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# Editor's Note: Increased Antitrust Enforcement: A Prescription for Lower Health Care Costs?

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FOR MONTHS, THE HEADLINES HAVE been filled with stories about health care reform. Will it happen and will it solve the problems of high costs and limited access for some? Some of the questions have focused on competition issues: would a public access option lead to increased competition or instead to a single-payer system that effectively ends the private insurance market? Whatever the ultimate fate of health care legislation, efforts to ensure a competitive health care environment through aggressive antitrust enforcement remain alive and well at the enforcement agencies both in the United States and Europe.

It cannot come as a surprise that there is a major focus on health care at the antitrust agencies. Health care is a key component of consumer welfare, affecting people's health and well-being, in addition to their pocketbooks. It represents a substantial percentage of the economy. At the same time, the health care industry is under significant pressure. Pharmaceutical companies are looking to reap the rewards of heavy expenditures in innovation, particularly while many current blockbuster drugs face impending patent termination. Independent hospitals are finding it harder to survive, as they confront higher expenses from more sophisticated technology, while insurance companies are trying to lower rates in the face of employer concern about high insurance premiums. And physicians find themselves squeezed by Medicare and Medicaid reimbursements and difficult rate negotiations with health insurers.

All the actors in the health care arena are trying to find ways to overcome the obstacles before them. These efforts often result in litigation—whether offensively, as part of their strategy to survive, or defensively, because someone else views their activities as crossing the line.

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***Pharmaceutical patent settlements:*** Nowhere is the concern about anticompetitive behavior in the health care arena more evident than with respect to patent litigation settlements between brand and generic pharmaceutical companies, where the brand pays value to the alleged generic infringer ("reverse payments") and the latter agrees to defer its entry into the market, known at the FTC as "pay-for-delay" cases. Earlier this year, the Commission announced a study showing that the cost to consumers from these settlements is an estimated $3.5 billion per year and has led to generic delays of up to seventeen months.[1] This study was based on the patent settlement agreements filed with the FTC pursuant to mandatory filing requirements. The FTC has brought lawsuits challenging these agreements, only to lose or get tied up in ongoing litigation, while the courts, so far, have been mostly unsympathetic to the FTC's theory of anticompetitive harm.

The FTC is now aided in its efforts by the Department of Justice, which in the Bush Administration was not aligned with the FTC on this issue. The article by Jim O'Connell takes the reader through the twists and turns that brought the Department to its current stance on reverse-payment patent settlement cases—a standard that, while not per se, arguably provides defendants with only limited rights to rebut the presumption of illegality.

While the Commission argues that these settlements are unbridled agreements not to compete, the agency's track record in court shows that this issue is far more controversial. The article by Ken Glazer and Jenee Desmond-Harris in this issue explains that "[r]everse payments remain one of the most contentious areas of antitrust." Their article goes beyond the debate, focusing on what would happen if the FTC gets its wish and Congress passes legislation prohibiting patent settlements in which the brand pays the generic something of value in exchange for deferred entry. The authors explore how the agency and courts will determine whether the settling generic's receipt of "value" was pursuant to an anticompetitive agreement or instead part of a legitimate, procompetitive relationship between the parties.

***Private challenges to branded pharmaceutical company conduct:*** Challenges by private plaintiffs to conduct by branded pharmaceutical companies are no less difficult. As the article by Royall and Lipton notes, "Antitrust suits involving generic drug exclusion claims raise complexities of proof at virtually every stage. Issues of patent law, biotechnology, and FDA practice often intersect with sophisticated issues of economics and antitrust law, presenting significant challenges for both the litigating parties and the courts." The article offers practical suggestions for potential defendants. Nonetheless, it is inevitable that pharmaceutical companies will continue to be embroiled in antitrust litigation, given the high stakes of these cases for consumers and for the companies.

***European Pharmaceutical Sector Report:*** The United States is not alone in having a pharmaceutical industry that is a magnet for criticism—as readers will certainly conclude

after reading David Rosenberg's fascinating critique of the EC Pharma Sector inquiry. This EC initiative involved "dawn raids" (unannounced inspections) on branded and generic drug companies and allegations that "innovator" company conduct has cost consumers millions of Euros. It has also led one European judge to call the report "ignorant, arid and incompetent." Rosenberg explains shortcomings he sees in the Commission's report, and points to steps that he contends could have been taken to reach better conclusions as to whether improper behavior indeed occurred. And, as Simon Priddis and Simon Constantine discuss, the implications of the report go well beyond the pharmaceutical sector, and offer lessons for other industries in which intellectual property plays an important role.

***Hospital merger enforcement:*** Previous articles have discussed the FTC's use of new hospital merger simulation tools to determine whether a hospital merger is anticompetitive, and of the agency's new tactics in administrative litigation to challenge mergers that it alleges are anticompetitive.[2] Recently, the Massachusetts Attorney General issued a report that found that hospitals with greater market power charged more than others, but without providing superior quality.[3] Findings like these are likely to further energize the Commission's enforcement efforts. Yet at a time when hospitals—particularly stand-alone community hospitals—are facing increased financial pressure, and often failing, their need to find a merger partner has become more pressing.

Those conflicting dynamics played out in the latest chapter of the FTC's hospital merger enforcement activities. The FTC recently cleared a hospital merger, but not without a few twists and turns along the way. At the end of the year, the Commission voted to close its investigation of Scott & White Healthcare's merger with King's Daughters Hospital in Temple, Texas.[4]

FTC staff was prepared to challenge the non-reportable transaction because it eliminated the only independent competitor to Scott & White, and would have turned the hospital into a children's hospital rather than keep it as a provider of general acute care services. Yet King's Daughters was on the verge of closure because of serious financial difficulties. The parties took the unusual step of agreeing that Scott & White would offer to sell King's Daughters to another buyer on specific terms to avoid litigation. When that sales agreement fell through, the Commission closed the investigation. That the Commission sought to challenge such a transaction—one that was not reportable under Hart-Scott-Rodino, and that involved a failing hospital—shows that the agency is still very aggressive in the arena of hospital competition.

***Insurance company mergers:*** While the concern with hospital mergers is that prices will increase to insurance companies (and potentially get passed down to employers and insurers), the agencies are equally concerned about mergers between insurance companies. Blue Cross Blue Shield of Michigan's (Blue Cross-Michigan) subsidiary, Blue Care Networks of Michigan, abandoned its attempt to purchase Physicians Health Plan of Mid-Michigan (PHP) after the Department of Justice informed the companies that it would file an antitrust lawsuit to block the acquisition. The DOJ had concerns both about the high combined share in the insurance market in Michigan but also the combined firm's ability to control physician reimbursement rates in a manner that could harm the quality of health care delivered to consumers.[5]

***Physician conduct cases:*** And to round out the array of actors subject to antitrust enforcement, the FTC has recently settled charges of physician price fixing. *Roaring Fork Valley Physicians I.P.A.* involved what has become a "garden-variety" type of physician case—this time, one in which eighty-five doctors allegedly fixed prices outside the context of any integrated joint venture.[6] A second consent agreement, *In the Matter of Catherine Higgins*, involved an unusual situation. A physician's association previously was ordered to cease and desist in price fixing. When the FTC believed the executive director of the association attempted to evade the terms of the order by telling insurers she could continue negotiating in her own capacity, the Commission put her under order.[7] This case included a harsh dissent from Commissioner Rosch, who described the majority's action as lacking sufficient basis in fact, "unnecessarily punitive," and "reneging on" a prior deal.[8]

The variety of recent antitrust enforcement actions makes clear that no sector of the health care economy is safe from scrutiny by the antitrust enforcers. Whether this ultimately leads to lower costs is surely open to question. But preserving competitive markets is the function of antitrust enforcement and the agencies have embraced that role. ■

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1 See Fed. Trade Comm'n, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

2 *See, e.g.*, Jeffrey W. Brennan & Sean P. Pugh, Inova *and the FTC's Revamped Merger Litigation Model*, ANTITRUST, Fall 2008, at 28; David A. Argue & Richard T. Shin, *An Innovative Approach to an Old Problem: Hospital Merger Simulation*, ANTITRUST, Fall 2009, at 49.

3 See Liz Kowalczyk & Scott Allen, *AG Finds Clout of Hospitals Drives Cost*, BOSTON GLOBE, Jan. 29, 2010, *available at* http://www.boston.com/news/health/articles/2010/01/29/attorney_general_says_clout_drives_up_health_costs.

4 *See* Statement of Bureau of Competition Director Richard Feinstein on the FTC's Closure of Its Investigation of Consummated Hospital Merger in Temple, Texas (Dec. 23, 2009), *available at* http://www.ftc.gov/os/closings/091223scottwhitestmt.pdf.

5 Press Release, U.S. Dep't of Justice, Blue Cross Blue Shield of Michigan and Physicians Health Plan of Mid-Michigan Abandon Merger Plans (Mar. 8, 2010), *available at* http://www.justice.gov/atr/public/press_releases/2010/256259.htm.

6 Roaring Fork Valley Physicians I.P.A., Inc., FTC No. 061-0172 (Feb. 3, 2010) (Agreement Containing Consent Order to Cease and Desist), *available at* http://www.ftc.gov/os/caselist/0610172/100203roaringforkagree.pdf.

7 Statement of the Commission, In the Matter of M. Catherine Higgins, FTC No. 051-0252 (Feb. 5, 2010), *available at* http://www.ftc.gov/os/caselist/0510252/higgins/100205bouldervalleystmt.pdf.

8 Dissenting Statement of Commissioner J. Thomas Rosch, In the Matter of M. Catherine Higgins, FTC No. 051-0252 (Feb. 5, 2010), *available at* http://www.ftc.gov/os/caselist/0510252/higgins/100205bouldervalley-jtrstmt.pdf.