Second, there appears to be a unique disconnect between the level of the federal antitrust enforcement and state antitrust and consumer protection enforcement. Anyone examining the

to challenge a variety of unfair methods of competition which undermine and threaten to the integrity and competitiveness of the healthcare intermediary system. In assessing the federal healthcare enforcement program the American Antitrust Institute observed in its transition team report that "[t]he priorities of the health care enforcement agenda need to be realigned with a greater focus on health insurers, PBMs, GPOs, and hospitals."[1] That focus should include a renewed attention to the use of Section 5 to attack practices in this area.

The problem of the failure to use Section 5 to address unfair competitive conduct in healthcare markets was highlighted for me when I spoke at the Fifth Annual Seoul International Competition Forum earlier last month. Of course, since this was a Southeast Asia conference, we all held our breath when the representative of the Chinese antimonopoly authority spoke because we wanted to learn about how one of the world's largest economies was implementing its new anti-monopoly law.[2] Where had the Chinese focused their new enforcement power? Commercial bribery that undermined healthcare markets. The speaker noted that:

> It is found that the medical treatment, medicine and healthcare product selling are prone to commercial bribery. Some producers and retailers, including large multinational medical medicine manufacturers have acquired, through commercial bribery, unfair transaction opportunities and sought unreasonable super-profits, which naturally results in the price hike of medicines in health

which it imposed a fine of 20 billion won for kickbacks including "providing undue private benefits to doctors and medical institutions, such as supporting their overseas travel expenses." The Korean FTC concluded that "the provision of undue private benefits ultimately incurs consumer damage by hampering fair competition among pharmaceutical companies and offering a cause to raise drug prices."[3]

Indeed, even FTC Commission Rosch noted that Section 5 might be an appropriate tool to use when looking at efforts that specialty hospitals engage in to cherry-pick the most attractive patients while leaving the more expensive charity-type patients for more traditional hospitals. He observed that many of the disputes surrounding specialty hospitals are over issues of fairness, and arguably are not straightforward antitrust violations; but that those types of violations fit within his own view of a potential Section 5 case.

The question [of the reach of Section 5] is a double one: first, does Section 5 empower the Commission to define and proscribe an unfair competitive practice, even though the practice does not infringe either the letter or the spirit of the antitrust laws. Second, does Section 5 empower the Commission to proscribe practices as unfair or deceptive in their

such as Medicaid managed care and nursing-home drugs, little-known intermediaries rack up tens or hundreds of millions of dollars in profit.[5]

During the past administration, there have been no federal antitrus

PBMs' promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, deception, and anticompetitive conduct. The dominant PBMs have been characterized by opaque business practices, limited market competition, and widespread allegations of fraud. As a bipartisan group of state legislators noted:

> We know of no other market in which there have been such a significant number of prominent enforcement actions and investigations, especially in a market with such a significant impact on taxpayers. Simply put, throughout the United States, numerous states are devoting considerable enforcement resources to combating fraudulent and anticompetitive conduct by PBMs. This is because those activities are taking millions of taxpayer dollars and denying government buyers the opportunity to drive the best bargain for the state.[8]

In an important decision upholding state regulation of PBMs, one federal court observed "[w]hether and how a PBM actually saves an individual benefits provider money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider." The court elaborated:

> This lack of transparency also has a tendency to undermine a benefits provider's ability to determine which is the best among competing proposals from PBMs. For example, if a benefits provider had proposals from three different PBMs for pharmacy benefits management services, each guaranteeing a particular dollar amount of rebate per prescription, the PBM proposal offering the highest rebate for each prescription filled could actually be the worst proposal as far as net savings are concerned, because that PBM might have a deal with the manufacturer that gives it an incentive to sell, or restrict its formulary, to the most expensive drugs. In other words, although PBMs afford a valuable bundle of services to benefits providers, they also

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closed on a "quick look" review. *See* Jonesday.com, Experience Details: Caremark, http://www.jonesday.com/experience/experience_detail.aspx?exID=S9298 (last visited July 1, 2008). The CVS/Caremark merger was resolved without the FTC's issuing a second request.

[8] Letter from Mass. State Senator Mark Montigny to FTC Chairman Deborah Platt Majoras (May 11, 2005).

> introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs.[9]

In the past four years alone, cases brought by DOJ and state attorneys general attacking unfair, fraudulent and deceptive have secured over $300 million in penalties and fines against the three major PBMs.[10] A group of state attorneys general and DOJ are continuing to conduct several investigations of the three major PBMs, and several private actions challenging their conduct have been brought by unions and other customers. The current concentration of the national full service PBM market only exacerbates these problems, increasing the need for government enforcement and potential regulation of the industry.

Some of the problematic practices challenged in these cases include:

- Á secretly retaining most manufacturer payments, e.g., rebates, discounts and other fees, instead of passing through such payments to clients;
- Á switching plan members from low- to high-cost drugs;
- Á favoring higher-cost drugs on their formularies;
- Á manipulating generic (maximum allowable cost) pricing;
- Á entering into exclusivity arrangements with specialty pharmaceutical manufacturers that raise the prices of those drugs;
- Á conspiring with manufacturers to violate Omnibus Budget Reconciliation Act and "best pricing" regulations; and

[9] Pharm. Care Mgmt. Ass'n v. Rowe, 2005 U.S. Dist. LEXIS 2339, at *7-8 (D. Me. Feb. 2, 2005), *aff'd*, 429 F.3d 294 (1st Cir. 2005).

[10] *See, e.g.*, United States v. Merck & Co., Case No. 00-CV-737 (E.D. Pa., filed Feb. 10, 2000) (final settlement in this case was reached with Merck-Medco agreeing to pay $155 million); United States v. AdvancePCS, Inc., Case no. 02-cv-09236 (E.D. Pa., filed Dec. 20, 2002) (defendant agreed to a $137.5 million settlement and a five-year injunction); Ohio v. Medco Health Solutions, Inc., Case No. A 0309929 (Hamilton Cty., Ohio 2005) (verdict finding Medco liable for constructive fraud and awarding $7.8 million total, $6.9 million in damages plus $915,000 for the State Teachers Retirement System); West Virginia v. Medco Health Solutions, Inc., Case no. 02-C-2944 (Kanawha Cty., W.Va., 2002) ($5.5 million settlement).

Á committing other contract or fiduciary breaches.

One chronic problem with PBMs is that of self-dealing. Plan sponsors purchase PBM services with the assumption they are a "fair broker" that will select the lowest cost, best product on an objective basis. These concerns of self-dealing were part of the reason the FTC challenged the acquisition of PBMs by pharmaceutical manufacturers in the mid-1990s – Merck's acquisition of Medco and Lilly's acquisition of PCS. The concern was that the pharmaceutical manufacturers would favor their own drugs on the PBM formulary. These cases were resolved with orders that protected plan sponsors from the risks of self-dealing.

Unfortunately, these problems of self-dealing have continued to exist for PBMs. Almost all PBMs have their own mail order operations. Often, PBMs may favor drugs in which they receive a greater margin because they are dispensed by mail order, even though the plan sponsor or consumer may pay more. PBMs often seek to drive consumers to more highly profitable mail order distribution and away from independent pharmacies that offer the level of quality, advice and personal service consumers prefer. Consumers often suffer from the conversion to mail order: they are given little choice, there is a greater chance of adverse reactions, and there is little if any consumer service. Any consumer who has spent hours on the phone waiting for an answer on a mail order prescription sees little "efficiency" from these efforts to drive independent pharmacies from the market. Although an FTC study appeared to find little evidence of these problems of self-dealing, the recent state enforcement actions have demonstrated that these problems are ongoing.

operations to target other pharmacies, by attempting to steal customers. At times the PBMs owned by chain pharmacies have attempted to deceive consumers to drive them from their rivals.

Unfortunately, the FTC has failed to investigate or take any enforcement action against this anticompetitive, fraudulent, and deceptive conduct. Perhaps the FTC sees its enforcement powers as too limited. Even more problematic, when individual states have attempted to regulate PBMs to address the lack of enforcement, increase transparency or address forms of this deceptive conduct, the FTC has advocated on the side of the PBM industry in opposition to the proposed legislation.[11] This is a mistake. As the AAI report observed: "[c]onsidering 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."[12]

Group Purchasing Organizations

GPOs negotiate contracts for their member hospitals with numerous entities, including medical device manufacturers. The original purpose of GPOs was to obtain better pricing on products than hospitals could obtain individually, and to provide value-added services. Although GPOs may reduce purchase costs by giving hospitals greater bargaining power, growing GPO consolidation and market power has increased the exclusionary potential of some of the GPO

[11] Letter from Maureen K. Olhausen, on behalf of the Fed. Trade Comm'n, to Sen. Richard L. Brown, North Dakota Senate (Mar. 8, 2005), *available at* http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf.

[12] The Next Antitrust Agenda: The American Antitrust Institute's Transition Report on Competition Policy to the 44th President (Albert A. Foer ed., 2008).

contracting practices.[13] Moreover, the payment of kickbacks is pervasive and undermines the product selection system.

Many small medical device manufacturing start-ups have claimed that contracting practices by GPOs have effectively foreclosed them from entering the market. Examples of alleged exclusionary practices include kickbacks, sole-source contracts, market share discounts, and bundling of products so hospitals must purchase the bulk of their supplies from a single vendor to qualify for a discount on any one product. Small manufacturers argue that incumbent suppliers, together with GPOs, use these practices to eliminate competition and preserve their market share.[14]

As in the Chinese and Korean cases suggest, particularly problematic are kickbacks paid by manufacturers to the GPOs. These kickbacks deceive buyers and third parties (including government entities) that are responsible for payment for the products of the real costs of the products. They may distort demand and provide the opportunity to artificially increase prices. Although there are regulations that prohibit kickbacks in many healthcare markets, the GPO payments fall into a safe harbor.

In the past seven years, the Senate Judiciary Committee has held four hearings concerning kickbacks and other exclusionary conduct by GPOs.[15] The FTC also addressed the

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[13] *See Hospital Group Purchasing: Has the Market Become More Open to Competition?: Hearing Before the S. Comm. on the Judiciary*, 107th Cong. 3 – 4 (2003) (statement of Lynn James Everard).

[14] *See, e.g., Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?: Hearing Before the S. Comm. on the Judiciary*, 107th Cong. (2002) (statement of Joe E. Kiani, President and CEO, Masimo Corp.).

[15] *Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?, supra* note 14; *Hospital Group Purchasing: Has the Market Become More Open to Competition?, supra* note 13; *Hospital Group Purchasing: How To Maintain Innovation and Cost Savings: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (2004); *Hospital*

issue in its 2003 health care competition hearings.[16] Over a dozen private suits have been brought, some successfully, by small innovative medical device manufacturers against exclusionary practices by GPOs and device manufacturers.[17] Yet the FTC has failed to bring any enforcement actions in this area.

Section 5 may provide a useful tool in two respects to cure the harmful practices in the medical device market. First, to the extent that potential enforcement actions against market share discounts, or other forms of de facto exclusivity seem deficient for some element necessary for a Sherman Act challenge, Section 5 may enable the FTC to overcome that deficiency. Second, the practices of kickbacks can be addressed under Section 5 as an unfair method of competition. A gap in enforcement currently exists because of the difficulty in proving that a kickback scheme constitutes a violation of the Sherman Act. The Ninth Circuit, after acknowledging the existence of a kickback scheme by an alleged health insurance monopolist caused higher co-payments and premium payments, found no antitrust violation because of a lack of evidence of harm to the relevant market.[18] Carried to its logical extreme that decision

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Group Purchasing: Are the Industry's Reforms Sufficient To Ensure Competition?: Hearing Before the S. Comm. on the Judiciary, 109th Cong. (2006).

[16] FED. TRADE COMM'N, HEALTH CARE AND COMPETITION LAW AND POLICY PUBLIC COMMENTS (2003), *available at* http://www.ftc.gov/os/comments/healthcarecomments2/index.shtm.

[17] *See* Masimo Corp. v. Tyco Healthcare Group, LP, Case No. 02-CV-4770 (C.D. Cal. 2002). *See also* Genico, Inc. v. Ethicon, Inc., No. 04-CV-00229 (E.D. Texas 2004); Rochester Medical Corp. v. C.R. Bard Inc., Case No. 5:04-CV-060 (E.D. Tex. 2004); Applied Med. Res. Corp. v. Johnson & Johnson, Inc., No. 03-CV-1329 (C.D. Cal. 2003); ConMed Corp. v. Johnson & Johnson, Inc., No. 03-CV-8800 (S.D.N.Y. 2003); Medtronic AVE Inc. v. Cordis Corp., Case No. 03-CV-212 (E.D. Tex. 2003); Retractable Techs., Inc. v. Becton Dickinson & Co., Case No. 5:01CV00036 (E.D. Tex. 2001); Kinetic Concepts, Inc. v. Hillenbrand Industries, Inc., Case No. 5:95CV00755 (W.D. Tex. 1995).

[18] *See* Forsyth v. Humana, Inc., 114 F.3d 1467, 1477-79 (9th Cir. 1997) (rejecting a claim that an insurance company's alleged kickback scheme caused antitrust injury to group health insurance customers where the evidence showed the scheme caused higher co-payments and premium payments, but did "not explain how the scheme reduced competition in the relevant market"), *aff'd on other grounds*, 525 U.S. 299 (1999).

would mean that the antitrust laws would not prevent every insurance company from engaging in kickbacks that raised costs to consumers. However, under Section 5 a kickback scheme could be an unfair method of competition particularly where there is evidence of consumer harm.

Insurance Companies

Like PBMs and GPOs, the health insurance market has the factors that make it a fertile environment for harmful conduct – concentration and complexity. Almost every metropolitan health insurance market is highly concentrated. There have been over 400 health insurer mergers in the last decade and only three have been challenged by the Justice Department – with modest divestitures. The entire nation is basically dominated by four major insurance companies.

There are a wide variety of practices that insurance companies engage in which undermine and threaten to undermine the competitive process and ultimately harm consumers. Some of these practices are similar to the practices engaged in by PBMs in that they deprive buyers from securing sufficient information to make intelligent decisions and insure that the

Health insurers also engage in a variety of deceptive and fraudulent practices that limit consumer choice and maintain information asymmetries. Examples of health insurer practices that harm consumers are legion, including onerous preapproval requirements and preexisting condition policies. Many insurers prevent consumer choice by imposing "gag" clauses that prevent physicians from informing patients of insurance plans providing superior coverage. Some health insurers also manipulate their claims processing systems to the disadvantage of both consumers and providers.

Let me focus on some of the more straightforward forms of harmful conduct:

- Most favored nations provisions. Most favored nation provisions require healthcare providers to provide an insurer the best price that it offers any other insurer. Most favored nation provisions can raise competitive concerns because they may limit the ability of providers to engage in selective discounting, which may facilitate the entry of new providers. Moreover, in other instances, most favored nations provisions can facilitate collusion among competitors. The Justice Department and the FTC properly attack6Innation provisiancs can aam35.465 -1.15 TD.0

- Fraudulent reimbursement schemes. In February of this year, New York Attorney General Andrew Cuomo announced an industry-wide health insurance investigation into a fraudulent reimbursement scheme, and potential litigation specifically naming Ingenix, the nation's largest health care billings information provider, as well as Ingenix's parent company, UnitedHealth Group ("United"). Findings of the investigation revealed that Ingenix operates a "defective and manipulated database" which is utilized by most major health insurers to set reimbursement rates for out-of-network medical expenses. United used Ingenix's data to "dramatically under-reimburse" their members for out-of-network medical expenses. By distorting the "reasonable and customary" rates, which are paid for out-of-network expenses, United kept the reimbursements artificially low forcing patients to burden a higher share of the cost. This distortion resulted in United effectively only covering roughly 30 percent of out-of-network medical expenses, leaving consumer to cover 70 percent of these expenses when they were promised 80 percent out-of-network coverage.

- Improper claims payment and claims denials. In February 2008, California regulators imposed a potential penalty of $1.3 billion in fines against United for violating the law more than 130,000 times[19] after acquiring PacifiCare. Upon reviewing 1.1 million claims, the investigation found that after United acquired PacifiCare in 2005, United failed to pay claims in a timely manner and had over a 10 percent overall error rate in processing claims. United wrongfully denied claims for covered medical care, with regulators finding that 30% of reviewed HMO claims were denied incorrectly and