 2010

Submitted electronically to e-ORI@dol.gov

Office of Regulations and Interpretations
Employee Benefits Security Administration
Attn: 408(b)(2) Hearing on Fee Disclosures to Welfare Benefit Plans
Rooms N-5655
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Re: Supplemental submission with respect to Hearing on Fee Disclosures to Welfare Benefit Plans under Section 408(b)(2)

Dear Sir or Madam:

I commend the Department of Labor for the significant effort that it has put into establishing adequate fee disclosures to welfare benefit plans. I specifically applaud the Department of Labor for holding the hearing on Fee Disclosures to Welfare Plans under Section 408(b)(2) on December 7, 2010. I appreciated the opportunity to testify at this hearing on behalf of consumers and the raise concerns surrounding the lack of transparency in the pharmacy benefit manager (PBM) industry. This letter is submitted to elaborate on the issues concerning PBM transparency that were raised during my testimony and during the question-and-answer period.

I. Transparency is not harmful.

One of the most puzzling arguments presented by opponents is that transparency is harmful. To an antitrust enforcer or any consumer this seems perplexing. After all, information enables a buyer to determine the costs, qualities and characteristics of what is being sold. Assistant Attorney General for Antitrust Christine Varney highlighted the importance of transparency when she said:

I am a firm believer in what Justice Brandeis said in another context: “Sunlight is said to be the best of disinfectants; electric light the most efficient policeman.” Markets work better and attempted harms to competition are more likely to be thwarted when there is increased transparency to consumers and government about what is going on in an industry.

The fundamental debate at the hearing on transparency was between theory and market reality. The central argument against pricing or rebate transparency rests largely on the theory that these prices would be widely disclosed to manufacturers and hurt a PBM’s ability to negotiate for rebates and discounts. According to this theory, plan sponsors would disclose this information to drug manufacturers who would in turn tacitly collude to fix prices. **I understand this theory, but in my over 15 years as an antitrust enforcer I can recall no occasion where firms disclosed information in this fashion and that led to tacit collusion.** In addition, there have been no enforcement actions against this kind of tacit collusion. In any case, this theoretical concern falls apart when confidentiality of shared information is required between the disclosing PBM and the plan sponsor.

Marketplace realities show that these theoretical concerns bear little fruit. The market demonstrates that transparency is helpful and has not led to inadvertent collusion or higher prices. In fact, the opposite has occurred – it is an invaluable tool to lower drug costs. In the past few years, some major corporations and government entities have switched to transparent contracts, giving us a number of examples of the effects of transparency. And the evidence overwhelmingly suggests that transparency does indeed lead to savings: the states of New Jersey and Texas are savings hundreds of millions of dollars on their state employees’ prescription drug benefit by requiring transparency of their PBMs; TRICARE and the University of Michigan have achieved significant savings by taking on key tasks, including rebate negotiation; and some of the country’s largest and most sophisticated corporations have used their bargaining power to demand transparency of their PBMs.

If transparency was truly risky we would not see major plans, government entities, state attorneys generals and Congress enacting and securing transparency in PBM arrangements.

II. Plan fiduciaries need access to more disclosure from PBMs to assess the reasonableness of PBM compensation and conflicts of interest.

Plan fiduciaries need improved access to information on the relationships, financial interests, and revenue streams of contracting PBMs. Without a broader picture of the structure and operations of PBM operations, plans cannot fully assess the accurate cost and value of their service agreements. Moreover, a lack of disclosure enables PBMs to “play the spread” and pocket indirect compensation that would otherwise result in lower costs for the plan. Some large plans and multi-employer groups may have access to ample resources and sophisticated tools to accurately assess PBM bids, however,

smaller plans and employers lack these advantages. Some smaller plans may be able to rely on consultants to choose and negotiate their PBM contract. However, these consultants often receive financial incentives from PBMs that distort their assessment of the contracts. Other small plans lack even those alternatives. Broader fee disclosures requirements are necessary to arm all plan fiduciaries with the information necessary for making informed decisions about their PBM contracts.

The crucial element of the interim final rule for retirement plans also helps to negate troubling conflicts of interest. Applying this provision to welfare benefit plans can help plans identify relationships that may prevent them from getting the best deal possible. These plans expect that their PBM will be a tough negotiator with pharmacies and seek the lowest reimbursement rates possible for them. In the case of CVS Caremark, where the largest PBM is owned by the largest pharmacy chain, there is a clear conflict of interest since the company has no incentive to seek lower reimbursement rates from its own pharmacies. At the same time, CVS Caremark has a large incentive to get customers into CVS pharmacies, and will go to any length – including restrictive plan designs or aggressive marketing tactics – to achieve that goal, even if it means decreasing service quality or limiting patients’ access to crucial medications. Greater disclosure will enable plans to identify these conflicts of interest.

The witness from the National Coordinating Committee for Multiemployer Plans (NCCMP) suggested that increased transparency would be helpful for plan fiduciaries. In his testimony, Randy DeFrehn, Executive Director of NCCMP suggested that plan fiduciaries need access to disclosures on all instances in which PBMs receive payments from drug manufacturers, retail pharmacies, and data managers. Mr. DeFrehn argued that current PBM practices can “prevent plan sponsors (board of trustees) from fulfilling their fiduciary responsibility of assuring that the fees paid for such benefits are ‘reasonable.’” Plan sponsors can better fulfill this role and improve their bargaining position by simply understanding the extent of a PBM’s financial relationships. To emphasize the lack of transparency in the PBM market, Mr. DeFrehn explained that many PBMs routinely quote a \$0.00 dispensing fee for mail-order prescriptions. This rate is analogous to a 401(k) provider saying that recordkeeping is “free.” This pricing is clearly unrepresentative of the costs associated with drug dispensing and demonstrates the lack of information available to plan sponsors when making plan design decisions for their participants.¹

III. The FTC/DOJ study and FTC letters on the PBM industry are not a basis to reject the proposed regulation.

Opponents of increased PBM transparency made very broad statements at the hearing to suggest broad DOJ and FTC opposition to transparency. However, this seems inconsistent with AAG Varney’s more recent statements. A careful examination of the sources relied on by opponents suggests that these broad assertions are unsubstantiated.

¹ See Testimony by Randy DeFrehn, Executive Director, NCCMP before the Office of Regulations and Interpretations, Employee Benefits Security Administration, Department of Labor hearing on Fee Disclosures to Welfare Benefit Plans Under Section 408(b)(2) Regulation (December 7, 2010).

First, the opponents point to the report released in 2004 by the Federal Trade Commission (FTC) and the Department of Justice (DOJ) on “Improving Health Care: A Dose of Competition.” While it is true that this study took over 2 years to complete and involved testimony from numerous market participants and experts, the vast majority of this research focused on topics that did not involve PBMs. The report is hardly exhaustive; it includes a handful of pages detailing the structure of the PBM market but only two short paragraphs on the issue of transparency. This inquiry was based on only one half day of testimony by a handful of witnesses. In addition, it did not include any empirical examination of the market. The report preceded the numerous multistate actions which found substantial ongoing fraud and deception. This report hardly provides a comprehensive perspective of competition in the PBM market and the potential risks of transparency.²

In addition to this study, opponents of PBM transparency frequently point to FTC letters objecting to proposed state laws mandating disclosures.³ The sum and substance of these letters is that unrestrained disclosure could theoretically lead to tacit collusion. The letters do not cite a single case in which some type of disclosure led to the type of tacit collusion the FTC is concerned about. Rather they rely on a single economic study that suggests that increased disclosures may lead to tacit collusion. The study has nothing to do with the pharmaceutical market or even the United States -- it relies on a singular experience in Sweden’s cement industry.⁴ Beyond this study, the FTC letters fail to cite any enforcement actions or others examples of increased transparency leading to tacit collusion or price increases. The analysis advanced by the FTC letters and the 2004 FTC and DOJ study lacks empirical evidence or historical cases that would practically suggest that transparency increases the risk of collusion. Moreover, there are several examples of transparency within the PBM market that have existed for many years, none of which have led to evidence of tacit collusion or price increases.

Finally, it is important to remember that the FTC’s mandate is different than DOL’s. The FTC’s sole concern is competition and low prices. DOL’s mandate is larger – protecting the ability of plan administrators to carry out their fiduciary obligation. For that reason, regulators and state legislatures often reject FTC advocacy. For example, the Minnesota state legislature recently enacted legislation to provide antitrust exemption for rural health cooperatives over the objections of the FTC.⁵

² U.S. Federal Trade Commission and the U.S. Department of Justice, *Improving Health Care: A Dose of Competition*, July 2004.

³ See, e.g., Letter from Susan A. Creighton, Director, Bureau of Competition, Luke M. Froeb, Director, Bureau of Economics, Maureen K. Ohlhausen, Acting Director, Office of Policy Planning and David Hyman Special Counsel, U.S. Trade Commission, to Greg Aghazarian, Assemblyman, California Legislature (September 3, 2004).

⁴ Svend Albaek et al., Government Assisted Oligopoly Coordination? A Concrete Case, 45 J. INDUS. ECON. 429 (1997).

⁵ Minnesota Health Care Cooperative Act, Minn. Statute §62R.01, et seq. (2010).

IV. Major consumer groups have supported greater PBM transparency.

During the hearing, the opponent of transparency seemed to suggest that pharmacies were the only advocates for transparency and their views should be discounted because they are competitors of PBMs. They are mistaken. Many consumer groups, including AARP⁶, Consumer Federation of America, US PIRG and the National Legislative Association on Prescription Drug Prices (NLARx), a nonpartisan alliance of state legislatures from 10 states and the District of Columbia, have advocated for bipartisan legislative efforts to increase PBM transparency. NLARx in particular has demonstrated that the FTC's comments lack an empirical basis for their broad conclusions. NLARx highlights the lack of "on-the-ground facts" cited by the FTC and the need for a fully informed debate on the impact of PBM transparency.⁷

In addition to opposition by NLARx, the American Antitrust Institute (AAI) has criticized the FTC's advocacy. In *The Next Antitrust Agenda*, the AAI found that the FTC's position on state legislative efforts to increase PBM transparency is particularly problematic. The AAI argues that "considering the substantial number of enforcement actions and the severity of the PBM conduct, we believe these efforts at regulating PBMs are well founded and that the FTC's advocacy has been ill-advised."⁸

Again, thank you for the opportunity to provide testimony on behalf of consumers and answer your questions on these issues. As you look further into fee disclosures and PBM transparency, please let me know if I can be of further assistance.

Sincerely,



David A. Balto

⁶ See AARP's amicus brief in support of the District of Columbia's PBM transparency statute. Brief of Amici Curiae of AARP, Legal Counsel for the Elderly and The Prescription Access Litigation Project in Support of Appellees, *Pharmaceutical Care Management Association v. District of Columbia, et. al.* U.S. Court of Appeals for the District of Columbia Circuit. No. 07-0762. (December 20, 2007).

⁷ Letter from Mark Montigny, Chair of the Board, National Legislative Assembly on Prescription Drug Prices to the Honorable Deborah Platt Majoras, Chair, Federal Trade Commission (May 11, 2005).

⁸ Albert Foer (editor). *The Next Antitrust Agenda: The American Antitrust Institute's Transition Report on Competition Policy to the 44th President*. American Antitrust Institute. Vandeplass Publishing. September 2008. Page 327.