This material is for reference only.

On July 20, 2023, the Federal Trade Commission issued a "Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities" cautioning the public and policymakers against relying on certain FTC materials. Accordingly, j 1against

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 EI

Assembly Member Greg Aghazarian
September 7, 2004

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

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,

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.,*

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,

Susan A. Creighton, Director
Bureau of Competition

Luke M. Froeb, Director
Bureau of Economics

Maureen K. Ohlhausen, Acting Director
Office of Policy Planning

David A. Hyman
Special Counsel