The Federal Trade Commission hosted a two-day workshop on September 9 -10, 2002 on health care competition law and policy. Key topics addressed included hospital merger enforcement, group purchasing organization activities, collaborative actions by physicians, conduct and mergers by managed care companies, and brand name pharmaceutical companies actions to retard entry by generic competition. The following is a brief summary of the presentations at the workshop. If you are interested in learning more about any of these session or presentation topics, or would like copies of any of the presented materials, please contact any of the attorneys in our health or antitrust practice groups.

SEPTEMBER 9, 2002, MORNING SESSION

FTC Chairman Tim Muris opened the workshop, stating that its purpose was to address the impact of health care competition on cost, quality, and the incentive for innovation. The goal of the workshop was to promote dialogue, learning, and consensus among interested parties.

William Brewbaker from the University of Alabama gave an overview of health care competition policy. He anticipates dramatically increased health care costs in the next 10 years. Professor Brewbaker noted a shift in the burden of health care costs from consumers (in 1988) to private insurance (in 2000). More recently, however, increases in expenditures have led to increases in premiums and co-payments for employees, and that trend is likely to continue. Brewbaker also noted a trend toward defined contribution plans that may involve giving money to employees to purchase their own coverage, but also include such provisions as flexible spending accounts. Brewbaker anticipates that plans will become broader (covering more items) but shallower. According to Brewbaker, policymakers' challenges will be:

- market structure (geography, demographic, differentiated products and technology growth);
- political structure (conflicting expectations regarding costs containment and access to care, accountable regulators, and the existing regulatory and enforcement structure);
- coverage (unpredictable, "uncontrollable" market); and
- quality (effect of cost on quality, need to reward quality, medical uncertainty, need for providers to have most recent data)

The second speaker was William Vogt of Carnegie Mellon University. Professor Vogt conducted a study, published in 1999, which focused primarily on hospital mergers. Vogt pointed out that the government has lost every recent challenge it has mounted against a hospital merger. A hospital needs to prevail on only one of the following criteria in order to defeat a government challenge:

- product market definition
- geographic market definition
Winning arguments for hospitals tend to be based on efficiencies, market definition, or that the hospital is not-for-profit. Vogt noted that there is no significant difference (in the context of competition) between not-for-profits and for-profit hospitals.

On the question of whether mergers lead to increased prices, studies are mixed. Several studies indicate that managed care reduces price and cost, and there is some indication that hospital mergers actually lead to higher prices.

Providing a community perspective, Cara Lesser of the Center for Studying Health Systems Change said the two trends in shaping health care markets are the growth of managed care and consolidation. Ms. Lesser spoke about the trend toward consolidation among hospitals, physicians, and health plans. The consequences of these market trends are:

- market instability (characterized by contract showdowns);
- a return to the "medical arms race," including the proliferation of specialty hospitals and stand-alone surgery centers; and
- rapidly rising costs.

Lesser sees a potential for a decrease in provider leverage in the future, although private rates will be pushed up by the labor shortage in nursing and pressure to contain Medicare payments. Plan leverage has the potential to increase due to employers' interest in controlling premium costs, and consumers' interest in controlling co-payment and deductible costs.

Several speakers addressed government involvement in the health care competition arena.

**FTC**

The directors of all three FTC bureaus appeared. Joe Simons of the Bureau of Competition, Howard Beales of the Bureau of Consumer Protection, and David Scheffman of the Bureau of Economics outlined FTC initiatives. Simons defended the Commission's enforcement against physician price fixing, and said the Commission is very sensitive to efficiencies claims and quality concerns. The FTC is looking to alter the government's abysmal record in challenging hospital mergers, and will do so by looking back at mergers to see if price was affected.

Beales focused on consumer protection and the need to combat fraudulent marketing and advertising, while Scheffman focused on mergers. The FTC wants to improve analysis of geographic market issues in health care cases.

**DOJ**

Deborah Majoras of the Department of Justice defended the recent relocation of the Antitrust Division health care task force to the Litigation Division. She said DOJ will examine mergers for potential price increase effects. DOJ is also interested in insurer activity, including collusion, "all products" clauses and "most favored nation" clauses.

**State AGs**
Ellen Cooper of the Maryland Attorney General's Office spoke about the states' role in antitrust issues. States tend to focus on issues which impact consumers, such as delivery of health care in rural areas, home health agencies, and ambulance companies, although state AG functions may sometimes conflict, given the non-antitrust activities that are within the responsibilities of state AGs. The pharmaceutical industry is a primary concern of many state attorneys general at the moment.

SEPTEMBER 9, 2002 AFTERNOON SESSION

The afternoon session involved two panel discussions covering issues related to payor and provider concentration and integration. Each panel had speakers who provided the viewpoint of hospitals, managed care organizations, and physicians.

The discussion highlighted the physicians' perspective that all physician integration should be subject to rule of reason analysis, and that risk sharing and capitation are not necessary to make integration efficiency-enhancing. Physicians' representatives (Catherine Hanson, California Medical Association; Donald Palmisiano, AMA; and Ellen Burkett, MedSouth) believe that the FTC's MedSouth opinion "set the bar too high" for most physicians to contemplate affordable integration without running afoul of antitrust laws. Physician interests also criticized the FTC for focusing too little attention on health plan mergers. They noted that because doctors cannot change their patients rapidly in response to changes in payment, physicians often are subject to monopsony power.

The lone hospital representative (Stuart Fine of Grand View Hospital) painted a bleak picture in which health plans in Pennsylvania were paying Grand View monopsonistically low rates, and forcing them to accept contracts that included MFN, all products, and evergreen clauses. He contended that there are substantial barriers to entering the health plan market in Pennsylvania, including the health plans' "deep pockets." Addressing hospital mergers, he said it was very important for agencies to look not just at cost-related efficiencies, but to merger-related increases in quality.

The health plan representatives (Henry Desmarais, HIAA; Stephanie Kanwit, AAHP) argued that current antitrust treatment of physician integration is appropriate, and that there should be no antitrust exemption for physicians jointly to set rates charged to health plans. These representatives believe that Med South struck the correct balance, by allowing flexibility in enforcement to recognize clinical integration efficiencies. Health plan representatives also took the position that consolidation in the hospital market was a key primary driver of increased premiums; they noted that hospitals often have increased leverage vis a vis health plans because of their increasingly close integration with physicians.

The Agency moderators (FTC's John Wiegand - first panel, and DOJ's Mark Botti - second panel) posed questions related to the following topics:

- The importance of increases in quality - and the difficulty of measuring such increases - that arise from physician integration and hospital mergers;
- the difficulty in distinguishing price increases associated with higher quality levels from those associated with market power;
- the presence of health plan monopsony power vis a vis physicians/hospitals;
- the welfare considerations of allowing hospitals and/or physicians jointly to negotiate with health plans to achieve greater bargaining power;
- the value of per se rules applied to certain health care provider activities.
In the morning's opening session, Peter Hammer, Professor at the University of Michigan Law School, presented his recent study, "Empirical Perspectives on Health Care Competition Policy," which focused on the ability of the judicial system in health care antitrust litigation to examine quality and non-price concerns in health care. The study was based on 539 health care antitrust cases, between 1985 and 1999, and each case was coded according to a variety of criteria ranging from the business conduct at issue, to the allegation(s) made or cause of action, to the legal analysis. Two-thirds of the cases involved staff privileges and hospital contracting issues, while just over fifteen percent of the cases pertained to insurance or managed care.

In looking at quality concerns, Hammer grouped cases as to whether they involved "firm specific characteristics" such as clinical structure and process or administrative structure, or "market-level concerns" like freedom of choice, range of choices, innovation and information. Hammer also stated that courts rarely dealt with health services research in their analyses. Also, quality was rarely discussed as an independent factor. Instead, courts tended to use factors such as physician or hospital reputation or malpractice history, for example, as ways to look at quality.

Hammer cited the importance of looking at advisory opinions and consent decrees issued by the FTC in addition to the case law to obtain further analysis and a more complete view of health care competition issues. In designing a policy to address issues of competition in health care setting, Hammer suggested revising antitrust doctrine to better address quality and non-price concerns. Also, policy should be integrated with the government's role as both regulator and purchaser of health care services.

The remainder of the morning session concentrated on Group Purchasing Organizations. A panel discussion on GPOs presented varying perspectives from integrated delivery systems, small device manufactures, group purchasing associations, the government, and academia.

Joanne Bailey from the General Accounting Office introduced the discussion by speaking about a recent GAO study on group purchasing organizations. The study examined the operations of 18 hospitals in one urban area and found great variation in trends across the sample. In particular, the study aimed to address concerns that GPOs blocked small medical device manufacturers' access to hospitals and patients, thus sometimes preventing innovative products from reaching the market. The study further looked at the ability of large GPOs to leverage and negotiate for smaller prices. The study's results included a finding that hospitals using GPOs would not always receive better prices. For example, those hospitals buying safety needles through a GPO incurred a 1 to 5% increase in their prices as compared to those buying outside of a GPO. However, the GPO provided a price for pacemakers that was 25-39% cheaper than that offered to those purchasing outside the GPO. The study also found that smaller and mid-sized hospitals received more cost savings than larger hospitals who fared better when buying on their own.

Bruce Clark and Carl Manley represented the perspective of integrated delivery systems. Clark, Vice-President of Intermountain Healthcare, an integrated delivery system in Idaho and Utah, cited the extreme financial pressures facing providers as the impetus behind finding tools to reduce operating expenses. GPOs, he explained, are one of these tools. For Intermountain, GPO contracts provide a better deal than its hospitals would be able to get by contracting on their own. Manley, Vice-President for Materials Management at Sentara Healthcare in Virginia echoed Clark's sentiments, stating that GPOs will continue their place in the market because of the value they bring to both providers and manufacturers. He further explained that in addition to the price benefits that GPOs bring, they also provide efficacy, quality and safety benefits.
Cliff Goodman, Senior Scientist at the Lewin Group, discussed his study on the clinical review process conducted by GPOs and healthcare systems. Looking at five health systems and six GPOs, the study found that future considerations for GPOs should include focusing on new technologies as a priority along with better information retrieval, filtering and interpretation to assess the impacts of GPOs on access, economics and quality. Additionally, he recommended an interdisciplinary approach to expert assessments.

Bob Berns, a professor of health and economics at the University of Pennsylvania's Wharton School of Business, and Steve Latham, professor at Quinnipiac School of Law, spoke from the academic perspective. Berns mentioned his book, "The Healthcare Value Chain" in which he offers that GPOs are intermediaries in the chain, between the payers and the producers. He describes GPOs as strategic pooling alliances that exert leverage over suppliers while adding other value-adding services. He stated that while there are about 600 GPOs in the healthcare industry, seven of them account for 85% of the business. The top four GPOs account for 76% of the dollars spent in GPOs. Despite this, Berns contended that hospitals still deal directly with manufacturers outside of their GPO contracts, and that GPOs face a challenge to control their membership because they are not always the cheapest alternative.

Professor Latham was the first member of the panel to speak to the so-called "dark side" of the GPO controversy. He discussed the FTC/DOJ statement of policy, and, in particular the "danger harbors." First, concern is raised when a GPO's purchases account for over 35% of the total sales from product vendors in a market. Second, additional concern arises where sales of group purchased items by competitors in the same market represent at least 20% of their revenues, which might contribute to stabilization of competitive pricing. Latham also mentioned a New York Times article on GPOs and its allegations regarding their anti-competitive effects:

- GPOs do not save money because they share market power with vendors;
- Discounts based on percentage of hospital purchases, not volume which confines market share and enables GPOs to limit people from purchasing from outside of the GPO by reducing or taking away rebates;
- Exclusionary contracts prevent small manufacturers from breaking into the market;
- Venture capital does not flow to the smaller manufacturers.

Latham made the argument that none of these allegations correspond to what he calls the "danger harbors" set forth in the FTC's policy statement because they are not based on an idea of cost-standardization or a decrease in prices due to market power.

The final two speakers presented the two polar views of the GPO controversy. First, Larry Holden, President of the Medical Device Manufacturers Association set forth numerous reasons why GPOs operate to exclude certain manufacturers, and reduce competition, including, but not limited to:

- Sole-sourcing agreements
- Bundling of unrelated products
- Exclusionary pricing
- Vendor fees
- Price controls
He provided illustrations of the above examples with current GPO arrangements by such companies as Tyco/Nelicor, Novation and Premier. He said that for two particular products, pulse-oximeters and retractable needles, smaller companies were adversely affected by GPOs and faced obstacles in contracting with hospitals. Holden argued that GPOs resulted in fewer innovations and fewer products reaching the market.

In contrast, Robert Betz, President of the Health Industry Group Purchasing Association, provided a positive perspective on GPOs, stating that no GPO has a market share greater than 15%, and only two have market shares greater than 10%. Additionally, he illustrated the financial and economic problems that would be posed if there were just a one percent reduction in the rate of GPO savings per year:

- An increase in total healthcare expenditures between $1.9 and $2.3 billion;
- An increase in federal expenditures of $86.6 million;
- An increase in Medicare and Medicaid expenditures by $1 billion.

Betz also talked about the Code of Conduct being implemented in the GPO industry. Though it only provides a baseline, Betz expects companies individually to implement within the next year their own versions of the Code with more stringent requirements.

SEPTEMBER 10, 2002 AFTERNOON SESSION

This session, which included individual speakers and panelists, focused on the pharmaceutical industry.

Michael Wroblewski of the FTC reviewed the FTC's recent study on generic drugs, which now constitute 47% of total prescriptions filled, in contrast to 17% before enactment of the Hatch-Waxman Act. Wroblewski stated that Hatch-Waxman does not provide an adequate remedy for generic drug manufacturers to get into the market, and recommended that Hatch-Waxman be amended to permit only one 30-month stay per product per ANDA (Abbreviated New Drug Application). Wroblewski was also concerned that the FDA doesn't review the propriety of patents listed in the Orange Book, and the courts have ruled that there is no private right of action to challenge a listing administratively. (Antitrust challenges have been permitted.)

Patent listing practices were a main concern of the first panel discussion, which included representatives of brand-name manufacturers, the generic industry, consumer groups, and the government. Panelists expressed widely divergent views on brand-name manufacturers' ability to obtain multiple, successive 30-month stays by listing a second, third or fourth patent on a product after an ANDA has been filed.

Representatives of the pharmaceutical industry emphasized the need for patent protection in order to provide incentives for innovation, which is extremely costly. They believe Hatch-Waxman provides sufficient protections and should not be amended; they specifically oppose a limit on 30-day stays and creation of a private right of action to challenge an Orange Book listing of a patent.

Consumer advocates spoke about the high cost of pharmaceuticals, and the urgent need to make generics available to the public, especially for uninsured and elderly consumers. Consumer groups want to close loopholes in Hatch-Waxman, imposing a limit of one 30-month stay, creating a right for generic companies to challenge inappropriate Orange Book listings, requiring disclosure of agreements restricting marketing of generics, and aggressive monitoring of the industry.
The generic drug manufacturers also advocate a limit to one 30-month stay and creation of a right to challenge an Orange Book listing.

The last panel discussion dealt with Direct-to-Consumer ("DTC") advertising of pharmaceuticals. FDA research has concluded that in general, consumers understand the risk information provided by ads and in prescription drugs' package inserts. The government seeks truthful advertising that is consumer friendly, with increased enforcement against fraudulent advertising claims. Most panelists agreed that there is some benefit to DTC advertising, especially in consumer education. The only panelist who was strongly opposed to DTC advertising was Peter Lurie of Public Citizen.

Studies show that although consumers are skeptical of the veracity of DTC ads, advertising can prompt patients to discuss a condition with their physicians that they would not otherwise have mentioned. It also prompts patients to inquire about specific drugs. Studies on the effect of DTC advertising on the market are mixed.

The FTC workshop concluded with Tim Greaney of St. Louis University and his remarks on "What Does the Future Hold for Health Care Competition Policy?" He characterized his view as "gloomy," stating that competition has not curbed costs, while physicians, hospitals and managed care companies point fingers at each other as to who bears the blame.

Greaney highlighted government enforcement failures at DOJ. He blames the courts for permitting mergers based on incorrect market definition. He criticized prevailing court treatment of key antitrust issues, specifically oligopoly/oligopsony, monopsony, and the rule of reason, which he characterized as a "defendant's paradise." Greaney also criticized the private bar for supporting the view that that "any merger is worth trying." As a result, we are headed for more concentrated provider markets and higher costs. To combat that, Greaney recommends FTC amicus filings, revitalized enforcement, increased state enforcement, and targeted research.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.