UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
Washington, DC 20580

Bureau of Competition
Bureau of Economics
Office of Policy Planning

September 7, 2004

Assembly Member Greg Aghazarian
State Capitol, Room 2130
Sacramento, CA 95814

Dear Assemblyman Aghazarian:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics are pleased to respond to your requests for comments on the competitive effects of California Assembly Bill No. 1960 ("AB 1960").[1] AB 1960 requires pharmacy benefit managers (PBMs) to make specified disclosures to "purchasers" and "prospective purchasers" with regard to their revenues and drug formularies.[2] AB 1960 also requires PBMs to make specified disclosures to prescribers and consumers, and sets certain requirements for PBM contracts, formularies, and staffing.[3] In your letter dated May 6, 2004, you asked us to analyze the competitive implications of AB 1960 and discuss whether it is likely to "result in the increased cost of pharmaceutical care for consumers."

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[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] AB 1960 defines a "purchaser" as "any person who enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services," and a "prospective purchaser" as "any person to whom a pharmacy benefits manager offers to provide pharmacy benefits management services." AB 1960 § 1 (150000)(d)-(e).

[3] AB 1960 does not formally define "prescribers," but the context makes it clear that it is the health care professional who originally prescribed the pharmaceutical in question. AB 1960 § 1 (150007)(a).

AB 1960 has been amended seven times since its introduction, but the bill's fundamental objectives (increasing cost transparency in transactions between PBMs and their health plan clients, providing more information to consumers and prescribers with respect to certain drug substitutions,[4] and ensuring that realized cost savings are passed on to consumers) do not appear to have changed.[5]

We believe that AB 1960, if enacted, may have the unintended consequences of limiting competition, thus increasing the cost of pharmaceuticals and ultimately decreasing the number of Americans with insurance coverage for pharmaceuticals. Specifically, we believe that AB 1960 may make it more difficult for PBMs to generate cost savings (including rebates) and may well make those cost savings smaller. To the extent that AB 1960 increases the cost of pharmaceuticals, it may result in an increase in health insurance premiums and reduced availability of insurance coverage for pharmaceuticals.

Although AB 1960 appears likely to discourage drug substitutions that may be aimed only at increasing PBM profitability, it does so by making all substitutions more difficult, time-consuming, and expensive. Drug substitutions can save money for consumers without placing their health at risk. As a recent Food and Drug Administration ("FDA") white paper noted, use of generic drugs can "significantly reduce overall health care costs" by providing "medicines that are just as safe and effective as their brand-name counterparts."[6] California already requires prior prescriber approval for therapeutic interchange, thus limiting the risk associated with substitution to a lower-cost alternative brand name drug. To the extent AB 1960 makes generic substitution and therapeutic interchange more difficult, it again has the potential to increase health insurance premiums and restrict the availability of insurance coverage for pharmaceuticals. Finally, we do not believe AB 1960 will materially increase the probability that realized cost savings (including rebates) are passed on to consumers.

In this letter, we focus on cost transparency, drug substitution, and whether cost savings are being passed on to consumers. We do not address other provisions in AB 1960.

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[4] Drug substitution encompasses generic substitution and therapeutic interchange (or clinical interchange). *See* page 6 *infra*. Different disclosure is required, depending on the type of drug substitution at issue. *Id.*

[5] This letter refers to the version of AB 1960 voted on favorably by the Senate on August 24, 2004, and the Assembly on August 25, 2004. We note that the amendments made to AB 1960 since its introduction have lessened the bill's likely anticompetitive effects. Generally, in the spectrum of PBM regulation, disclosure-based regulations such as AB 1960 are likely to raise fewer competitive concerns than regulation that imposes greater restrictions on PBM contracts, such as mandating that rebates be returned to purchasers or consumers, or requiring that PBMs enter into a fiduciary relationship with purchasers.

[6] Food and Drug Administration, NEW FDA INITIATIVE ON "IMPROVING ACCESS TO GENERIC DRUGS," (June 12, 2003), available at http://www.fda.gov/oc/initiatives/generics/whitepaper.html.

Interest and Experience of the Federal Trade Commission

The Federal Trade Commission (Commission) is charged by statute with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[7] Pursuant to this statutory mandate, the Commission seeks to identify business practices and regulations that impede competition without offering countervailing benefits to consumers. For several decades, the Commission and its staff have investigated the competitive effects of restrictions on the business practices of health care providers.[8] The Commission has brought numerous enforcement actions against entities involved in the pharmaceutical industry,[9] and the Commission and its staff have issued reports and studies regarding various aspects of the pharmaceutical industry.[10]

The Commission also has extensive recent experience with PBMs. On April 8, 2004, Commission staff commented on proposed legislation in Rhode Island directly affecting PBMs.[11] Earlier this year, the Commission investigated the competitive implications of a proposed merger between Caremark and AdvancePCS.[12] On June 26, 2003, the Commission and Department of Justice Antitrust Division (Division) held a half-day of hearings on PBMs, as part of their Hearings on Health Care and Competition Law and Policy (Health Care Hearings).[13] The report jointly issued by the Commission and the Division on July 23, 2004, addressed the issues raised by PBMs as well.[14] Finally, Commission staff currently are conducting a

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

[8] *See* Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products*, available at http://www.ftc.gov/bc/hcupdate031024.pdf.

[9] *See* Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products*, available at http://www.ftc.gov/bc/0310rxupdate.pdf.

[10] *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; Roy Levy, THE PHARMACEUTICAL INDUSTRY: COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, Federal Trade Commission Bureau of Economics Staff Report (March 1999), available at http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

[11] Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, April 8, 2004, available at http://www.ftc.gov/os/2004/04/ribills.pdf.

[12] 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.

[13] Health Care Hearings, June 26, 2003. http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf. S*ee also* http://www.ftc.gov/ogc/healthcarehearings/03062526agenda.htm. All subsequent references to the hearings will identify a panelist, affiliation, and transcript page. Affiliations are as of the date of the hearing.

[14] Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Chapter 7 (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

Congressionally mandated study on the cost implications of PBM use of mail order pharmacies.[15]

Description of AB 1960

AB 1960 requires PBMs to disclose the following information to purchasers and prospective purchasers of PBM services: the aggregate amount of rebates received for drug benefits specific to the purchaser or prospective purchaser; aggregate rebates for each therapeutic class of pharmaceuticals specific to the purchaser or prospective purchaser; nature and amount of revenue received from pharmaceutical manufacturers and labelers for drug benefits related to the purchaser or prospective purchaser; administrative fees charged to the purchaser; and arrangements with providers, pharmacists and other entities to encourage formulary compliance or manage prescription drug benefits.[16] AB 1960 also requires PBMs to disclose drug utilization information to purchasers (but not prospective purchasers). AB 1960 provides that a PBM need not make these disclosures unless the purchaser or prospective purchaser agrees to protect the confidentiality of any proprietary information.[17] AB 1960 excludes health plans and health insurers that provide pharmacy benefit management services to their own enrollees from these disclosure requirements.

AB 1960 also imposes disclosure requirements to prescribers and patients before a PBM may substitute one medication for another. AB 1960 requires a PBM that is requesting authorization from a prescriber to substitute a medication to disclose a range of information, including the cost savings (if any) to the purchaser; the difference (if any) in the consumer co-payment; the existence of any payments received by the PBM as a result of the substitution; the circumstances (if any) under which the existing prescription would be covered; the circumstances under which health care costs arising from the change in medications will be compensated; and any known differences in potential effects on health and human safety of the new medication.[18] AB 1960 states that this information need not be provided to the health care

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[15] Federal Trade Commission, *Pharmacy Benefit Manager Conflict of Interest Study Public Notice*, March 26, 2004, available at http://www.ftc.gov/os/2004/03/040326pnpbm.pdf.

[16] AB 1960 §§ 150001, 150002. This information is to be provided to the purchaser no less frequently than quarterly. A PBM is not required to disclose discounts associated with prescription drugs purchased for sale and distribution through the PBM's mail order pharmacy. AB 1960 §§ 150001 (c), 150002 (c).

[17] AB 1960 § 150003 (b).

[18] AB 1960 § 150006 (a). California law prohibits the dispensing of a prescription pharmaceutical without a valid prescription. Although California law permits pharmacies to substitute a generic equivalent for a brand name drug in certain circumstances (*see* CA. BUS. & PROF'L CODE § 4073) a pharmacy may not dispense to a patient a different drug than the one prescribed without prescriber approval. Combined with this existing approval requirement, § 150006 (a) has the effect of requiring disclosures to prescribers whenever a PBM wants to effect a therapeutic interchange.

provider in five circumstances, including substitution of a generic equivalent of the prescribed medication.[19]

AB 1960 also prohibits a PBM from making any drug substitution unless certain information is communicated to the consumer, including the identity of the proposed and current medication, the difference (if any) in the consumer co-payment, the circumstances (if any) under which the existing prescription would be covered, the circumstances under which health care costs arising from the change in medications will be compensated, and any potential side effects of the new medication.[20] AB 1960 provides no circumstances where PBMs are not required to make consumer disclosures when there is a drug substitution. Thus, we interpret AB 1960 to require that this information be disclosed to consumers even when a bio-equivalent generic drug is substituted for a brand-name drug. The bill also requires a PBM to monitor the health effects on patients of medication substitutions requested by the PBM, and report the results of this monitoring on a quarterly basis to the PBM's Pharmacy and Therapeutics Committee.[21]

AB 1960 states that the PBM should reverse any drug substitution upon written or oral instructions from a prescriber or consumer, unless the prescribed drug is no longer on the purchaser's formulary or the consumer is unwilling to pay any higher applicable co-payment associated with the prescribed drug.[22]

Finally, AB 1960 requires PBM contracts to address a number of issues, including the amount of revenues, rebates and discounts identified previously that will be passed on to the purchaser, any administrative fees charged by the PBM, and the conditions under which an audit of the contract for PBM services may be conducted.[23]

Background on PBMs

There are approximately 60 PBMs operating in the United States today. There are three large independent, full-service PBMs with national scope: Medco, Express Scripts, and Caremark. Some large insurers manage pharmacy benefits internally. A few PBMs are owned by large retail supermarket/pharmacy chains. In addition, there are many smaller privately held PBMs. The relative size and ranking of these companies varies according to the measure used. The three large national PBMs are the major players in many markets, but anywhere from one-third to one-half of the market is made up of the other PBMs listed above. In our most recent

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19 AB 1960 § 150006 (b)(1).

20 AB 1960 § 150006 (d).

21 AB 1960 § 150007.

22 AB 1960 § 150006 (e).

23 AB 1960 § 150004.

antitrust investigation in the PBM industry, we found the competition between PBMs for contracts with plan sponsors to be "vigorous."[24]

PBMs manage the pharmacy benefits of group health plan sponsors. At the Health Care Hearings, one panelist estimated that ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.[25] A PBM's contract with group health plan sponsors specifies the amount that plan sponsors will pay per prescription of each drug, and the charges for the variety of PBM services that plan sponsors may utilize.

One important tool used by PBMs to manage pharmacy benefits is the formulary, which is a list of PBM-approved drugs for treating various diseases and conditions. PBMs use the formulary to guide drug substitution (both generic substitution and therapeutic interchange) in an effort to reduce costs. Generic substitution is the dispensing of a bio-equivalent generic drug product that contains the same active ingredient(s) as the brand-name drug and is, among other things, chemically identical in strength, concentration, dosage form, and route of administration as the substituted brand-name product. Generally, generic substitution is allowed without prior prescriber authorization.[26] Therapeutic interchange involves substitution of a therapeutically equivalent, but pharmacologically distinct, drug product for the drug product referred to on the consumer's prescription (*e.g.*, two brand-name drug products that treat the same ailment). As noted *supra*, California requires prior prescriber authorization before a pharmacist is allowed to interchange one brand-name drug for another. Therapeutic interchange allows a PBM to encourage implementation of its formulary, by steering utilization toward or away from a particular pharmaceutical.

Because the formulary affects the mix of drugs used by enrollees in a plan, its design can significantly affect the cost to the plan sponsor. Because generic drugs are substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs. Further, preferential placement on a formulary, accompanied with reduced co-payments, can cause a drug product to obtain higher market share within a drug plan. Accordingly, competition between pharmaceutical companies for preferred placement on the formulary can lead to lower drug prices.

PBMs also enter into contracts with pharmaceutical manufacturers.[27] The contract often

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[24] Commission Statement, *supra* note 12.

[25] John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 8.

[26] Indeed, nearly all state pharmacy assistance programs require generic substitution. *See* The Commonwealth Fund, State Pharmacy Assistance Programs Provide Lessons for Reducing Costs and Improving Patient Safety (Feb. 12, 2004), available at http://www.cmwf.org/newsroom/newsroom_show.htm?doc_id=223655. Further, some states require pharmacists to make generic substitutions unless the consumer objects or the prescription specifically states "dispense as written." *See*, *e.g.*, MINN. STAT. Chapter 151.21 (2003).

[27] PBMs also enter into contracts with retail pharmacies to create a retail network. The contract generally

provides that the pharmaceutical manufacturer will pay a rebate, based on some combination of a percentage of a reference price, achieving certain specified sales or market share targets, and preferred placement of certain drug products on the PBM's formulary. These rebates are either paid to the group health plan sponsor, retained by the PBM, or shared between them depending on the specifics of the contract between these parties.[28]

Group health plan sponsors generally procure PBM services through a bidding process. They typically issue requests for proposals to several PBMs and then evaluate the proposals based on costs and the package of services offered by each bidder. Plan sponsors or their consultants conduct these bidding processes, which may go through multiple iterations.

PBMs compete on price and non-price dimensions. One survey of plan sponsors using PBM services showed that the financial terms of the bid (such as the reimbursement rate and dispensing fee paid to pharmacies, the rebates paid to plan sponsors based on formulary drugs utilized, mail order pricing, and administrative fees) often were the key determinants in the selection of the winning bid.[29] This study also found that plan sponsors were concerned about non-price dimensions of service, such as plan design, the extent of the retail network, and mail order components. These terms and features are balanced against each other and the particular mix of terms and features is driven by the needs of the plan sponsor. For example, at the Health Care Hearings, panelists stated that some health plan sponsors want to maximize generic substitution, whereas others want to maximize rebates from manufacturers.[30] Panelists also noted that some plan sponsors want to receive all rebates from manufacturers, while others allow the PBM to retain the rebates – and many plan sponsors fall somewhere in-between.[31]

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specifies the amount the PBM will reimburse the pharmacy for dispensing a prescribed pharmaceutical, expressed as a discount from a reference price plus a dispensing fee. Because AB 1960 does not target the relationship between PBMs and retail pharmacies, such issues are not discussed in this letter. An extensive discussion of these issues is found in the Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, *supra* note 11.

[28] John Richardson, Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 23-24 (PBMs "can be paid through administrative fees, share of rebates, or some combination."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 124.

[29] *See* Health Care Financing Administration, Study of Pharmaceutical Benefit Management, June 2001, available at http://www.cms.gov/researchers/reports/2001/cms.pdf.

[30] Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 65; Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 13, at 105.

[31] John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 18 ("A lot of PBMs don't retain any of the rebates; others retain a portion in addition to whatever percent of the revenue they will keep as their administrative fees. So again, that's going to differ in each arrangement that is out there."); John Dicken, General Accounting Office, Health Care Hearings, *supra* note 13, at 40 ("of those contracts -- not all, but some -- would have the PBMs retaining some portion of those rebates to cover their administrative services."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 58-59.

The Government Accountability Office (formerly the General Accounting Office) released a study in January 2003 that examined the effects of PBMs on the Federal Employees Health Benefits Program, enrollees, and pharmacies.[32] The report considered the prescription benefits programs offered within three health plans available to federal government employees. The study compared prices that three types of customers paid for 14 brand name drugs and 4 generic drugs: (1) cash-paying customers, who buy at retail pharmacies; (2) health plan sponsors and their enrollees, who buy at retail pharmacies; and (3) health plan sponsors and their enrollees, who buy from a PBM's mail order facility. The study found that the lowest average prices for 30-day supplies were obtained when the drug was purchased through the PBM's mail order pharmacy, and that cash-paying customers at retail pharmacies paid the highest prices.[33]

Likely Effects of AB 1960

One of the primary goals of AB 1960 is to provide purchasers of PBM services with detailed information about the cost structure of the PBMs with whom they do business.[34] In the overwhelming majority of markets, however, consumers have limited or no information about the cost structure of those with whom they do business. More importantly, in general, consumers do not need such information to make efficient purchasing decisions. Instead, consumers make purchasing decisions based on the price and value of goods and services, without regard to a vendor's costs of production. AB 1960 thus holds PBMs to a standard that does not apply to other industries.

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[32] *See* General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, available at http://www.gao.gov/cgi-bin/getrpt?GAO-03-196. *See also* Sara Fisher Ellison and Christopher M. Snyder, *Countervailing Power in Wholesale Pharmaceuticals*, MIT Working Paper 01-27 July 2001, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=277290. ("buyers of wholesale drugs that can use restrictive formularies obtain substantially lower prices than buyers without this ability.")

[33] Similar cost savings for PBM clients have been reported in another study. *See* Cindy Parks Thomas et al., *Impact of Health Plan Design And Management On Retirees' Prescription Drug Use And Spending, 2001*, Health Affairs Web Exclusive W2-408, December 4, 2002, available at http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.408v1.

We note the filing of a lawsuit alleging that the largest PBMs have violated California state law by receiving rebates from pharmaceutical manufacturers that did not benefit employers and/or consumers but instead increased PBM profits and overall health care costs. *See* First Amended Representative Action and Complaint for Violation of the Unfair Competition Law, AFSCME v. AdvancePCS, *et al*., Superior Court of the State of California, case No. BC292227 (Apr. 4, 2003) at ¶ 4. We also note that the United States, along with 20 states (including California), recently announced a settlement of claims for injunctive relief and state unfair trade practices against Medco Health Solutions, Inc., and that New York recently filed a lawsuit against Express Scripts alleging various forms of misconduct relating to pharmaceutical pricing practices.

[34] Although it may seem that rebates are revenues received by the PBMs from manufacturers, they are frequently booked as reductions in the cost of sales.

AB 1960 also requires PBMs to disclose certain financial information to purchasers, prospective purchasers, and prescribers. AB 1960 specifies that rebate information may be provided in a somewhat aggregated form to purchasers and prospective purchasers and does not have to be provided unless purchasers and prospective purchasers agree to keep the information confidential. No such confidentiality restrictions apply to the disclosure of information to prescribers. Thus, financial information disclosed by PBMs to prescribers may become public, and a knowledgeable pharmaceutical manufacturer might well be able to use this information to calculate the rebate a competitor was offering. If pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors (either because the safeguards on subsequent disclosure by purchasers and prospective purchasers are insufficient or because the mandated disclosure to prescribers provides sufficient information for pharmaceutical manufacturers to calculate these amounts) then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and pharmaceuticals.

Inclusion in a PBM formulary offers pharmaceutical manufacturers the prospect of substantially increased sales opportunities. Whenever PBMs have a credible threat to exclude pharmaceutical manufacturers from their formulary, manufacturers have a powerful incentive to bid aggressively. Willingness to bid aggressively, however, is affected by the degree of transparency with respect to the terms that pharmaceutical companies offer PBMs. Whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely.[35] It is for this reason that California law requires the state to use sealed bids to procure desired goods and services whose value exceeds $25,000.[36]

When group health plan sponsors contract with PBMs, they know the price of the services they are obtaining. AB 1960 is premised on the belief that greater transparency with regard to the PBM's costs, which are affected by the rebates they are able to secure, will allow group health plan sponsors to ensure they are "getting the best deal." From the purchaser's perspective, there is no functional difference between a higher list price coupled with a rebate and a lower list price. We also note that some health plan sponsors are large, sophisticated, repeat-purchasers of health care services, and many use a bidding process to decide which PBM they will contract with. It is possible that AB 1960 may provide some additional information to these plan sponsors about the revenue streams obtained by PBMs, but it does not necessarily follow that this would make the PBMs compete more aggressively to do business with this plan sponsor. Indeed, to the extent AB 1960 makes tacit collusion more likely, these plan sponsors may end up with "worse" contractual terms.

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[35] *See, e.g.,* Svend Albaek *et al., Government Assisted Oligopoly Coordination? A Concrete Case,* 45 J. INDUS. ECON. 429 (1997).

[36] *See* http://www.pd.dgs.ca.gov/sell2state/default.htm.

AB 1960 may also inadvertently increase health care costs in another manner. As noted previously, AB 1960 excludes health plans and health insurers that provide pharmacy benefit management services to their own enrollees from the disclosure requirements. To the extent the disclosures mandated by AB 1960 chill the willingness of pharmaceutical manufacturers to offer substantial rebates to non-integrated PBMs, or otherwise increase non-integrated PBMs' costs, AB 1960 ultimately will increase health plans' and health insurers' costs of administering pharmacy benefits through non-integrated PBMs. In this way, AB 1960 will encourage health plans and health insurers to bring "in-house" the management of pharmacy benefits. To the extent that AB 1960 causes firms that would prefer to turn to the market for PBM services to instead provide such services internally, AB 1960 will induce inefficiency and may well increase the cost of PBM services. As before, increases in the cost of PBM services may well lead to increases in health insurance premiums and reductions in the availability of insurance coverage for pharmaceuticals.

There do not appear to be any significant barriers to negotiation between health plan sponsors and PBMs over all the terms of their agreement, including how PBMs are to be paid for their services and the disposition of any rebates.[37] At the Health Care Hearings, one panelist suggested that many health plan sponsors have decided to allow PBMs to keep rebates in exchange for lower administrative fees.[38] We are informed that one major PBM voluntarily discloses extensive information regarding rebates and administrative fees.[39] Press reports indicate that some PBMs have made formal promises to inform their customers about all rebates they receive from drug manufacturers, and a coalition of major employers are attempting to bypass PBMs entirely, and negotiate with pharmaceutical manufacturers directly.[40]

As these developments indicate, vigorous competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms. Just as competitive forces encourage PBMs to offer their best price and service combinations to health plan sponsors in order to gain access to subscribers, competition also encourages disclosure of the information group health plan sponsors require to decide which PBM to contract with, including but not limited to the magnitude of any rebates the PBMs might receive, the circumstances under which those rebates will be paid, and how those rebates will be shared between PBMs and group health plan sponsors.

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[37] S*ee* Jack Calfee, American Enterprise Institute, Health Care Hearings, *supra* note 13, at 99; David Balto, White & Case, Health Care Hearings, *supra* note 13, at 99.

[38] S*ee* Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 13, at 105.

[39] S*ee* Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 103. *See also* http://www.express-scripts.com/client/business_principles.htm.

[40] *See* Milt Freudenheim, *Big Employers Joint Forces in Effort to Negotiate Lower Drug Prices*, N.Y. TIMES, June 12, 2004; Milt Freudenheim, *Critics Attack Secret Deals By Middlemen to Buy Drugs*, N.Y. TIMES, Dec. 20, 2003.

One of the central premises of AB 1960 is that information regarding a PBM's rebates from drug makers is relevant to a purchaser's decision-making process. However, if AB 1960 were to pass, insurers with integrated PBM services would not face the same disclosure requirements as independent (non-integrated) PBMs. In general, better informed purchasers are able to make better decisions, but more information is not necessarily better. For example, when only a subset of competitors are required to disclose certain financial information, purchasers may not be able to discern the true price of a service and may mistakenly choose a higher-priced option.[41] The different types of information potential purchasers would receive from integrated and non-integrated suppliers of PBM services is the type of asymmetry that could lead less-sophisticated purchasers mistakenly to choose higher cost services. Similarly, the mandated disclosure of information to prescibers and consumers prior to a drug substitution (and the absence of such disclosure if no such substitution is contemplated) may have the effect of misleading prescribers and consumers about the costs and benefits of continuing a currently prescribed drug compared to the proposed substitute.

AB 1960 also has a number of provisions that are likely to raise the costs of drug substitution. As noted previously, PBMs frequently use drug substitution to reduce costs and promote competition between branded drug makers. Instead of distinguishing between appropriate and inappropriate drug substitution and targeting the latter, AB 1960 imposes modest procedural barriers to drug substitution for a generic equivalent (by requiring disclosure to consumers and follow-up health monitoring) and substantial procedural barriers to drug substitution for a therapeutic equivalent (by requiring disclosure to consumers and prescribers, and follow-up health monitoring). These procedural barriers are likely to discourage both generic substitution and clinical interchange. To the extent AB 1960 makes safe and cost-reducing drug substitutions less probable, it is likely to increase the cost of pharmaceuticals, which in turn is likely to increase health insurance premiums and reduce the availability of insurance coverage for pharmaceuticals. Our concerns about AB 1960's impact on consumers and competition are far greater to the extent it has a material effect on the frequency of generic substitution.

As noted previously, generic substitution is encouraged by the FDA and widely recognized as safe, and California already requires prescriber approval for therapeutic

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[41] A recent Commission staff report studied the impact of providing more detailed information to borrowers when a mortgage was obtained through a broker than when it was obtained through a direct lender. The study found that borrowers more frequently selected higher cost loans when given the choice between loans accompanied with more detailed information and loans without such information than when choosing between loans with the same baseline information. These results are consistent with the hypothesis that the additional information impaired consumers' ability to discern the low cost provider. James M. Lacko & Janis K. Pappalardo, THE EFFECT OF MORTGAGE BROKER COMPENSATION DISCLOSURES ON CONSUMERS AND COMPETITION: A CONTROLLED EXPERIMENT, at 8-9, Federal Trade Commission Bureau of Economics Staff Report, available at http://www.ftc.gov/os/2004/01/030123mortgagefullrpt.pdf (Feb. 2004).

interchange. As such, the disclosures mandated by AB 1960 are likely to prove unhelpful to most prescribers and consumers. More broadly, because current safeguards appear sufficient to protect consumers, AB 1960 is likely to increase costs to consumers without providing any countervailing benefits.

To the extent AB 1960 increases prices for pharmaceutical and health insurance and restricts the availability of insurance coverage for pharmaceuticals, the result is likely to be an increase in the number of Americans who do without pharmaceuticals and/or health insurance. As an article in *Health Affairs* last year 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."[42]

Conclusion

AB 1960 is more likely to undermine competition than promote it. AB 1960's mandated disclosure of information may increase the cost of pharmaceuticals and health insurance premiums by attenuating competition between pharmaceutical companies and by raising the cost of generic substitution and clinical interchange. Any such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford. Any additional amendments to AB 1960 that have the effect of broadening and strengthening its provisions would be even more problematic from a competitive perspective.

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[42] 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 http://papers.nber.org/papers/W8802.

Respectfully submitted,

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