

It Is All About the Facts: Commentary on the Current State of Antitrust Enforcement in Health Care

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INTRODUCTION

This Essay specifically addresses the conference presentations of Professors Barak Richman and Tim Greaney, but also shares my own views on the current state of antitrust enforcement in health care, including current challenges and potential reforms.

In summary, both Professors Richman and Greaney seemed critical of

* Partner, Hogan Lovells U.S. LLP. Pursuant to the 2016 Symposium on Reconciling Competition and Consumer Protection in Health Care that the American Bar Association and the Loyola University Chicago School of Law cosponsored, I was asked to provide comments on Professors Tim Greaney’s and Barak Richman’s presentations at the conference. I very much appreciate the opportunity to participate in a panel discussion with these esteemed academics.

the antitrust laws and argued that the antitrust laws failed to prevent the level of concentration that we see in the health care industry today, or that they are poorly suited to regulate anticompetitive conduct related to the pharmaceutical industry. I disagree. Antitrust jurisprudence is an enforcement tool available to state and federal agencies, as well as to private citizens. And agencies and private citizens use these laws in traditional and novel ways to challenge anticompetitive conduct. The outcome of enforcement actions, however, depends in large part on the specific facts and circumstances of each individual case. This is the benefit of the case-based nature of the competition regulation and this approach arguably prevents antitrust laws from having a chilling effect on growth, innovation, and the achievement of economic efficiencies.

This Essay argues that antitrust laws are not to blame for the perceived high levels of concentration in certain health care markets and maintains that the United States should not abandon these laws in favor of alternatives. The beauty of the antitrust laws is that they are applicable to all industries (with very few exceptions), and before a court can rule the combination or conduct unlawful, it must conduct a rigorous analysis into the facts, circumstances, and actual or potential outcomes of combinations or conduct at issue—there are very few bright-line rules that apply in antitrust jurisprudence.

I. RESPONSE TO PROFESSOR RICHMAN'S PRESENTATION: THE LIMITS OF, AND ALTERNATIVES TO, ANTITRUST IN THE HEALTH CARE SECTOR

One can interpret Professor Richman's conference presentation as arguing that antitrust law may not appropriately or adequately address competitive concerns related to "product hopping."¹ Product hopping is the practice of extending a pharmaceutical product's exclusive intellectual property rights by introducing a modified version of the original product before (or just as) the original formulation is set to lose its patent protection. Professor Richman's presentation offered alternative solutions to antitrust law aimed to address the concerns regarding reduced competition in the pharmaceutical marketplace raised by this practice, including alternative regulatory, policy, or other solutions that may be better suited than antitrust enforcement to address this issue. For example, some alternatives to antitrust law to improve the competitiveness of the pharmaceutical industry suggested by Professor Richman include: (1) improved administrative procedures at the United

1. Barak D. Richman, Professor, Duke University School of Law, Presentation at the American Bar Association and Loyola University Chicago School of Law's Symposium: Reconciling Competition and Consumer Protection in Health Care (Sept. 20, 2016).

States Patent and Trademark Office (“USPTO”); (2) better regulatory regimes governing drug substitution laws; and (3) increased pressure imposed by health plans on physicians and patients to encourage more cost-conscious decision making.

Although these alternatives may potentially enhance marketplace competition, it would be misplaced to abandon the use of antitrust laws to enforce against anticompetitive conduct. For example, the most notable case on “product hopping” thus far is the New York Attorney General’s case against Actavis (formerly Forrest Laboratories), related to its product extension strategy for its Namenda product—a drug for the treatment of Alzheimer’s disease.² In *New York ex rel. Schneiderman v. Actavis PLC*, the Second Circuit upheld the finding that Actavis’ conduct related to Namenda was unlawful under the antitrust laws.³ This Essay posits that *Actavis* is a practical example of the successful prosecution of anticompetitive conduct under the antitrust laws, and would suggest that alternative approaches to regulation are neither more efficient than antitrust laws nor better suited to prevent unlawful conduct similar to the unlawful activity in *Actavis*.

A. Are USPTO Reforms Better Than Antitrust Laws?

Professor Richman suggests that the USPTO could revise its processes to deny patents for immaterial innovations or reformulations.⁴ Theoretically this might work, but this Essay suggests that such reforms are neither easily enacted nor enforced. Even if the USPTO is the right place for these types of determinations, it is not clear whether this would actually prevent anticompetitive “product hops.”

In *Actavis*, the reformulation involved a switch from a twice-a-day immediate release formulation to a once-a-day extended release product.⁵ The New York Attorney General’s complaint in *Actavis* interestingly did not focus on the issue of whether the extended-release (“Namenda XR”) formulation was truly innovative or a material improvement over the immediate-release (“Namenda IR”) formulation. In its prosecution under the antitrust laws, the Attorney General posed that the court did not need to reach this issue.⁶ Rather, the court looked at the conduct of Actavis as

2. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 642–43 (2d Cir. 2015).

3. *Id.* at 659 (holding that “the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates [section] 2 of the Sherman Act”).

4. Richman, *supra* note 1.

5. *Actavis*, 787 F.3d at 642–43.

6. Brief for the Appellee, *Actavis*, 787 F.3d 638 (No. 14-4624), 2015 WL 1010525 (C.A.2) (“If there were any non-pretexual, efficiency-related, procompetitive justification for defendants’

a monopolist to determine whether its actions constituted anticompetitive conduct under section 2 of the Sherman Act.⁷ The New York District Court found that forgoing profits from sales of Namenda IR for the purpose of constructing a barrier to entry for generics was the exact type of conduct prohibited under the Sherman Act.⁸ Therefore, it was irrelevant whether Namenda XR was a material improvement or innovation over Namenda IR (i.e., the original formulation).⁹

The Namenda reformulation was arguably a material innovation from the original Namenda IR formulation and, as a result, the current regulations and processes of the USPTO granted additional patent protection to the reformulated product. It is unclear whether Richman's suggested reforms at the USPTO can address the specific issues that arise in the "product hopping" context without potentially curbing the incentive for innovators to introduce new and improved versions of legacy products. In other words, if the USPTO raises the bar for obtaining additional patent protection for new formulations or improvements to existing pharmaceutical products, the obvious concern is that pharmaceutical companies would not invest in important modifications to existing products because of a lack of adequate intellectual property protection.

B. Are Improvements in Regulation of Drug Substitution a Solution?

Professor Richman also indicated that state drug substitution laws should be more relaxed so that pharmacists have a greater ability to substitute generic pharmaceuticals not necessarily AB-rated by the Food and Drug Administration ("FDA").¹⁰ An AB rating indicates whether a drug is therapeutically equivalent to another approved pharmaceutical product. Although relaxing state drug substitution laws could ultimately make it easier for generics to compete against branded drugs, particularly when a branded company introduces a new formulation for which no generic is yet available, changing substitution laws raises other concerns. Most importantly, it puts the discretion in the hands of the pharmacists to determine appropriate substitutes for the prescribed product. This would effectively require thousands of pharmacists across the country to step into the role of the FDA in terms of determining whether any particular generic drug is appropriate to be dispensed as a substitute for the

exclusionary conduct, it would be weighed against the anticompetitive effects of the conduct to determine whether [section] 2 liability is appropriate.”)

7. *Actavis*, 787 F.3d at 655–58.

8. *Id.* at 658.

9. *Id.* at 658–59.

10. Richman, *supra* note 1.

prescribed branded drug.

C. Can Payor Pressure on Physicians and Patients Create a More Competitive Environment for Pharmaceuticals?

Health care payors need to play a role in bending the cost curve of health care by holding physicians and patients accountable for their choices of providers, location for care, and pharmaceuticals. But one of the greatest challenges in this area is the lack of transparency and accountability in terms of who is paying for health care services and what those services or products actually cost. Furthermore, to the extent that health care markets are concentrated either at the provider level or payor level, the drive to innovate is potentially stifled. For example, if a payor enjoys a market where there is relatively little competition, then it may not feel the competitive pressure to lower prices or create new product designs that shift responsibility downstream to the provider or patient. Put simply, why would a large payor worry about pressuring physicians and patients to make better, lower-cost choices as to pharmaceuticals, if in doing so, the payor might risk losing consumers and, in turn, market share?

Rather than swapping out the antitrust laws in favor of merely relying on payors to pressure physicians and patients to make better choices, we should advocate for increased transparency in all aspects of health care, including payors, providers, pharmaceuticals and pharmacy benefit managers. We need better tools to educate providers—as prescribers and referral sources—and consumers on the costs of different services or products. And, for purposes of antitrust enforcement, we need better tools at the agencies to recognize and credit innovative and disruptive actors that are trying to drive improvement in the pharmaceutical marketplace, health plan products, or health care delivery systems, and that will shake up entrenched payors and provider systems that hold high market shares.

II. RESPONSE TO PROFESSOR GREANEY'S PRESENTATION: ANTITRUST AND REGULATORY RESPONSES TO DOMINANT HEALTH CARE PROVIDERS AND PAYORS

Professor Greaney's symposium presentation suggested that antitrust laws are important, but limited in their ability to address the issues of payor or provider market power in health care markets that arise through mergers or consolidation.¹¹ He claimed that judicial errors contributed

11. Thomas Greaney, Professor, Saint Louis University School of Law, Presentation at the American Bar Association and Loyola University Chicago School of Law's Symposium: Antitrust

to the current concentration levels of health systems and health plans, and that attempts by regulators, at the state level, to regulate prices and other competitive dynamics (e.g., quality and efficiency) through legislation have been inadequate in stemming rising costs in health care. Professor Greaney proposed that the better approach would be for antitrust regulators to target the conduct of payors and health care providers with high market shares to prevent anticompetitive behavior of these entities.

A. Has Antitrust Enforcement “Abjectly Failed to Lower Provider Prices” Thereby Failing to Preserve Competitive Markets?

The idea that antitrust laws are solely responsible for lowering provider rates places a very high and undue burden on the antitrust laws. Instead, one must recognize that health care in the United States is a heavily regulated industry, and the government itself is the largest payor. Just scratching the surface of government regulation over health care would reveal that: (1) the FDA is responsible for the process, review, and eventual approval of new drug applications and new medical devices; (2) the Centers for Medicare and Medicaid Services, along with state agencies, regulate providers with respect to reimbursement rates for the Medicare and Medicaid populations, and prices of pharmaceuticals for a similar population; and (3) state insurance commissioners regulate health insurance plans and, in certain states, the health insurance exchange market. Because of the interplay of regulatory bodies in the United States’ health care system, it is overzealous to blame antitrust laws for failing to protect against increases in provider rates and health care costs. In fact, no single regulatory regime or body of law can adequately solve all the issues regarding pricing, quality, and competition that arise in our health care system.

B. How Can Antitrust Laws Impact Future Consolidation?

As for antitrust laws and their enforcement, this Essay posits that there is an important need for better tools to distinguish anticompetitive transactions from procompetitive or neutral consolidation in the health care field. Specifically, antitrust analysis requires tools that can more accurately anticipate whether consolidation will lead to price increases versus greater price competition, and tools that can predict the potential for benefits to patients from enhanced quality or increased innovation in health care delivery or payment methodologies.

What does it mean to develop “better tools?” In practice, when health care providers or payors consolidate, the procompetitive rationale is

typically related to opportunities to improve efficiency or quality in the delivery system or scale and efficiency in the payor market. At present, there is a lack of appropriate ways to measure and test the potential and likelihood for these efficiencies, particularly around quality gains and innovation. This Essay proposes that current methods for evaluating price effects and quality impacts from consolidation need to evolve to remain relevant in a changing health care landscape. In particular, antitrust enforcers need to consider how to evaluate and credit arguments of improved quality and innovation, which are particularly notable as hospitals and physicians form more integrated delivery systems and health plans adopt new payment models that can have a real impact on improving health care outcomes and lowering costs.

CONCLUSION

In considering Professors Greaney's and Richman's presentations, I was struck by how critical both professors were of the antitrust laws and their alleged failings with respect to protecting competition in the health care system. This Essay posits that the antitrust laws are not the only factor influencing our health care system such that they can be blamed entirely for the system's failings. Rather, antitrust laws have played, and will continue to play, an important role as health care delivery and coverage continue to evolve in this country. The facts of the situation are critical in every instance in which the antitrust laws are applied to health care consolidations or conduct. The importance of facts in antitrust law is evident in *Actavis* where the facts led the court to conclude that conduct at issue violated the antitrust laws.¹² The same can be said for antitrust enforcement in health system consolidations—these cases and therefore judicial decisions in this area largely turn on the facts as they fit into the antitrust doctrine.

12. *Actavis*, 787 F.3d at 659–60.