



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

March 31, 2009

Hon. James L. Seward
Senator, 51st District
Legislative Office Building
Albany, NY 12247

Dear Senator Seward:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics¹ are pleased to respond to your request for comments on the likely competitive effects of the pharmacy benefit manager ("PBM") related provisions of New York Senate Bill 58 ("SB-58" or "the Bill"), which would regulate the contractual relationships between PBMs and health benefit plans ("health plans").² You asked the FTC to examine the Bill to determine "whether the proposed legislation is anti-competitive and will likely result in the increased cost of pharmaceutical care for consumers."³

We are concerned that SB-58, if enacted, may increase pharmaceutical prices and may reduce the number of New York consumers with insurance coverage for pharmaceuticals. The bill creates mandatory disclosures that PBMs must make to health plans and, in some cases, doctors and imposes fiduciary-like duties on PBMs in their relationships with health plans, all of which will increase the cost of the services PBMs provide. At the same time, these added requirements are unlikely to generate many

¹ This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the Federal Trade Commission (Commission) or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

² PBMs contract with Health plans to manage the cost and quality of the plans' drug benefits. They act as clearinghouses for health plans, covered individuals, and retail pharmacies, and may provide a variety of related services. These include: 1) developing drug formularies and negotiating discounts and rebates from drug companies in exchange for preferential placement in the formulary; 2) developing networks of local pharmacies; 3) providing access to mail order pharmacies; 4) providing analysis of physician prescribing patterns; and 5) providing treatment information and monitoring of covered individuals with certain chronic diseases.

³ Letter from Hon. James L. Seward to James Cooper, Acting Director, Office of Policy Planning, Federal Trade Commission (Jan. 26, 2009). This comment addresses SB-58, as requested, but staff notes that parallel legislation has been introduced in the New York Assembly as AB-58.

benefits. Although the bill attempts to eliminate perceived conflicts of interest (and some lawsuits have challenged particular types of PBM conduct),⁴ empirical evidence suggests that those conflicts of interest are not prevalent. Health plans are sophisticated companies capable of preventing the conflicts of interest that the Bill attempts to address. Indeed, the Commission's recent study of the PBM industry finds that health plans protect themselves from potential conflicts of interest in arms-length contracts with PBMs.⁵

Interest and Experience of the Federal Trade Commission

Congress has charged the Federal Trade Commission ("FTC" or "Commission") with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.⁶ 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,⁷ issued reports and studies regarding various aspects of the pharmaceuticals industry,⁸ and brought numerous enforcement actions against entities in that industry.⁹

Of particular relevance is the Commission's "Conflict of Interest Study" regarding PBM practices. In response to a request from Congress in 2003, the FTC analyzed data on PBM pricing, generic substitution, therapeutic interchange, and repackaging practices. The study examined whether PBM ownership of mail-order pharmacies served to maximize competition and lower prescription drug prices for plan sponsors. In its 2005 report based on the study ("PBM Study"), the FTC found, among

⁴ See, e.g., *United States v. Merck-Medco Managed Care, L.L.C.*, Case No. 00-CV-737 (E.D. Penn. Dec. 9, 2003); *In re Pharmaceutical Industry Wholesale Price Litig.*, MDL No. 1456, Civ. Act. No. 01-cv-12257-PBS (D. Mass. 2002). Some complaints allege that failure to disclose or remit rebates either breached a contractual requirement or breached an asserted duty to disclose or remit rebates under some other existing law. See, e.g., *New York v. Express Scripts, Inc.* (N.Y. Sup. Ct. Aug. 4, 2002). Because these duties to disclose or remit rebates allegedly arise under existing legal obligations, it is unclear how SB-58's additional legal requirements that, e.g., PBMs disclose sensitive financial information to various parties are likely to serve as direct or effective means of improving compliance with the existing obligations that have been subject to legal controversy.

⁵ See generally Federal Trade Commission, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (Aug. 2005) ("PBM STUDY"), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>.

⁶ Federal Trade Commission Act, 15 U.S.C. § 45.

⁷ See Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products* (Oct. 2003), available at <http://www.ftc.gov/bc/hcupdate031024.pdf>.

⁸ See Federal Trade Commission, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION* (July 2002); DAVID REIFFEN AND MICHAEL R. WARD, *GENERIC DRUG INDUSTRY DYNAMICS*, Federal Trade Commission Bureau of Economics Working Paper No. 248 (Feb. 2002), available at <http://www.ftc.gov/be/econwork.htm>.

⁹ See Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products* (Oct. 2005), available at <http://www.ftc.gov/bc/0310rxupdate.pdf>.

other things, that competition affords health plans substantial tools with which to safeguard their interests.¹⁰

This study continued the FTC's ongoing experience with PBMs. PBM practices were a particular focus of hearings on health care markets jointly conducted by the FTC and the Department of Justice Antitrust Division ("DOJ") in 2003 ("Health Care Hearings").¹¹ In 2004, the FTC and DOJ issued a report based on the hearings, a Commission-sponsored workshop, and independent research.¹² The FTC investigated the competitive implications of a proposed merger between two PBMs, Caremark and AdvancePCS.¹³ In addition, FTC staff have analyzed and commented on proposed PBM legislation in several states.¹⁴

Likely Effects of SB-58

Several provisions of the Bill could be read in ways harmful to competition and consumers. First, mandatory disclosures of PBM business information to health plans may excessively restrict the abilities of PBMs and health plans to negotiate efficient, mutually advantageous contracts. To the extent that mandatory disclosures may increase the risk that sensitive business information becomes public, they may also facilitate collusion among third parties. Second, mandatory disclosures to physicians may be overbroad, and open-ended requirements that PBMs disclose financial information to physicians may chill the implementation of cost-saving drug interchange programs. Third, the general duties of PBMs described in the Bill are unclear and may suggest significant and costly risks, including forms of liability beyond those contemplated under contract law or health regulations. Collectively, these requirements may increase the prices that health plans, and ultimately New York consumers, pay for pharmaceuticals.

(a) Disclosures to Health Plans

SB-58 would require a PBM to make substantial disclosures to a health plan during contract negotiations, both before entering into an initial contract and annually thereafter.¹⁵ These disclosures include extensive details of the PBM's underlying cost

¹⁰ PBM STUDY, *supra* note 5 at 58 (noting diverse audit rights and reporting under PBM contracts).

¹¹ See Hearings on Health Care and Competition Law and Policy, June 26, 2003, *available at* <http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf>. ("Health Care Hearings") Subsequent references to the hearings will identify a panelist, affiliation (as of hearing date), and transcript page.

¹² See FEDERAL TRADE COMMISSION AND DEPARTMENT OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), *available at* <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

¹³ Statement of the Federal Trade Commission, *In re Caremark Rx, Inc./AdvancePCS*, File No. 0310239 (Feb. 11, 2004), *available at* <http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf>. The Commission closed the investigation because it concluded that the transaction was unlikely to reduce competition.

¹⁴ See, e.g., Letter from FTC staff to New Jersey Assemblywoman Nellie Pou (Apr. 17, 2007), *available at* <http://www.ftc.gov/be/V060019.pdf>; Letter from FTC staff to Virginia Delegate Terry G. Kilgore (Oct. 2, 2006), *available at* <http://www.ftc.gov/be/V060018.pdf>.

¹⁵ See generally SB-58 at § 4453.

structure and business strategies. For example, under SB-58, before entering into a contract with a health plan, a PBM must disclose not only “all the goods and services it offers to provide the health plan” but “the net cost for each such service or good.”¹⁶ Before entering into a contract, and periodically thereafter, a PBM must disclose “the content of all contracts and other agreements it directly or indirectly has with, and all payments it receives from a drug manufacturer . . . or other third party in connection with any [PBM] service it provides to the health plan.”¹⁷ Quarterly disclosures must include, for example, not just actual conflicts of interest but “every activity, policy or practice of the [PBM] that directly or indirectly presents any actual or potential conflict of interest with the health plan”; quarterly disclosures must also include “any increase in the dispensing fee paid to any pharmacy and the reason for such increase” (independent of the question whether the increase is passed on to the health plan).¹⁸ The Department of Health is given broad latitude to “promulgate regulations that set out the nature, content and format of the disclosures required.”¹⁹

(1) Potential Harms to Consumers

Staff’s two principal concerns about the disclosure provisions are these: first, they may increase the cost of the PBM’s services because it will preclude health plans and PBMs from entering into efficient (*i.e.*, cost-effective) contracts for the administration of pharmacy benefits; and second, they may have the unintended consequence of publicizing proprietary business information in a way that could foster collusion among third parties. As to the first of these concerns, if the health plan and PBM both prefer and, in the absence of the legislation, would agree to different disclosure and audit terms than those mandated by SB-58, the bill may impose costs on both parties.²⁰ Health plans appear to have diverse business interests in disclosures and audit rights, because individual plans tend to negotiate for very different disclosure and audit terms in different circumstances.²¹ Hence, the bill by imposing unneeded and unwanted disclosures will increase health care costs, and such costs may be reflected in the price of drug plans that health plans are able to offer New York health care consumers, the scope of coverage consumers receive under such plans, or the number of consumers who have access to such coverage.²²

¹⁶ *Id.* at § 4453(2)(A).

¹⁷ *Id.* at § 4453(2), (3).

¹⁸ *Id.*

¹⁹ *Id.* at § 4453(5).

²⁰ It is not that any particular set of PBM disclosures to a health plan provides an ideal competitive model that is inconsistent with SB-58, but its imposition of disclosures that health plans may neither want nor need that is problem. In addition to any direct costs imposed, mandatory disclosures would limit a health plan’s ability to bargain over various disclosure terms in the interest of other contract terms that may be more important to its particular business interests.

²¹ PBM Study, *supra* note 5 at 58.

²² In addition to costs that may be entailed by specific restrictions on established preferred contract terms, health plans and PBMs may be concerned that numerous statutory restrictions on their ability to contract freely will harm their ability to develop and test innovations in this relatively new marketplace. *See, e.g.*,

In addition – discussed in more detail below – ambiguous language in the Bill’s confidentiality provisions may undermine their effectiveness. Although SB-58 provides confidentiality protections for some information disclosed to health plans, the scope of those protections is unclear. To the extent that confidentiality provisions in the Bill are inadequate, they may permit the broader disclosure of sensitive financial information, which may, in turn, facilitate collusion, raise prices, and harm the patients the Bill is supposed to protect. If, for example, pharmaceutical manufacturers know the precise details of rebate arrangements offered by their competitors, then tacit collusion among them may be more feasible.²³ Absent such knowledge, manufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment may yield increased sales. Unprotected disclosures thus may raise the price that New York consumers pay for pharmaceutical coverage by undermining competition among pharmaceutical companies for preferred formulary treatment.

Consumers need accurate information on price and quality to make efficient purchasing decisions. For this reason, the FTC has challenged collusive attempts to suppress price information for consumers²⁴ and has opposed government regulation that restricts advertising to consumers.²⁵ Pharmaceutical payments PBMs receive from manufacturers, however, are just one factor among many that determine PBM pricing – in essence, the payments function as manufacturer discounts on the cost of drug products.

Neil Model, *PBM transparency: More than meets the eye*, Employee Benefit News (Nov. 2006), available at <http://www.benefitnews.com/detail.cfm?id=9740> (new contract provisions addressing pass-through pricing and disclosure and possible advantages and disadvantages to exploring different contract options). Finally, some PBMs may curtail or terminate services offered in N.Y., especially as some of the information that they would have to disclose is not state-specific.

²³ Economists have long understood that when oligopolists share information on transaction prices and other competitively sensitive variables, it makes coordination among rivals more likely. See Kai-Uwe Kuhn, *Fighting Collusion: Regulation of Communication Between Firms*, 16 ECON. POLICY. 169, 170 (2001) (“The notion that communication is central to collusion is without doubt part of the general folklore of competition policy at least going back to Adam Smith.”); Svend Albaek, Peter Møllgaard, & Per B. Overgaard, *Government-Assisted Oligopoly Coordination? A Concrete Case*, 45 J. INDUS. ECON. 429, 430 (1997) (“At least since Stigler’s seminal article, [industrial organization] literature has stressed the importance for (tacitly) colluding oligopolists of observing firm-specific transactions prices of their rivals and rapidly detecting changes in these. Otherwise, collusion is prone to break down.”). Several empirical studies have shown transparency policies to be associated with higher prices. See Stephen W. Fuller et al., *Effect of Disclosure on Price: Railroad Grain Contracting in the Plains*, 15 W. J. AGRICULTURAL ECON. 265 (1990); see also Maura P. Doyle & Christopher M. Snyder, *Information Sharing and Competition in the Motor Vehicle Industry*, 107 J. Pol. Econ. 1326 (1999) (finding evidence that automakers respond strategically to production announcements by rivals).

²⁴ See, e.g., *Fair Allocation System, Inc.*, FTC Docket No. C-3832 (1998) (consent order) (challenging concerted action by auto dealers to restrict a competing dealer’s ability to advertise over the Internet); see also *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447 (1986) (challenging a dental association rule that prohibited dentists from submitting x-rays to dental insurers in connections with claims forms).

²⁵ See, e.g., *Massachusetts Bd. of Registration of Optometry*, 110 F.T.C. 549 (1988); FTC Staff Comments in the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion, Before the FDA, Docket No. 2004D-0042 (May 10, 2004), available at <http://www.ftc.gov/os/2004/05/040512dtcdugscomment.pdf>.

Thus, the disclosure requirements are analogous to requirements that firms reveal aspects of their cost structures to customers. There is no theoretical or empirical reason to assume that consumers require sellers' underlying cost information for markets to achieve competitive outcomes

(2) Undemonstrated Need

Although sometimes mandatory disclosures of price and quality information can improve how markets function – and the Commission enforces several rules that require sellers to disclose this type of information – health plans do not need them.²⁶ Although a few lawsuits have challenged particular types of PBM conduct,²⁷ empirical evidence suggests that the conflicts of interest that the Bill attempts to address are not prevalent. In addition, the Commission's analysis of PBM/health plan contracts in its PBM STUDY shows that health plans already are able to negotiate contract terms – including diverse disclosure and audit rights – that protect them from conflicts of interest.²⁸ Press reports too suggest that many contracts provide for full disclosure to client health plans.²⁹ Allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms mandated by government regulation.

(3) Confidentiality Provisions are Unclear and Potentially Inadequate

Although SB-58 provides confidentiality protections for some information disclosed to health plans, the scope of those protections is unclear. To the extent that confidentiality provisions in the Bill are inadequate, they may permit the broader disclosure of sensitive financial information, which may, in turn, facilitate collusion, raise prices, and harm the patients the Bill is supposed to protect.

Under SB-58 a PBM is required to make certain disclosures to health plans, but “may designate information it discloses to a health plan as confidential, and the health plan shall not re-disclose such information to other entities,” except in certain circumstances.³⁰ Among other possible exceptions, “with respect to documents disclosed to a health plan that are subject to article six of the public officers law, the [PBM] shall

²⁶ See, e.g., 16 CFR Part 453 (“Funeral Rule,” requiring disclosure to consumers of an accurate itemized “General Price List” that they can keep and that includes the prices for the commonly used funeral goods and services the funeral home offers); 16 CFR Part 436 (“Franchise Rule,” requiring certain disclosures in connection with “the advertising, offering, licensing, contracting, sale, or other promotion in or affecting commerce . . . of any franchise, or any relationship which is represented either orally or in writing to be a franchise.”) In addition, as noted above, the Commission has opposed artificial restrictions on commercial information available to consumers. See, e.g., *supra* notes 24-25, and accompanying text.

²⁷ See *supra* note 4.

²⁸ See PBM STUDY, *supra* note 5, at 58.

²⁹ See, e.g., Milt Freudenheim, *Employers Unite in an Effort to Curb Prescription Drug Costs*, N.Y. Times, Feb. 3, 2005; Milt Freudenheim, *Big Employers Join Forces in Effort to Negotiate Lower Drug Prices*, N.Y. TIMES, June 12, 2004.

³⁰ SB-58 at § 4453(1).

not designate as ‘confidential’ any document to which the public would have broad access under said law, and the provisions of article six of the public officers law shall apply to the documents disclosed to such health plan.”³¹ Article six of the New York Public Officers Law, known as the “Freedom of Information Law,”³² includes a legislative declaration that the people have a “right to know the process of government decision-making,” and that “access to [pertinent information] should not be thwarted by shrouding it with the cloak of secrecy or confidentiality.”³³ As a general requirement, subject to certain exceptions, every state agency “shall . . . make available for public inspection and copying all records.”³⁴

Staff believes that the interaction between the general disclosure requirements of SB-58 and FOIL is unclear and raises concerns about the extent to which a PBM can designate as confidential its proprietary business information. Although FOIL does provide that an agency may deny access to certain records or portions thereof if those records pertain to a competitive enterprise and “if disclosed would cause substantial injury to the competitive position of the competitive enterprise,”³⁵ certain concerns remain. First, the Bill could render a PBM’s private and proprietary business information subject to public inspection via the Department of Health, under FOIL. That concern is bolstered by (1) the background presumption in favour of disclosure, (2) the full range of PBM business information available to the Department of Health, and (3) the lack of clarity in the law as to specific types of business information that will not be made public because, in the judgment of the Department, disclosure “would cause substantial injury to the competitive position of the [PBM].”³⁶ Second, to the extent that the scope of public access to PBM business information under FOIL may be unclear, and given that a PBM may not designate as confidential “any document to which the public would have broad access under [FOIL],” a PBM simply may not know what business information it is able to designate as confidential under SB-58.

(b) Disclosures to Physicians

Required PBM disclosures to physicians under the Bill appear to be overbroad. In addition, open-ended requirements that PBMs disclose financial information to physicians may be unduly costly and a risk to the confidentiality of proprietary business information. As such, the requirements may chill the implementation of cost-saving drug

³¹ *Id.* In addition, the “applicability of article six of the public officers law to a health plan’s records does not affect the [PBM’s] obligation under this article to disclose documents to the health plan.” *Id.*

³² NY CLS Pub O § 85 (2008).

³³ *Id.* at § 84.

³⁴ *Id.* at § 87(2). The reference to FOIL Law raises two questions: (1) what is the information that PBMs must disclose to health plans that PBMs cannot designate as confidential? And (2) what PBM business information may be open to public inspection under FOIL in any case?

³⁵ *Id.*

³⁶ As previously noted, public disclosure of a PBM’s private and proprietary business information may facilitate tacit collusion among drug manufacturers, resulting in higher drug prices and harming consumers.

interchange programs.

SB-58 places certain restrictions on drug substitutions used under some PBM/health plan contracts to lower overall costs of drug benefits by increasing the use of lower cost, therapeutically effective drugs.³⁷ When a “drug switch” is requested, the PBM must “provide the prescriber with all of the financial and clinical information the prescriber needs to determine whether the drug switch is in the patient’s best interest.”³⁸ As drafted, the provision is vague and potentially over-broad. The FTC staff does not mean to express any opinion on the clinical considerations a prescribing physician should undertake prior to the issuance of a lawful prescription or in evaluating any amendment to that prescription. At the same time, the staff notes that “all of the financial and clinical information” that may be pertinent to a patient’s best interests includes, on its face, non-clinical financial information. The scope of that required disclosure is unclear. That lack of clarity, and potential concerns about the disclosure of proprietary financial information to physicians who are not required to maintain that information in confidence, may work to chill otherwise cost-effective interchange programs.

To the extent that SB-58 reduces the incidence of cost-saving substitution, it will increase pharmaceutical costs for health plans. Therapeutic interchange programs have the potential to increase usage of less expensive, but therapeutically effective, branded drugs or their generic equivalents.³⁹ The PBM Study noted that interchange programs are costly to implement and that, in practice, interchanges have been relatively rare.⁴⁰ Nonetheless, the Study data confirm that, if implemented, interchange programs should tend to reduce costs for health plan sponsors that use them.⁴¹ Furthermore, interchange programs can play a useful role in the negotiation of discounts with manufacturers.⁴²

(c) General Duties

³⁷ Therapeutic interchange is the substitution of a drug that is designed to have similar therapeutic effects, and is approved by FDA for treatment of the same indication, but is in some regard pharmaceutically different. *See* R. Herdman & D. Blumenthal, eds., *Description and Analysis of the VA National Formulary* (Institute of Medicine June 2000), available at www.nap.edu/books/0309069866/html. Certain instances of therapeutic interchange are likely to be considered drug switches under SB-58.

³⁸ SB-58 at § 4454.

³⁹ *See, e.g.*, PBM STUDY, *supra* note 5, at 28, Fig. II-2, and 61.

⁴⁰ Two large PBMs submitting data for the PBM STUDY under special orders employed therapeutic interchange in filling “less than one-half of one percent (0.5%) of prescriptions dispensed at retail and at PBMs’ owned mail-order pharmacies.” *Id.* at 84. The data represent the practices of two large PBMs in 2002 and 2003 and may not represent the frequency of therapeutic interchange across the industry. *See id.*

⁴¹ *See id.* at 81. Examining data regarding drug pairs for which PBMs had authorized a program to substitute (interchange) one member of the pair for the other provides some indication of the potential for therapeutic interchange to lower costs if implemented. “In the 10 therapeutic categories the Commission examined, study participants’ data showed that the use of TI could reduce plan sponsors’ costs in a majority of cases.” *Id.*

⁴² The PBM STUDY reports that “[o]ne PBM indicated that it regards the real value of [therapeutic interchange] programs as a negotiating tool with manufacturers to obtain higher pharmaceutical payments or allowance rates.” PBM STUDY, *supra* note 5, at 84.

Among the proposed general obligations of a PBM are that it perform, “in connection with [PBM] services it provides to a health plan or participants in the state with care, skill, prudence, and diligence.”⁴³ These duties are not defined in the Bill, and without further clarification, they may suggest PBM liability for civil actions sounding in torts or agency, above and beyond any potential liability established under contract law. In particular, the suite of duties enumerated in SB-58 – “care, skill, prudence, and diligence” – may suggest an agency relationship, such as a fiduciary relationship, between PBMs and health plans, as these are traditional fiduciary duties of service or performance.⁴⁴ Moreover, the Bill’s language is similar to the federal ERISA statute’s definition of fiduciary duties.⁴⁵ If the duties are read as fiduciary duties, they may further restrict the formation and interpretation of contracts in this area because, although a fiduciary relationship generally may be defined by the terms of a contract between the fiduciary and its principal, “even specific agreements ... must be interpreted in the light of the principles which are applicable to the relation of principal and agent.”⁴⁶ A fiduciary may, for example, owe its principal a “duty to give information” that is independent of any express disclosure requirements imposed under contract or statute, as well as a “duty to account for profits” that may require the pass-through of payments to the principal.⁴⁷

As noted above, our analysis of PBM/health plan contracts shows that health plans already are able to negotiate diverse payment terms – which sometimes include the pass-through of pharmaceutical payments – and diverse information disclosure and audit

⁴³ N.Y. S.B. 58, § 4452.

⁴⁴ See, e.g., RESTATEMENT (THIRD) OF AGENCY § 8.08 (duties of care, competence, and diligence among duties of performance); J. Dennis Hynes, *Freedom of Contract, Fiduciary Duties, and Partnerships: The Bargain Principle and the Law of Agency*, 54 WASH. & LEE L. REV. 439, 443 (1997).

⁴⁵ 29 USC 1104(a)(1)(B) (fiduciary “shall discharge his duties with respect to a plan ...with ...care, skill, prudence, and diligence”). The Supreme Court has observed that, “rather than explicitly enumerating all of the powers and duties of trustees and other fiduciaries, Congress invoked the common law of trusts to define the general scope of their authority and responsibility.” *Central States, Southeast & Southwest Areas Pension Fund v. Central Transport, Inc.*, 472 US 559, 570 (1985). The Court further observed that the statutory duties of “care, skill, prudence, and diligence” were required under the traditional fiduciary duty of care at common law. *Id.* at 571. FTC staff does not suggest that the Bill seeks to alter the meaning or application of the federal ERISA statute – the Bill expressly disclaims alteration of certain fiduciary relationships established under ERISA. SB-58 at § 4451.

⁴⁶ RESTATEMENT (SECOND) OF AGENCY, at Chapter 13, introductory note; see also, e.g., *Ulico Casualty Co. v. Wilson*, 56 A.D.3d 1 (N.Y. App. Div. 2008) (because attorney is fiduciary, his “obligations transcend those prevailing in the commercial market place, and a firm may not circumscribe its professional obligations by purporting to transform [the relationship] into an arm’s length commercial affiliation.” *Id.* at 5 (citations omitted)).

⁴⁷ See, e.g., *The Bank of New York AS TRUSTEE FOR THE CERTIFICATEHOLDERS CWABS, INC. ASSET-BACKED CERTIFICATES SERIES 2006-22 v. Cremston Myers*, 2009 N.Y. Slip Op 50159U, [*3] (Feb. 3, 2009) (agent as fiduciary must “account to his principal for secret profits” and forfeits right to compensation for services rendered he violates fiduciary duty of loyalty); RESTATEMENT (THIRD) OF AGENCY §§ 8.02 (material benefit arising out of position) and 8.11 (duty to give information).

rights.⁴⁸ The FTC staff's concern in the instant case is not that any particular terms are anticompetitive. The concern, rather, is that the general duties of PBMs as drafted in SB-58 may (a) be read to suggest substantial restrictions on the formation of mutually advantageous contracts between PBMs and health plans and (b) introduce additional risk into such contracts to the extent that the precise nature of those restrictions is unclear.

In making these comments, staff is analyzing the duties imposed by the bill; staff is not taking a position on the question whether ERISA would preempt this legislation. Courts have taken different positions on the extent to which ERISA preempts state laws regulating the relationship between PBMs and health plans.⁴⁹

Conclusion

Allowing competition among PBMs is more likely to yield efficient levels of payment sharing, disclosure, and price than contract terms mandated by government regulation. By forcing PBM's to disclose more information than the health plans want or need, SB-58 may unnecessarily increase the costs of providing pharmaceutical coverage. The additional costs could be passed on to plan sponsors and individual health plan consumers in the form of higher prices, and may ultimately reduce the number of New York consumers who have pharmaceutical coverage and the quality of the coverage available. As an article in *Health Affairs* noted, "when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions."⁵⁰

At the same time, there does not appear to be any compelling reason to restrict competition to protect health plans. While some lawsuits have raised concerns about certain PBM conduct, as we concluded in the PBM Study, health plans appear able to protect themselves from potential conflicts of interest for PBMs already through arms-length contracts.

We appreciate this opportunity to share our views and welcome any further discussions regarding competition policies.

⁴⁸ See PBM STUDY, *supra* note 5, at 58.

⁴⁹ In *Pharmaceutical Care Mgmt. Ass'n v. District of Columbia*, Civ. Action No. 04-1082 (RMU) (D.D.C. Mar. 19, 2009), Mem. Op. & Order, the DC district court held that ERISA preempted state law that regulated "the relationship between PBMs and ERISA plans." The court found that the "proposed regulations would require a PBM to disclose to the plan 'the compensation it will receive, directly or indirectly, and any conflicts of interest that may arise in connection with its service to the plan,' *Id.* at 17. In contrast, in *PCMA v. Rowe*, 429 F.3d 294 (1st Cir. 2005), the First Circuit found that ERISA did not preempt a Maine statute imposing similar obligations on PBMs.

⁵⁰ William Sage, David A. Hyman & Warren Greenburg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (March/April 2003). Although estimates of the elasticity of demand for health insurance coverage vary, the empirical evidence is clear that higher costs result in less coverage. See David M. Cutler, HEALTH CARE AND THE PUBLIC SECTOR, NBER Working Paper W8802, Table 5 (Feb. 2002), available at <http://papers.nber.org/papers/W8802>.

Respectfully submitted,

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James Cooper
Acting Director
Office of Policy Planning

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Pauline M. Ippolito
Acting Director
Bureau of Economics

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David P. Wales
Acting Director
Bureau of Competition