INSIDE THE MINDS

Understanding Antitrust Issues in Health Care

Leading Lawyers on Analyzing the Impact of Health Care Reform, Managing Antitrust Enforcement Concerns, and Preparing Clients for Change

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Meeting the New Challenges for Mergers in the Health Care Realm

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Introduction

The focus of my practice is primarily antitrust and trade regulation matters, including litigation, merger defense, and counseling. I represent a number of health care clients, including pharmaceutical and medical device companies, hospitals and health care systems, and various provider entities. We represent pharmaceutical companies in a variety of litigation matters as well as a broad array of Hatch-Waxman-related issues. We regularly provide health care providers with antitrust counseling, and have handled numerous hospital mergers.

The Latest Developments in Health Care Antitrust Law

Health care reform is a fundamental goal of the current administration. In addition to the desire for reform, we are experiencing a distressed economy and a greater demand for health care. Health care providers must therefore determine how to deliver health care most efficiently and cost-effectively. As a result, providers across a broad spectrum are likely to collaborate in the future, some in very innovative ways.

Collaborative Activities

One of the interesting developments we are likely to see is the advent of "accountable care organizations" (ACOs). One of the goals of the new health care reform bill—the Patient Protection and Affordable Care Act (PPACA)—is to afford health care providers financial incentives to promote delivery of care to Medicare patients in a coordinated manner across a continuum of care. *See* PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010). The PPACA effectively mandates that an ACO have enough providers to care for its patients, a medical infrastructure that would promote coordinated care, and a legal infrastructure that provides financial incentives for providers who met quality benchmarks. *See Id.* at § 3022. Providers in an ACO may be reimbursed on a mixed for-fee service and shared savings basis or based on a partial capitation model, depending on the level of integration and the performance measures met. *See Id. at* § 3022(d). The PPACA also foresees other collaborative efforts as providers take advantage of the law's innovation incentives.

Federal Trade Commission (FTC) Chairman Leibowitz noted that as long as the government purchases the services and unilaterally sets payment levels, there is unlikely to be many antitrust concerns, but that ACOs may move into the private sector. Jon Leibowitz, Chairman, F.T.C., Address at the American Medical Association House of Delegates: A Doctor and a Lawyer Walk into a Bar: Moving beyond Stereotypes, 7 (June 14, 2010), *available at* www.ftc.gov/speeches/leibowitz/100614amaspeech.pdf. Obviously, an ACO that combines competing providers, such as an independent practice association or physician-hospital organization, carries with it antitrust risk. The level of clinical and/or financial integration is key to assessing the antitrust risk of any provider collaboration, and dovetails nicely with the objectives of the PPACA, which is designed to promote such integration. Clinical integration is always a tricky concept to negotiate, but as Markus Meier, the assistant director in the FTC's Health Care Services and Products Division, stated, "Clinical integration is an active and ongoing program to evaluate and modify the practice pattern of physicians and create cooperation to control costs and ensure quality."

As provided in Statement 8 of the Department of Justice (DOJ) and FTC "Statements of Antitrust Enforcement Policy in Health Care (1996)," clinical integration:

> can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further these efficiency objectives; and (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.

U.S. D.O.J. and F.T.C., Statements of Antitrust Enforcement Policy in Health Care, 72 (1996), *available at* www.ftc.gov/bc/healthcare/industryguide/policy/hlth3s.pdf.

Questions that must be answered are: Does the collaborative entity develop and invest in mechanisms to provide cost-effective quality care? Are there standards and protocols to govern treatment and utilization of services? Are there information systems to measure and monitor individual physician and aggregate network performance? Are there procedures to modify physician behavior and assure adherence to network standards and protocols?

In addition to integration issues, counsel for ACOs must be mindful of market power issues. Given the aggregation of providers within an ACO among a continuum of providers, it is conceivable that ACOs may "lock up" a large portion of the providers in a geographic market, leading to antitrust concerns. Accordingly, ACOs (as well as other joint ventures) will implicate the range of antitrust concerns, including Sherman Act Section 1 (agreements in restraint of trade) and Section 2 (monopolization and attempted monopolization), as well as Clayton Act Section 7 (mergers and acquisitions leading to a reduction of competition).

Besides the incentives for creating an ACO provided by the PPACA, whenever there is a slowdown in economic activity, there is a desire to consolidate and coordinate. Consequently, issues involving the sufficiency of the clinical and financial risk integration among the parties are going to become more prevalent among the enforcement agencies as well as in private counseling. For instance, in April 2009, the FTC's Bureau of Competition informed TriState Health Partners Inc., a Maryland hospital organization, that it would not recommend that the commission challenge a proposed clinical integration program. The bureau determined that the program, which would provide for joint contracting between its 200 physician members and health plans and self-insured employers, could lower health care costs and enhance quality of care. Participation in the program would require physicians to adhere to performance standards and clinical practice guidelines, as well as provide financial and personal time and effort to enable the program to succeed. Physicians would have to refer patients to other providers within the network and would use a Web-based health technology system to determine which patients and providers would require intervention to facilitate effective care and beneficial patient results. Press Release, F.T.C., F.T.C. Staff Advises Maryland Physician-Hospital Organization That It Will Not Recommend Antitrust Challenge to Proposal

to Provide Member Physicians' Services Through 'Clinical Integration' Program (Apr. 14, 2009), *available at* www.ftc.gov/opa/2009/04/tristate.shtm. *See also* Letter from Markus H. Meier, Assistant Dir., F.T.C. Bureau of Competition, to Christi J. Braun, Counsel for TriState Health Partners Inc. (Apr. 13, 2009), *available at* www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf.

Providers will also seek other ways to coordinate to increase profits and/or efficiency. For example, in April 2010, the DOJ approved a proposed data exchange program for hospital services that will collect data on the relative costs and efficiency of more than 300 California hospitals, only after determining that the exchange could actually lower health care costs by increasing competition among hospitals in California. The department concluded that the proposal likely would not generate anti-competitive effects because the information exchange would involve data that is at least ten months old and the program would not disclose disaggregated data or hospitals' actual service fees. *See* Press Release, D.O.J., Department of Justice Will Not Challenge Hospital Cost Information Exchange Program in California (Apr. 26, 2010), *available at* www.justice.gov/atr/public/press_releases/2010/258016.htm.

The FTC recently announced that it "will hold a public workshop on competition policy, payment reform, and the new models for delivering high-quality, cost-effective health care. [They] will focus on how ACOs could affect competition among commercial payers and provide consumers with access to affordable health care services." Leibowitz, *supra*, 7. The workshop will no doubt generate additional insight into the type of collaborations we will see develop and the associated antitrust concerns with these collaborative efforts.

Pharmaceutical Company Activity

Battles in the pharmaceutical area will continue unabated. Chairman Leibowitz has reiterated time and again that stopping so-called "pay for delay" settlements—whereby the patent holder agrees to settle a patent challenge with a generic drug maker for money while the generic agrees to delay its entry—is his top priority. Chairman Leibowitz continues to lobby

Congress to enact legislation to make such settlements presumptively illegal, and the Second Circuit is currently entertaining a petition for rehearing *en banc* that could reexamine these settlements. Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010). Until now, most circuits that have considered the matter have held the agreements legal so long as the anti-competitive aspects of the settlement do not exceed the scope of the patent itself.

Another development that will be interesting to monitor is the growth of biosimilars, which are generic biological products. The PPACA set forth a regulatory pathway for biosimilars in the way the Hatch-Waxman Act did for small molecule generic drugs. As companies take advantage of this framework, issues similar to those seen in the small molecule arena might arise, such as submissions of citizen petitions by patent holders to delay approval of the biosimilar and restrictive settlement agreements.

Hospital Merger Enforcement

The FTC has been successful in the past few years securing victories against hospital mergers that it chose to challenge. One potential trend, particularly in the investigation stage, is a greater emphasis on whether the merger will facilitate an increase in quality of care. For example, in leading the defense against a challenge by the FTC to a consummated hospital merger, my partner, Michael Sibarium, developed a line of defense that the merger resulted in improved quality of services offered by the hospitals, an issue not often litigated in hospital merger cases. Although the commission found that the merger violated Section 7 of the Clayton Act, it did not order divestiture, the default remedy in such cases. *In re* Evanston Nw. Healthcare Corp., No. 011 0234 (F.T.C. 2008), *available at* www.ftc.gov/os/adjpro/d9315/index.shtm. Rather, the commission acknowledged that critical improvements in care were made and that divestiture was inappropriate. While the FTC remained skeptical as to whether clinical improvements could be demonstrated in the context of a prospective merger, as hospitals reinvent themselves in response to health care reform and the economic climate, it would not be surprising to see parties develop such defenses.

Interestingly, left unresolved in the *Evanston* case was how to balance quality improvements, which benefit payers (e.g., managed care companies, self-insured employers) as well as patients, against potential anti-competitive effects, such as price increases. Can the pro-competitive benefits of increased quality outweigh any of the merger's putative anti-competitive effects? Additionally, if a merger would lead (or has led, in the case of a consummated merger) to a better health care product, any increase in price might be attributable to the improved product as opposed to any market power being exercised by the merging parties. In other words, is a merger illegal if absolute prices increase even though quality-adjusted prices do not? The FTC did not answer these questions, nor did it provide a framework for how quality should be measured when utilized in an antitrust analysis. It will be interesting to see if it is forced to address these issues in the coming few years.

Financial Viability Considerations

Hospitals are under a tremendous amount of financial pressure these days. It is likely that merging parties will increasingly invoke the "failing firm" defense, or at least use the target's precarious financial position as part of its defense as to why the transaction will not be anti-competitive. The *Scott & White* hospital merger case, *Scott & White Healthcare/King's Daughters Hosp.*, File No. 091 0084, is a good example. The parties demonstrated that if Scott & White was not allowed to merge with the target hospital, King's Daughters Hospital, King's Daughters would close. The FTC allowed the merger to proceed, but first forced Scott & White to offer to divest the hospital to the only other potential alternative buyer. After due diligence, the other party walked away from the deal and the FTC allowed Scott & White to acquire the hospital. Even if it emerged as a monopoly, the FTC decided it would be better to have the assets in the market rather than have them exit the market. Press Release, F.T.C., Bureau of Competition Director Issues Statement on FTC's Closure of Its Investigation of Consummated Hospital Merger in Temple, Texas (Dec. 23, 2009), *available at* www.ftc.gov/opa/2009/12/scottwhite.shtm. *See also* Letter from Donald S. Clark, Sec'y, F.T.C., to Daniel L. Wellington, Counsel, Scott & White Healthcare (Dec. 23, 2009), *available at* www.ftc.gov/os/closings/091223scottwhitecletter.pdf.

We have handled several merger investigations that were not public where the financial viability of the target was not dispositive but certainly taken into account. The FTC recognizes in the appropriate circumstances that if certain hospitals are not infused with the necessary resources, the hospitals are going to fall into disrepair and will not be competitively viable down the road—and that does not satisfy anyone's concerns. Therefore, we will continue to see both formal failing firm defenses as well as a competitive effects analysis that considers the financial viability of the acquired institutions without a merger.

Focus on Other Types of Providers

As we have seen in the *Transitions Optical* case, *In re* Transitions Optical, Inc., 2010 WL 1804580 (F.T.C. Apr. 22, 2010), it is likely that all health care providers will be under a certain amount of scrutiny in the future. In this case, the FTC challenged Transitions Optical Company, the largest manufacturer of treatments that darken corrective eyeglass lenses, over its vertical practices involving exclusive agreements. In particular, the FTC charged the company with engaging in exclusive dealing at virtually every level of distribution: Transitions refused to work with lens manufacturers that sold competing lenses and signed exclusive agreements with retail stores and wholesale labs to limit their ability to sell competing lenses. The FTC concluded that because of the vertical agreements Transitions had with downstream customers, the company essentially foreclosed competition. In March 2010, Transitions settled with the FTC and agreed to a number of constraints, including an agreement to cease exclusive dealing practices that threaten competition. The broad consent order also restricts Transitions' ability to offer certain types of discounts; prohibits Transitions from limiting the information its customers can give to consumers about competing lenses; and bars Transitions from retaliating against customers that buy or sell Transitions' lenses non-exclusively. Press Release, F.T.C., FTC Bars Transitions Optical, Inc. from Using Anticompetitive Tactics to Maintain Its Monopoly in Darkening Treatments for Eyeglass Lenses (Mar. 3, 2010), *available at* www.ftc.gov/opa/2010/03/optical.shtm. Because of the FTC's investigation, class actions are being filed against Transitions on an almost daily basis.

Changes in Antitrust Case Law

The Status of Single Entities

Although not a health care case, the impact of the Supreme Court's recent opinion in *American Needle* will be interesting. Am. Needle, Inc. v. Nat'l Football League, --- U.S. ---, 2010 WL 2025207 (U.S. May 24, 2010). In that case, the court held that, under certain circumstances, an organization—the NFL in this case—can be judged as a collection of separate organizations that are capable of conspiring. *Id.* The first element to be proved in an alleged violation of Section 1 of the Sherman Act, 15 U.S.C. §1, is the existence of "contract, combination…or conspiracy" between distinct economic entities. In determining whether members of a collective cooperative are engaged in concerted action subject to Section 1, the court eschewed formalistic distinction and held that the inquiry must focus on whether the constituent entities are pursuing separate economic interests such that their coordination deprives the marketplace of an independent decision-maker.

With providers potentially coalescing into health care systems, *American Needle* may have particular applicability in the health care arena. Under some circumstances, an organization comprised of distinct parts that are not wholly owned by a single parent will be treated as a unitary entity that is not capable of conspiring, but for other activities, the system's constituent entities may be considered capable of conspiring amongst each other. Effective monitoring will therefore be required to ensure that the system's activities do not run afoul of the antitrust laws.

Health Care Policy Statements

It remains to be seen whether the antitrust agencies will revise the health care policy statements, which analyze various types of health care provider networks under general antitrust principles, in light of some of the new collaborations that will take place. The statements were last revised in 1996, and it is conceivable that, after the provisions of the health care reform bill are implemented and the agencies start working through some of the issues with the ACOs, the agencies will make some adjustments to the health care policy statements and the safe harbors they provide. These

"safety zones" encompass conduct that the DOJ and the FTC will not challenge under antitrust laws, barring extraordinary circumstances. For example, one such safe harbor relates to information exchanges. The agencies will not challenge health care provider participation in written surveys of prices for health care services, or wages, salaries, or benefits of health care personnel, if:

1. The survey is managed by a third party, purchaser, government agency, health care consultant, academic institution, or trade association)
2. The information provided by survey participants is based on data more than three months old
3. At least five providers are reporting data upon which each circulated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information distributed is aggregated so that it would not allow recipients to identify the prices charged or compensation paid by any specific provider

The agencies have set these conditions for falling within an antitrust safety zone to ensure that competing providers cannot use the exchange of price or cost data to coordinate provider prices or costs. U.S. D.O.J. and F.T.C., Statements of Antitrust Enforcement Policy in Health Care, 50 (1996), *available at* www.ftc.gov/bc/healthcare/industryguide/policy/hlth3s.pdf. Whether these and other safe harbors continue to reflect policy after providers organize under ACOs and in other ways is something to monitor going forward.

Advice for Attorneys

How to Work Successfully with Clients

If you are dealing with any sort of integration or consolidation issue, you have to focus your provider clients on exactly *how* they are going to accomplish their objectives. Doctors and hospital executives are great at devising what they want to do, but sometimes it is hard to get them to focus on the details until the last moment. You need to impress upon them

the need for details early, especially if you plan to seek a business review letter or advisory opinion. Even then, you must continue a running dialogue with the client about what its objectives are, how their objectives have changed, and why it wants to do something. Consequently, you need to stay in touch with your client early and often as they are devising protocols and infrastructure, whether it is a clinical integration, a financial integration, or the parties are coming together in some other collaborative effort.

Staying Up to Date in the Health Care Antitrust Area

It is important for lawyers to follow all of the changes in this area, as developments are so dynamic. For example, will the law exempting insurance companies from certain aspects of the antitrust law be repealed, and if so, how will that affect providers and patients? What types of new pressures is the new health care law placing on hospitals? What organizations can best succeed under the new law? We need to be cognizant of the way the enforcement agencies are viewing various collaborations in the health care area—what sorts of issues are interesting them, and what sorts of arguments they are receptive to. We must also understand what arguments can be proven in a limited amount of time, because parties in this industry cannot spend two years waiting for a merger to happen. Too many deals get killed just because they cannot get cleared fast enough.

Conclusion

Health care is ever changing, and the current economic and political environments provide further incentives for providers (and insurers) to change and become even more efficient. Such changes are likely to produce innovations in the delivery of care, and consequently in how providers across the continuum of care organize themselves and interact amongst each other. Over time, the antitrust laws have showed that they are flexible enough to adapt and apply to a myriad of changes in industry. Still, the next few years may be critical. After all, at its core, health care involves matters of life and death. Staying abreast of developments and developing methods of including quality of care improvements into traditional antitrust analysis will be key.

Key Takeaways

- Health care reform, as well as the state of the economy, provides a climate where provider collaborations will increase and become more innovative. Keeping abreast of these developments is critical.
- Similarly, staying informed as to how the antitrust enforcement agencies are analyzing these collaborations will allow you to help your client minimize antitrust risk right from the outset of your project. Guidance resulting from FTC advisory opinions, the FTC's upcoming workshop, the DOJ's business review letters, enforcement officials' speeches, as well as the guidelines that the Department of Health and Human Services will publish, should all be consulted at the planning stage.
- In defending mergers (and other joint activity), parties may increasingly rely on the improvements in quality that the merger or joint activity will produce to justify the transaction to the enforcement agencies. How the agencies will measure the quality improvements, and how they will balance quality improvements against potential anti-competitive effects, are issues the agencies will need to address.

Jay L. Levine is a partner with Winston & Strawn LLP's Washington, D.C., litigation department. His practice is concentrated in complex litigation, particularly antitrust and trade regulation matters. He has extensive litigation experience in a variety of industries, particularly health care, pharmaceuticals, and consumer products. Over the past few years, he has represented pharmaceutical companies in several antitrust and competition-related actions, many of which involved issues not previously litigated. A significant portion of his practice focuses on counseling clients engaged in mergers and acquisitions. He regularly counsels such clients before the Federal Trade Commission and the Antitrust Division of the Department of Justice, as well as before states' antitrust authorities. In addition to litigation and merger defense, he also counsels clients on a wide range of domestic and foreign antitrust and trade regulation matters, including pricing and distribution restrictions, joint ventures, exclusive dealing, price discrimination, and advertising matters. Earlier in his career, Mr. Levine was involved in a number of antitrust suits brought by various professional athletes, including football, hockey, and basketball players. He was an integral member of the legal team that represented

professional football players seeking free agency in McNeil v. NFL*, which culminated in a jury victory by the players and the institution of free agency in the NFL.*

Mr. Levine received a B.A. in interdisciplinary studies (economics and philosophy) from the University of Maryland and a J.D., cum laude, from Fordham University School of Law, where he was a member of the Law Review.

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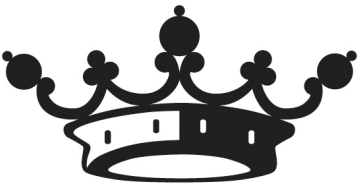

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