

*Chapter Nine****Competition in the Unhealthy Health Sector***

The federal antitrust agencies and the states have rightly been deeply concerned about the workings of the health care sector, which seems to be unduly expensive and leaves so many underprotected or unprotected from catastrophic loss. In this chapter, we urge a realignment of priorities for antitrust enforcement, as summarized below.

MAJOR RECOMMENDATIONS

- **Resources and Priorities.** The Federal Trade Commission (FTC) and Department of Justice (DOJ) have appropriately dedicated substantial resources to health care antitrust enforcement. However, lax or nonexistent enforcement has resulted in high concentration or cartelization in some sectors, such as pharmaceuticals, hospitals, and health insurance. The next administration should pay particular attention to preventing further erosion of competition in these areas while improving effectiveness in detecting, litigating, and obtaining remedies involving abuses by providers of health services.
- **Intermediaries.** Despite significant competition problems involving healthcare intermediaries, including health insurers, pharmacy benefit managers (PBMs), and group purchasing organizations (GPOs), there have been no enforcement actions against these entities. In the absence of federal enforcement, there has been a tremendous increase in consolidation in the health insurance and PBM markets and a significant number of state and private enforcement actions against all these entities. The health insurance market has experienced a rapid consolidation, and the vast majority of metropolitan markets have become highly concentrated. A similar trend has occurred in the PBM market. Abandoning enforcement in these key areas leads to significant harm to consumers
- **Pharmaceuticals.** The FTC has brought some of the most significant cases in the history of antitrust enforcement against anticompetitive conduct in the

pharmaceutical industry, involving efforts by brand name firms to divide markets and prevent entry by manufacturers of rival generic drugs. In spite of these efforts, anticompetitive conduct by brand name pharmaceutical companies continues, costing the public hundreds of millions of dollars in overpayments. The agencies should dedicate greater resources and bring more enforcement actions in this area. In particular, oversight of patent settlements between brand name and generic pharmaceutical firms has been confused by several questionable decisions of the appellate courts and the lack of support for the FTC's enforcement by DOJ. Congressional action is necessary to prevent the use of settlements to harm competition.

- **Physicians.** The FTC's numerous actions involving physician cartels have failed to secure compliance with the antitrust laws. The agency should target its cases against physician groups that knowingly violate the law and impose stiffer sanctions. It should also issue clearer guidance regarding permissible cooperative conduct, especially clinical integration.
- **Hospitals.** The FTC has appropriately renewed enforcement against hospital mergers and should continue to look for instances where hospital mergers lead to potential anticompetitive effects. In addition, where significant hospital consolidation has already occurred, the agencies should be alert to exclusionary conduct or conduct that raises rivals' costs, thus preventing entry by new entities (including specialty hospitals and ambulatory service providers).
- **Government Regulation.** Regulations and payment policies that inhibit competition must be closely examined. State and federal antitrust enforcers should actively advocate repeal or rejection of anticompetitive legislation, such as certificate of need laws and insurance mandates. In addition, the agencies should challenge overbroad application of the state action and Noerr doctrines where they permit monopoly-protecting regulation to trump antitrust law.
- **Government as a Purchaser.** Because the government is a major purchaser of health services, accounting for nearly half of all health care purchases, it exerts an extraordinary influence on the delivery of health services that spills over into

the private sector. To the extent that these purchases rely on administered pricing, they can distort the market and strongly influence practice patterns that often undermine the benefits of competition in those markets. Through competition advocacy and involvement in the policy decisions of the Centers for Medicare and Medicaid Services, the agencies can exert influence that will improve the workings of competition in the private sector.

I. Greater Resources and Readjustment of Priorities

Health care is perhaps one of the industries where antitrust enforcement is most needed, but also most difficult to implement successfully. Health care accounts for 16% of the total GNP¹ and over 23% of the total domestic budget.² Efforts to control health care costs are a critical public priority, and there are numerous reasons why health care markets do not function according to neoclassical economic models. Appropriately, the FTC and DOJ have dedicated substantial resources to health care antitrust enforcement. A substantial portion of the actions brought by the agencies involve the health care marketplace. In addition, over the past several years the FTC has significantly enhanced its advisory and advocacy efforts on health care competition issues in numerous forums.

Nevertheless, there are strong reasons to support a substantial increase in the resources and level of enforcement dedicated to health care. First, lax government enforcement of the antitrust laws has resulted in high concentration or cartelization in some sectors, most notably, pharmaceuticals, hospitals and health insurance. The next administration should pay particular attention to preventing further erosion of competition in these areas while improving the agencies' overall effectiveness in detecting, litigating, and obtaining remedies in cases involving providers of health services. Second, the government's track record in the cases it has pursued is less than stellar. For example, despite the many cases filed against physician cartels, blatantly objectionable practices have continued while, at the same time, providers lack specific guidance as to which activities are permissible. In addition, after losing seven consecutive hospital merger cases in federal court (some due to judicial error and others due to poor case selection),

¹ Centers for Medicare & Medicaid Services, National Health Expenditure Factsheet, http://www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp (last visited June 27, 2008).

² Congressional Budget Office, The Budget and Economic Outlook: An Update, Aug. 2007, <http://www.cbo.gov/doc.cfm?index=8565> (last visited June 27, 2008).

the agencies abandoned merger enforcement for almost six years. The result has been a significant increase in hospital market concentration, resulting in less competition, diminished access for patients, and increasing prices for health insurance. Third, the antitrust agencies have directed almost all of their enforcement actions against conduct by health care providers while forgoing enforcement against health care intermediaries, health insurers, and hospitals. While vigilance against provider cartels must remain an important priority, concentration and market power in insurance markets must also be addressed. Over 400 health care mergers have occurred in the past decade, with a significant number of health insurance markets becoming highly concentrated.³ The net result of these shortcomings in antitrust enforcement has been higher health insurance costs and more citizens uninsured. Health insurance premiums increased by over 87% between 2001 and 2007,⁴ while the number of uninsured has increased from 20 million to 47 million, or over 1 in 7 Americans.

As explained in greater detail below, the lack of antitrust enforcement against health insurers has been partially mitigated by actions of state officials and private litigants. These include litigation against health insurers for a variety of fraudulent and deceptive anticompetitive practices and occasionally litigation against hospitals. However, private and state litigation face high hurdles. Some difficulties are caused by mistaken and economically unsophisticated judicial precedent, others by obstacles to effective consumer redress posed by doctrine restricting standing for private litigants. Against this background, the need for effective federal antitrust enforcement is greater than ever.

Finally, it is very important to remember that antitrust policy does not exist in a vacuum. Effective competition depends on having a legal structure and regulatory policies that do not hinder rivalry. Health care, as we all know, is among the most heavily regulated industries and many state and federal regulations act at cross purposes with the competitive norms of antitrust. In addition, the government is a major purchaser of health services, accounting for nearly half of all health care purchases through Medicare, Medicaid, government and military employee insurance, and state and local health care programs. To the extent that these programs rely on administered pricing, they distort

³ *In the Matter of the Acquisition of Health Plan of Nevada, Inc. by UnitedHealth Group Inc.: Hearing Before the Nevada Commissioner of Insurance 9* (2007) [hereinafter *Nevada Hearings*] (testimony of David Balto).

⁴ KAISER FAMILY FOUNDATION, EMPLOYER HEALTH BENEFITS 18 (2007), available at <http://www.kff.org/insurance/7672/upload/76723.pdf>.

the market and strongly influence practice patterns that affect the private sector in ways that undermine the benefits of competition in those markets.

Recommendation

- Greater resources should be devoted to health care antitrust enforcement. The priorities of the health care enforcement agenda need to deal with the competitive issues created by nonenforcement or ineffective enforcement of antitrust law.

II. Health Care Intermediaries: Health Insurers, PBMs, and GPOs

Health care markets have evolved over time. In numerous situations, intermediaries have been formed to serve a variety of functions, including claims processing and adjudication, purchasing, and entering into contractual arrangements with a broad range of providers and other sources of supply. Often these intermediaries can enhance competition by achieving economies of scale, aggregating demand, and collecting purchasing power.

But there are significant competitive concerns raised by health care intermediaries. Several intermediary markets are very concentrated and have significant barriers to entry. Where the practices of the intermediaries are not wholly transparent, there may be opportunities for deceptive conduct. Intermediaries can use their power to foreclose competition through a wide variety of exclusionary practices. As a recent series of articles in the *Wall Street Journal* observed, intermediaries have not functioned effectively in the health care context and middlemen often seem to exercise market power:

[W]hile the Internet, deregulation and relentless corporate cost-cutting have squeezed middlemen elsewhere, the health-care middlemen are prospering. The three largest pharmaceutical benefit managers, for instance, had net income of \$1.9 billion last year, a sum that exceeds the annual operating budget of New York's Sloan Kettering cancer center. In corners of the system such as Medicaid managed care and nursing-home drugs, little-known intermediaries rack up tens or hundreds of millions of dollars in profit.⁵

⁵ Barbara Martinez et al., *Health-Care Goldmines: Middlemen Strike it Rich*, WALL ST. J., Dec. 29, 2006, at A1.

During the past administration, there have been no federal antitrust enforcement actions against intermediaries, including health insurers, PBMs, and GPOs. This is not to suggest that there are no competitive problems involving these firms. Indeed, there have been numerous private and state antitrust and consumer protection enforcement actions against these companies. Despite these efforts, the lack of federal enforcement results in higher prices and decreased choice for consumers.

A. *Health Insurance*

The health insurance market has undergone a remarkable period of consolidation in the past seven years. There were over 400 health insurer mergers in the past decade and now practically every major metropolitan market is highly concentrated.⁶ The number of insurers has fallen by just under 20% since 2000. These mergers have not led to benefits for consumers; instead, premiums have skyrocketed, increasing more than 87% over the past six years. Patient care has been compromised by the over-aggressive efforts of supposed managed care, and the number of uninsured Americans has reached record levels, reaching over 47 million. Four health insurers dominate the national marketplace, with one or two firms dominating practically every local market.⁷

The unprecedented level of concentration and lack of antitrust enforcement in the health care industry pose serious policy concerns. As Vermont Senator Patrick Leahy observed in hearings before the Senate Judiciary Committee on health insurance consolidation:

[A] concentrated market does reduce competition and puts control in the hands of only a few powerful players. Consumers – in this case patients – are ultimately the ones who suffer from this concentration. As consumers of health care services, we suffer in the form of higher prices and fewer choices.⁸

⁶ *Nevada Hearings*, *supra* note 3, at 9, 10 (testimony of David Balto).

⁷ *Id.*

⁸ *Examining Competition in Group Health Care: Hearing Before the S. Comm. on the Judiciary*, 109th Cong. 86 (2006) [hereinafter *Examining Competition*] (statement of Sen. Patrick Leahy).

In the past seven years the DOJ has required the restructuring of only two proposed health insurance mergers, in both cases mandating very modest divestitures.⁹ This lack of enforcement has led to higher premiums, higher deductibles, higher co-pays, a greater number of uninsured, and a variety of anticompetitive conduct by dominant health insurers.¹⁰ The most severe problems occur when employers or employees simply can no longer afford insurance. Increasingly, employers have been forced to downscale or even eliminate employee insurance benefits.¹¹ Consequently, the number of uninsured individuals has hit record levels. Moreover, the increased consolidation has given several insurers a greater degree of monopsony power. Insurers employ this buyer power to decrease compensation to health care providers, leading to a reduced level of health care.¹²

We believe this lax merger enforcement policy in health care needs to be reversed. In a recent major health insurance merger, DOJ permitted United Health Group Inc. to acquire Sierra Health Services, Inc., giving it a market share of over 50% in the Las Vegas market.¹³ DOJ's decision not to seek enforcement represented a clear break from the tougher stance on health insurance mergers pursued during the Clinton administration.¹⁴

Health insurers possess a variety of tools to exercise their market power and reduce the choices of providers and consumers. For example, health insurers use “most favored nation” provisions to prohibit health care providers from entering into arrangements to sponsor new entry into the insurance market or facilitate expansion. “All products”

⁹ See *United States v. UnitedHealth Group Inc.*, Case No. 05CV02436 (D.D.C. 2006) (merger of UnitedHealth Group Inc. and PacifiCare Health Systems, Inc.) and *United States v. UnitedHealth Group Inc.*, Case No. 08-cv-00322 (D.D.C. 2008) (merger of UnitedHealth Group Inc. and Sierra Health Services, Inc.).

¹⁰ *Consolidation in the Pennsylvania Health Insurance Industry: The Right Prescription? Hearing Before the Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, 110th Cong. (2008) (Testimony of David Balto) available at http://judiciary.senate.gov/testimony.cfm?id=3522&wit_id=7367.

¹¹ Examining Competition, *supra* note 8, at 79 (statement of Edward L. Langston, M.D., Am. Med. Ass'n).

¹² *Id.* at 9 (statement of Mark A. Piasio, President, Pa. Med. Soc'y).

¹³ *Nevada Hearings*, *supra* note 3, at 14 (testimony of David Balto).

¹⁴ For an extensive discussion of the impact of the UnitedHealth/Sierra merger, see *Nevada Hearings*, *supra* note 3 (testimony of David Balto).

clauses function like tying arrangements and may be used to coerce providers to participate in particular health plan programs.

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.¹⁵

B. Pharmacy Benefit Managers

PBMs play an important function in health care markets by setting up pharmaceutical benefit networks and adjudicating pharmaceutical claims. The PBM market has also faced rapid consolidation, in part due to lax antitrust enforcement. In the past seven years, over a dozen PBM mergers have occurred, leaving three major PBMs with approximately 80% of the national market. The FTC has not undertaken any enforcement activity in the face of this market consolidation. In fact, the past two substantial PBM mergers – Caremark’s acquisition of AdvancePCS and CVS’s acquisition of Caremark – were approved without a significant investigation, despite leading to a significant increase in concentration. Since the Caremark/AdvancePCS merger was

¹⁵ One statute that contributes to consumer-unfriendly and anticompetitive practices in the health insurance industry is the McCarran-Ferguson Act, 15 U.S.C. § 1011 (2007). The act includes a provision that sharply limits the scope of federal antitrust enforcement targeting the insurance industry, relying instead on state agencies to regulate the industry. Some observers contend these agencies have provided insufficient regulatory oversight and lax enforcement of insurance providers. Operating outside the oversight of federal agencies, insurers have been free to collaborate in ways that are potentially detrimental to consumers, for example, by developing industry-standard risk classifications and terms of service, which may artificially reduce consumer choice. See *The McCarran – Ferguson Act and Antitrust Immunity: Good for Consumers?: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 5 (2007) (statement of J. Robert Hunter, Director of Insurance, Consumer Federation of America), available at <http://judiciary.senate.gov/hearing.cfm?id=2581>. While the antitrust exemption was originally intended to be an interim measure, due to statutory interpretation in the courts, it has remained in place permanently. Although beyond the scope of this chapter, the AAI suggests that Congress consider abolishing the exemption.

consummated, national full service PBM market concentration has become more problematic as the largest organizations have grown significantly.¹⁶

PBMs' promise of controlling pharmaceutical costs has been undercut by a pattern of conflicts of interest, self-dealing, 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 has 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.¹⁷

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

¹⁶ The American Antitrust Institute provided a white paper assessing the structural issues posed by the proposed Express Scripts/Caremark merger. See American Antitrust Institute, *Express Scripts' Proposed Acquisition of Caremark* (2007), available at http://www.antitrustinstitute.org/archives/files/AAI_Express%20Scripts_Caremark_2-14_021520071110.pdf. We note that the law firm that represented one of the parties in the Caremark/AdvancePCS merger observed that the investigation was 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.

¹⁷ Letter from Mass. State Senator Mark Montigny (D) to FTC Chairman Deborah Platt Majoras (May 11, 2005) (on file with AAI).

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 introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs.¹⁸

In the past four years alone, cases brought by DOJ and state attorneys general have secured over \$300 million in penalties and fines for deceptive and fraudulent conduct by the three major PBMs.¹⁹ 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. The challenged practices include:

- secretly retaining most manufacturer payments, e.g., rebates, discounts and other fees, instead of passing through such payments to clients;
- switching plan members from low- to high-cost drugs;
- favoring higher-cost drugs on their formularies;
- manipulating generic (maximum allowable cost) pricing;

¹⁸ 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).

¹⁹ 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).

- entering into exclusivity arrangements with specialty pharmaceutical manufacturers that raise the prices of those drugs;
- conspiring with manufacturers to violate Omnibus Budget Reconciliation Act and “best pricing” regulations; and
- committing other contract or fiduciary breaches.

Unfortunately, the FTC has failed to investigate or take any enforcement action against this anticompetitive, fraudulent, and deceptive conduct. Even more problematic, when individual states have attempted to regulate PBMs to increase transparency, the FTC has advocated on the side of the PBM industry in opposition to the proposed legislation.²⁰ Considering 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.

C. *Group Purchasing Organizations*

On behalf of member hospitals, GPOs negotiate contracts 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 their contracting practices.²¹

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 sole-source contracts, market share discounts, and bundling of products so hospitals must purchase the bulk of their supplies from a

²⁰ Letter from Maureen K. Olhausen et. al., 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>.

²¹ 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).

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.²² These exclusionary practices are compounded by the fact that the suppliers fund the GPOs, not the customers (hospitals). In order to establish a truly competitive marketplace for medical supplies, GPOs should be prohibited from receiving any remuneration from suppliers.

In the past seven years, the Senate Judiciary Committee has held four hearings concerning exclusionary conduct by GPOs.²³ The FTC also addressed the issue in its 2003 health care competition hearings.²⁴ Over a dozen private suits have been brought, some successfully, by small innovative medical device manufacturers against exclusionary practices by GPOs and device manufacturers.²⁵ Yet the FTC has failed to bring any enforcement actions in this area.

Recommendations

- DOJ and the FTC should scrutinize mergers of health care intermediaries more carefully, particularly those of insurers and PBMs. Investigations of intermediaries should consider the impact on all groups of customers and the impact on the ultimate consumer. In addition, these investigations should

²² 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.).

²³ *Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation?*, *supra* note 22; *Hospital Group Purchasing: Has the Market Become More Open to Competition?*, *supra* note 21; *Hospital Group Purchasing: How To Maintain Innovation and Cost Savings: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. (2004); *Hospital Group Purchasing: Are the Industry's Reforms Sufficient To Ensure Competition?: Hearing Before the S. Comm. on the Judiciary*, 109th Cong. (2006).

²⁴ 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>.

²⁵ See *Masimo Corp. v. Tyco Healthcare Group, LP*, Case No. 02-CV-4770 (C.D. Cal. 2002) (ruling that Tyco pay \$14.5 million in damages – \$43.5 million after trebling – but denying Masimo's request for a permanent injunction; the case is now on appeal by both parties in the Ninth Circuit). 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).

carefully consider the potential impact on health care providers and health care quality.

- The agencies should aggressively investigate potentially exclusionary practices of GPOs and medical device companies. Evaluations should include not only immediate price effects, but the potential impact on medical device innovation. The agencies should also work with Congress to once again prohibit payments from suppliers to GPOs, eliminating the GPO safe harbor from the Medicare anti-kickback statute
- The agencies should investigate fraudulent and deceptive conduct of health care intermediaries. The FTC should be extremely judicious in offering comments opposing proposed state legislation addressing these types of anticonsumer practices.
- The agencies should attempt to identify exclusionary conduct by health insurers, recognizing that the concentrated nature of the market increases the incentive and ability to engage in this type of conduct.

III. Pharmaceutical Competition

It seems indisputable that competition from generic pharmaceutical manufacturers benefits every consumer in the United States. Generic drugs typically sell for approximately 70% less than their brand name alternatives.²⁶ Generic drugs are as safe and efficacious as brand name drugs. Generic drugs account for over 65% of all prescriptions yet account for less than 21% of pharmaceutical expenditures.²⁷ According to a Congressional Budget Office study, in 1994 (when the rate of generic substitution was far lower) generic drugs saved U.S. consumers \$8 to \$10 billion.²⁸ Generic drugs not only allow cost savings, but also enable more consumers to purchase essential drugs.

²⁶ Generic Pharm. Ass'n, Indus. Statistics, <http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm> (last visited July 1, 2008).

²⁷ *Id.*

²⁸ CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ix (1998).

Prescription drug spending was “the fastest growing segment of health care expenditures” between 1993 and 2003, rising from 5.8% to 10.7%.²⁹ Federal and state governments suffer from rapidly growing expenses. General Motors increases the price of its cars by \$1500 because of health care costs.³⁰

Antitrust enforcement in the pharmaceutical industry has so far played a vital role in the past several years in removing obstacles to generic competition, leading to a reduction in health care costs. Antitrust has been used to challenge a wide variety of exclusionary conduct by some brand name firms: in some cases the firms used questionable filings in the FDA orange book, in other cases they engaged in inequitable conduct before the Patent and Trademark Office, in other cases they paid “exclusion payments” to settle litigation, and in other cases they engaged in sham litigation. Thanks to the efforts of the FTC, state attorneys general, and private antitrust attorneys representing buyers of these drugs, antitrust litigation played a significant role in ending this anticompetitive conduct. Consumers save billions of dollars annually because of these enforcement efforts. The drugs involved in recent antitrust cases accounted for sales of over \$10 billion a year.³¹ Perhaps one sign of the importance of antitrust enforcement and litigation is that the rate of generic substitution has increased from 44% to 56% in the past decade. However, as we discuss below, brand name pharmaceutical companies have devised new forms of exclusionary conduct to delay the continued growth of generic drugs.

Policing exclusionary conduct by dominant pharmaceutical firms could not be a greater antitrust enforcement priority. By the end of the decade, over \$60 billion of brand name pharmaceuticals, including many blockbuster drugs, are scheduled to go off patent. The

²⁹ *The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs: Hearing Before the S. Spec. Comm. on Aging*, 109th Cong. 10 (2006) [hereinafter *Generic Drug Maze*] (statement of Jon Leibowitz, Commissioner, Fed. Trade Comm’n), available at <http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf>.

³⁰ Eduardo Porter, *Japanese Cars, American Retirees*, N.Y. TIMES, May 19, 2006, at C1. See generally *Paying Off Generics to Prevent Competition with Brand Name Drugs: Should it be Prohibited? Hearing Before the S. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Jon Leibowitz, Commissioner, Fed. Trade Comm’n), available at <http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf>.

³¹ *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the S. Comm. on Commerce, Science, & Transportation*, 107th Cong. 61 (2002) (statement of Kathleen D. Jaeger, Pres. & CEO, Generic Pharmaceutical Association), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_senate_hearings&docid=f:90155.pdf. See generally *Generic Drug Maze*, *supra* note 29, at 10 (statement of Jon Leibowitz, Commissioner, Fed. Trade Comm’n).

highly complex regulatory regime governing the pharmaceutical industry offers many opportunities for dominant brand name firms to secure monopoly profits, not through superior foresight, industry and innovation, but by finding loopholes to delay competition.

A. New Forms of Anticompetitive Conduct by Dominant Firms

Antitrust enforcement has successfully attacked many forms of exclusionary conduct by dominant brand name pharmaceutical manufacturers. But several problems persist and new forms of exclusionary conduct continue to appear.

To understand the nature of these practices it is important to recognize certain incentives created under the pharmaceutical regulatory system. The patent laws and the Hatch-Waxman Act provide a period of exclusivity for brand name drugs, during which there can be no competition. This period of exclusivity is important to provide the incentive for brand name firms to develop new drugs or improvements to existing drugs. Toward the end of patent life the brand name firm faces the loss of a significant revenue stream. The expectation is that once a patent has elapsed, been declared invalid, or a generic firm has developed a noninfringing version of the drug, generic entry will occur. Yet, as described below, there are several types of exclusionary conduct that the brand name firm may engage in to delay or dampen the effect of generic entry. As several consumer groups have observed:

When dominant firms face the threat of new entry they often turn to strategic conduct to hold rivals at bay. Facing the inevitable decrease in market share (and consequent decline in sales revenue) that follows the loss of patent protection and introduction of generics, brand name drug manufacturers increasingly have turned to underhanded means to delay competition.³²

We believe there is a wide variety of anticompetitive conduct that brand name firms engage in. Here are a few examples:

³² See Letter from American Antitrust Institute, Consumer Federation of America, Families USA, and US PIRG to the FTC on the Authorized Generic Drug Study (June 6, 2006), available at <http://www.antitrustinstitute.org/archives/files/509.pdf>.

- Fraud in obtaining the patent, such as false representations to the U.S. Patent and Trademark Office about a compound's novelty or effectiveness or the special properties held by formulations of sustained-release coatings.
- Sham litigation that discourages market entry through bringing or threatening frivolous patent claims against generic firms.
- Evergreening, or extending the period of patent protection by obtaining patents on trivial modifications of a drug.
- Authorized generics, or drugs manufactured by brand name companies sold under generic labels.
- Filing citizen petitions with the FDA to delay the approval of generic drugs during the regulatory process, imposing substantial delays on the drug approval.
- "Exclusion payments," or payments to the generic firm to settle litigation, which may delay the entry of the generic drug.

We focus here on two of these practices: citizen petitions and exclusion payments.

B. Citizen Petitions

The courts and regulatory process can be used as a tool to delay the entry or expansion of rivals to dominant firms. As the FTC's Staff Report on the Noerr-Pennington doctrine observes, "[o]ne of the most effective ways for parties to acquire or maintain market power is through the abuse of government processes. The cost to the party engaging in such abuse typically is minimal, while the anticompetitive effects resulting from such abuse often are significant and durable."³³ Anticompetitive conduct through regulatory abuse can be especially pernicious. When a firm acquires a dominant position through competition in the marketplace, we can expect other competitors to arise and

³³ FED. TRADE COMM'N, ENFORCEMENT PERSPECTIVES ON THE NOERR-PENNINGTON DOCTRINE (2006), available at <http://www.ftc.gov/reports/P013518enfperspectNoerr-Penningtondoctrine.pdf>.

possibly displace them. But no natural competitive force can displace dominance acquired through abuse of the regulatory process.

That is especially the case in the pharmaceutical industry, where litigation and regulatory approval are necessities to market entry. One category of this abuse is the practice of so-called citizen petitions.

The FDA, like other regulatory agencies, has a process that enables the public to petition the agency, known as citizen petitions. Citizen petitions can provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product any time before its market entry, and often make legitimate challenges. Increasingly, brand name pharmaceutical companies have been exploiting this process by filing baseless and redundant petitions in an effort to delay FDA approval of generic drugs. As one generic drug executive has observed in Senate testimony:

Frequently, a brand company will file a frivolous petition on the eve of FDA approval of a generic equivalent. This despite the fact that the FDA may have already granted a tentative approval, meaning that FDA already determined the generic product is safe and effective. The brand strategy is that it will take several months for the FDA to decide the petition, during which time approval of the generic drug is held in limbo. The brand is not required to submit petitions with merit. What the brand company can do is block competition for several months beyond the life of the 20-year patent, thereby extending its monopoly on the market.³⁴

In order to slow the approval process, citizen petitions are often submitted on the eve of the completion of FDA review, when the brand name company's patent is about to expire. These petitions are often based on information available well before the petitions are submitted. The citizen petition approval process is time-consuming. Despite tentative approval of the generic drug, it could take several months for the FDA to

³⁴ *Generic Drug Maze*, *supra* note 29, at 60 (testimony of Heather Bresch, Senior Vice President, Strategic Corporate Development, Mylan Laboratories).

respond to a petition. The qualified generic is held in administrative limbo. Consumers suffer as lower cost alternatives are kept off the market.

Only a trivial portion of the petitions are accepted by the FDA and require further action. Since the Medicare Modernization Act of 2003, brand name companies have filed 45 separate citizen petitions requesting that the FDA delay the approval of a generic drug.³⁵ Of these 45 petitions, the FDA has ruled on 21, of which they denied 20, or 95%.³⁶ Ten of the 21 petitions were “last-minute petitions” filed within 4 months of the generic drug’s scheduled entry into the market.³⁷ None of these last minute petitions were approved, but on average they caused delays ranging from a few months to over a year.³⁸ In one case, for each day that the petition delayed generic drug entry, the brand name company gained an estimated \$7 million.³⁹

C. *Exclusion Payments in Patent Settlements*

One of the most important antitrust issues deserving attention from the next administration involves patent litigation settlement agreements between brand name drug manufacturers and generic firms. In recent years, brand name firms have paid generics millions of dollars to drop lawsuits challenging patent validity and to refrain from entering the market.⁴⁰ The amount of these exclusion payments may sometimes exceed what the generic could have earned by entering the market. The brand name company may also deter any other generic from challenging the patent by stretching out litigation with an initial challenger.

These agreements contravene the intent of the Hatch-Waxman Act’s drafters to encourage generic competition and provide incentives for patent challenges. Challenges to invalid patents benefit consumers and reduce prices. As discussed below, many

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 71.

³⁸ *Id.* at 60.

³⁹ *Id.*

⁴⁰ See Brief for American Antitrust Institute as Amicus Curiae Supporting Petitioners, *Joblove v. Barr Labs, Inc.* (*In re* Tamoxifen Citrate Antitrust Litigation), 127 S. Ct. 3001 (2007) (No. 06-830).

patents, including those at the center of drug settlement agreements, are not valid. (Appendix A provides a brief review of the patent application process and some of its weaknesses.)

Such patent challenges are particularly important in the pharmaceutical context. In a study of generic challenges between 1992 and 2000, the FTC found that the generic firms prevailed in 73% of the cases.⁴¹ These figures are consistent with a survey of Federal Circuit decisions from 2002 through 2004 that found that pharmaceutical patentees were successful on the merits in only 30% of the cases.⁴² This invalidity rate is particularly troubling, and the potential anticompetitive effects especially staggering, given the importance of the drugs that have been the subject of lawsuits. In the FTC study of challenges between 1992 and 2000, sales were far higher in the cases in which brand name firms sued generics.⁴³

Beginning in the 1990s, brand name firms began entering into agreements with generic firms in which the brand name firm would pay the generic firm an exclusion payment to stay off the market. The initial cases were straightforward cash payments and were condemned by the courts and the FTC. However, in 2005, after two appellate courts took a lenient view of these agreements, firms returned to using exclusion payments.⁴⁴ In 2005, 3 of 11 final settlements between brand name and generic companies included such payments; in 2006, 14 of 28 settlements involved such provisions.⁴⁵

⁴¹ FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 10, 16, available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> [hereinafter *GENERIC DRUG STUDY*]. These challenges are limited to Paragraph IV certifications, in which the generic alleges that the patent is invalid or that it did not infringe its claims.

⁴² Paul M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 *AIPLA Q.J.* 1, 20 (2006).

⁴³ *GENERIC DRUG STUDY*, *supra* note 41, at 14 (noting that, for the 75 drug products subject to litigation, the first generic applicant gained \$190 million in median net sales the year it filed its application, while most of the 29 new drug applications not subject to suit had net sales of less than \$100 million).

⁴⁴ See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058 (11th Cir. 2005) and *Joblove v. Barr Labs, Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 193 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007).

⁴⁵ FED. TRADE COMM'N, *AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2005*, at 4 (Apr. 2006), available at <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf> [hereinafter *FY 2005 AGREEMENTS*].

More recent agreements have become increasingly nuanced and difficult to trace. No longer are brand name companies making simple cash payments for generics not to enter the market. Instead, they are paying generics for intellectual property licenses, for the supply of raw materials or finished products, and for helping to promote products. They are paying milestones, up-front payments, and development fees for unrelated products. They are also agreeing not to launch authorized, brand-sponsored generics.⁴⁶

One example of such a settlement is illustrative. The FTC recently sued Cephalon, Inc., which manufactures Provigil, a sleep disorder medication with \$800 million in 2007 sales that has been used by troops in Iraq to stay alert during long missions. In 2003, four of Cephalon's competitors tried to enter the market with generic versions of the drug. But Cephalon paid the generics more than \$200 million for side deals that the FTC alleged were “not independent business transactions” but instead were “inextricably linked with” a delayed generic entry date.⁴⁷ The company’s CEO, Frank Baldino, Jr., explained that Cephalon “w[as] able to get six more years of patent protection[, which was] \$4 billion in sales that no one expected.”⁴⁸

Despite the concerns presented by exclusion payment settlements, courts have recently blessed them. Recent decisions have reasoned that the agreements reduce costs and increase innovation. They have referred to settlements as “natural by-products” of the Hatch-Waxman Act. Also, they have pointed to patents’ presumption of validity in demonstrating the agreements’ reasonableness. Although the FTC, state antitrust enforcers, and scholars have voiced strong arguments against this leniency, these have recently fallen on judicial deaf ears.⁴⁹

⁴⁶ *Id.* at 4 – 5.

⁴⁷ Complaint at ¶ 57, *FTC v. Cephalon, Inc.*, No. 1 :08-cv-00244 (D.D.C. filed Feb. 13, 2008).

⁴⁸ John George, *Hurdles Ahead for Cephalon*, PHILA. BUS. J., Mar. 17, 2006, available at <http://www.bizjournals.com/philadelphia/stories/2006/03/20/story1.html>; see generally Jon Leibowitz, *This Pill Not to be Taken With Competition: How Collusion is Keeping Generic Drugs Off the Shelves*, WASH. POST, Feb. 25, 2008, at A15, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/02/24/AR2008022401669.html>.

⁴⁹ MICHAEL CARRIER, *INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW* (forthcoming 2009). The FTC’s aggressive challenges to exclusion payment settlements have not been matched by DOJ. Just to pick one example, the FTC sought certiorari in the *Joblove (Tamoxifen)* case while DOJ opposed it, stating that the “presence of a substantial reverse payment as part of the settlement of a patent infringement claim is not sufficient to establish” illegality and that “[t]he

Nor, as an empirical matter, are exclusion payments even necessary to settle disputes between brands and generics. Exclusion payments disappear when challenged and reappear when the antitrust coast is clear. Between 1992 and 1999, 8 of the 14 final settlements between brands and generic first-filers involved exclusion payments.⁵⁰ In 2000, the FTC announced that it would challenge such settlements.⁵¹ In the succeeding four years, between 2000 and 2004, not one of 14 agreements involved a brand name firm paying a generic filer to delay entering the market.⁵² During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry.

By encouraging generic patent challenges, but also providing for patent term extensions and marketing exclusivity periods, the Hatch-Waxman Act provides a delicate balance between competition and innovation. Unfortunately, mechanisms that Congress included to encourage patent challenges – such as an exclusivity period for the first generic to challenge validity – have been twisted into barriers preventing competition. Antitrust can play a central role in resuscitating the drafters’ intentions and promoting competition.⁵³

Given the Hatch-Waxman Act’s clear purpose of promoting patent challenges, as well as the parties’ aligned incentives and the severe anticompetitive potential of exclusion payments, courts should treat such settlements as presumptively illegal. If settling parties can demonstrate that the payments are reasonable and reflect an objective assessment of the patent’s validity, they remain free to rebut this presumption. A rule of presumptive illegality would resuscitate the goal of robust generic competition lying at the heart of the

correct approach is to apply the rule of reason.” Brief for the United States as Amicus Curiae, *Joblove v. Barr Labs, Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 127 S. Ct. 3001 (2007) (No. 06-830).

⁵⁰ FY 2005 AGREEMENTS, *supra* note 45, at 4.

⁵¹ Fed. Trade Comm’n, Statement of Chairman Robert Pitofsky et al., Abbott Labs. and Geneva Pharm., Inc., (Mar. 16, 2000) (No. 981-0395), *available at* <http://www.ftc.gov/os/2000/03/hoeschtandrxcmmstmt.htm> (in context of consent decree in connection with Abbott Laboratories’ reverse payments to Geneva Pharmaceuticals to not enter the market with a generic alternative to Abbott’s hypertension and prostate drug).

⁵² FY 2005 AGREEMENTS, *supra* note 45, at 4.

⁵³ For a more detailed elaboration of this issue, see CARRIER, *supra* note 49.

Hatch-Waxman Act. Given the importance of the drugs subject to exclusion payments and the far-reaching effects of skyrocketing healthcare costs, a more aggressive framework for monitoring these agreements would offer significant benefits.

The undue deference shown toward exclusion payments in such court decisions as *Joblove (Tamoxifen)* is even more problematic in light of recent case law curtailing the liability of drug manufacturers for fraudulent procurement of patents. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*,⁵⁴ the Supreme Court had held that enforcement by the holder of a patent procured by fraud is actionable under the antitrust laws as an act of monopolization. Subsequently, courts had permitted overcharged drug purchasers to pursue antitrust claims under that ruling when brand name drug manufacturers excluded generic competition through the enforcement of a fraudulently procured drug patent.⁵⁵ However, in *In re Remeron Antitrust Litigation*,⁵⁶ a court held for the first time that overcharged purchasers lack standing to assert antitrust claims under *Walker Process*. Since that time, two other courts have followed the ruling of the *Remeron* court.⁵⁷

Recommendations

- The next administration should make pharmaceutical antitrust enforcement a key priority. As drugs worth billions go off patent, the incentives for exclusionary conduct will increase dramatically, and antitrust enforcement is essential to prevent it.
- Exclusion payments are the source of substantial competitive harm. Unfortunately, courts have been overly deferential to the supposed justifications for such settlements and have applied rules approaching per se legality. This view is mistaken and the administration should work with Congress to enact legislation to prevent these payments.

⁵⁴ 382 U.S. 172 (1965). *See also* Brief for American Antitrust Institute et al. as Amici Curiae Supporting Plaintiffs, *In re DVAAP Direct Purchaser Antitrust Litig.*, No. 06-5525 (2d Cir. May 25, 2007).

⁵⁵ *See, e.g., In re Relafen Antitrust Litig.*, 360 F. Supp. 2d 166 (D. Mass. 2005); *In re Bupirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

⁵⁶ 335 F. Supp. 2d 522 (D.N.J. 2004).

⁵⁷ *In re DDAVP Direct Purchaser Antitrust Litig.*, No. 05 Civ. 2237 (S.D.N.Y. Nov. 2, 2006); *In re K-Dur Antitrust Litig.*, No. 01-1652 (D.N.J. Mar. 1, 2007).

- The FTC should investigate citizen petitions and other forms of regulatory abuse by brand name pharmaceutical firms. Because of the FTC's expertise in the Noerr-Pennington doctrine from both the FTC study and its enforcement action against Unocal, the FTC is uniquely suited to handle the issues surrounding the allegations involving sham petitioning. The FTC should use its litigation expertise to address sham and deceptive petitioning in the pharmaceutical industry, where there may be similar competitive harm.
- The FTC and DOJ should work closely with both state antitrust officials and private attorneys in litigation against anticompetitive conduct in the pharmaceutical market. The federal agencies possess limited resources and these other actors have pursued numerous cases on their own. The FTC and DOJ should assist these efforts through amicus briefs on critical issues such as standing and antitrust immunities, such as in the DDAVP Direct Purchaser Antitrust Litigation described above.
- The next administration should prioritize antitrust enforcement deterring brand name manufacturers' strategic conduct relating to weak or improper patents.

IV. Physicians

Competitive restraints by professionals have been a subject of close scrutiny from courts and antitrust enforcers for almost thirty years. Following the Supreme Court's landmark decision in *Goldfarb v. Virginia State Bar*,⁵⁸ the FTC and DOJ challenged a variety of ethical codes prohibiting advertising, contracting, and affiliation with HMOs or alternative care providers. Since then, federal and state enforcers also prosecuted scores of cases involving price-fixing cartels, physician boycotts (which sought to deter innovative financing plans or block competition from alternative care providers), and organization of collective bidding.⁵⁹

⁵⁸ 421 U.S. 773 (1975).

⁵⁹ See, e.g., *In re Am. Med. Ass'n*, 94 F.T.C. 701 (1979), *aff'd as modified*, 638 F.2d 443 (2nd Cir. 1980), *aff'd by equally divided Court*, 452 U.S. 676 (1982); *United States v. N.D. Hosp. Ass'n*, 640 F. Supp. 1028 (D.N.D. 1986); *Mich. State Med. Soc'y*, 101 F.T.C. 191 (1983). See generally BARRY R. FURROW ET AL., HEALTH LAW §14-10 (2000) and Thomas L. Greaney, *Whither Antitrust? The Uncertain Future of Competition Policy in Health Care*, 21 HEALTH AFF. 185 (March/April 2002).

Over the years, physician groups and associations have attempted to justify collective action as preserving professional sovereignty, “leveling the playing field” vis-a-vis insurers, facilitating efficient integration, and protecting patients from low quality care. On close inspection, antitrust agencies and Congress found these explanations wanting. Even where legitimate concerns are raised, the mechanism sought – collective bargaining outside the legal framework for labor unions – would have shielded physicians from market discipline with no guarantee that promised consumer benefits would be realized.

The government has dedicated substantial resources to prosecuting cases involving physician price fixing. But the continued prevalence of enforcement actions suggests that compliance is lacking. An examination of the cases brought by the agencies over the last thirty years reveals that despite repeated prosecution of clear-cut violations of settled antitrust norms, overt cartelization schemes have not disappeared and in fact may have increased in recent years.⁶⁰ Some confusion may exist about the standards applicable in cases involving legitimate efforts to integrate. However, many of the cases involved situations in which the physician network was operating as a “sham” PPO, or was misusing the so-called “messenger model” to disguise an attempt to engage in collective negotiations.⁶¹ Virtually all of the FTC’s cases have resulted in settlements that impose no significant penalties, such as disgorgement of profits or injunctions dissolving the organization. The lack of meaningful sanctions has permitted a climate of abuse to fester as illustrated by the fact that dozens of cases involving per se violations lacking any color of legitimate integration have been prosecuted in the last five years.⁶²

At the same time antitrust law should permit, in fact should encourage, physicians to undertake efficiency enhancing integration where the result is more cost-effective, higher-

⁶⁰ See Thomas L. Greaney, *Thirty Years of Solicitude: Antitrust Law and Physician Cartels*, 7 HOUS. J. HEALTH L. & POL’Y 189 (2007).

⁶¹ See, e.g., *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008). Under the messenger model, physicians using a common agent to convey information to and from payors about the prices and price-related terms they are willing to accept to escape charges of price fixing are deemed not to engage in an agreement cognizable under Section 1 of the Sherman Act, provided all participants comply with certain restrictions. See DEP’T OF JUSTICE & FEDERAL TRADE COMM’N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE, Statement 9.C (1996), available at <http://www.usdoj/atr/public/guidelines/1791.pdf>. See generally, Jeffrey L. Harrison, *The Messenger Model: Don’t Ask, Don’t Tell?*, 71 ANTITRUST L.J. 1017 (2004).

⁶² Greaney, *supra* note 60.

quality delivery of care. To that end, the agencies need to clarify the boundaries of the “clinical integration” option which, as expressed in several advisory opinion letters, recognizes that per se liability should not apply to legitimate efforts to improve quality of care. As expressed in the government’s Health Care Policy Statements, collective negotiations are not per se illegal where independent physicians undertake efforts that involve an “active and ongoing program to evaluate and modify practice patterns by the group’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality,”⁶³ and price agreements are reasonably necessary to realize those ends.

While these policies map out a rational antitrust agenda, the agencies’ implementation of them has created significant discord. Physicians’ frustration stems from a lack of clarity on legal requirements for clinical integration, uncertainty about other means to avoid charges of price fixing (such as the messenger model) and the lack of guidance as to whether new payment arrangements, such as pay for performance, will affect their ability to form networks. The current administration has issued relatively few business review letters and the business review process appears to have become overly expensive and cumbersome.⁶⁴

Enforcement actions are typically effective only to the degree there are sufficient sanctions to deter future wrongdoing. Although numerous cases have been brought, fees actions have not been successful at deterring anticompetitive conduct. What is needed, then, is an effort to promulgate clearer guidance to encourage legitimate efforts to improve quality and respond to the unquestioned need of the medical delivery system for greater integration, while at the same time making clear that patent abuses will meet with appropriate sanctions.

⁶³ U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996), *reprinted in* 4 TRADE REG. REP. (CCH) ¶ 13,153 (Sept. 5, 1996).

⁶⁴ The number of business review letters on provider collaboration has decreased significantly from 26 in the Clinton administration to 5 in the Bush II administration.

V. Hospitals

Beginning in the 1980s, the federal government took an active role in policing hospital mergers. Most of the early antitrust challenges to these mergers involved market shares approaching monopoly levels. Subsequent cases successfully challenged a number of mergers that involved lower levels of concentration and discouraged for a time anticompetitive mergers that would block the ability of payers and employers to bargain for lower prices. Over the last decade however, the antitrust agencies have foundered in the area of hospital merger enforcement, with disastrous results for the American consumer. Beginning in the mid-1990s, the FTC, DOJ, and one state attorney general accumulated seven consecutive losses in federal court cases seeking to enjoin hospital mergers. The results are the product of a variety of factors: plain judicial error, poor case selection, failure to focus on the differentiated nature of hospital markets, and perhaps a growing antipathy by the courts toward the effects of managed care.⁶⁵

Unfortunately, these setbacks chilled the government's willingness to challenge hospital mergers: for six years it brought no challenges to hospital mergers, a period in which a huge wave of hospital consolidation occurred. Instead, the agencies produced a lengthy report on healthcare competition⁶⁶ and undertook a "retrospective review" of consummated hospital mergers in the hopes of demonstrating the harmful effects of anticompetitive mergers on consumers. This interlude resulted in one case, the FTC's post-consummation challenge to the Evanston Northwestern Healthcare Corporation-Highland Hospital merger.⁶⁷ Although the FTC found that merger in violation of the antitrust laws, the agency's relief was unprecedented and of dubious value: rather than order a divestiture to restore competition as the agency's staff had urged, the FTC instead required the two hospitals to bargain separately with insurers for managed care contracts, while remaining under common ownership.

During the agencies' hiatus from hospital merger enforcement, extraordinary

⁶⁵ See Thomas L. Greaney, *Chicago's Procrustean Bed: Applying Antitrust in Health Care*, 71 ANTITRUST L.J. 857 (2004).

⁶⁶ FEDERAL TRADE COMMISSION & DEPT. OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004).

⁶⁷ *In re* Evanston Nw. Healthcare Corporation, F.T.C. Docket No. 9315 (2005), available at <http://www.ftc.gov/os/adjpro/d9315/070806opinion.pdf>.

consolidation occurred in hospital markets around the country. Studies demonstrate that hospital consolidation in the 1990s raised overall inpatient prices by at least 5% and by 40% or more when merging hospitals were in close geographic proximity.⁶⁸ Anecdotal evidence suggests that payers in many local markets faced increased resistance to bargaining by hospitals and that this led to higher prices.⁶⁹

The consequences of increased hospital market power extend beyond higher prices and reduced consumer choice. Tight oligopoly markets increase the risks that hospitals will engage in exclusionary practices involving physicians, such as anticompetitive exclusive dealing and tying arrangements, which may enable them to extend market power beyond the hospital services market. Because hospital prices paid by Medicare are subject to limits (under the prospective payment system), tying arrangements with physician services may enable the hospitals to avoid price regulation. In addition, favoring one group of physicians through exclusive dealing may be a way of raising rivals' costs in hospital markets, assuring higher rates of admission to their facilities or limiting consumer choice and variety among alternative providers.⁷⁰ Hospital concentration may also facilitate collusion in the setting of nurses' wages and the wages of other health care providers as alleged in several ongoing antitrust cases.⁷¹

A further risk of abuse of hospital market power has been seen in recent efforts by some hospitals to bar entry into hospital markets of physician-controlled specialty hospitals or into ambulatory care by ambulatory surgery and medical centers. While hospitals have the right to engage in economic credentialing (selecting or deselecting doctors for staff privileges based on the doctors' effect on the hospital's costs and quality), some have

⁶⁸ See ROBERT WOOD JOHNSON FOUNDATION, THE SYNTHESIS PROJECT, HOW HAS HOSPITAL CONSOLIDATION AFFECTED THE PRICE AND QUALITY OF HOSPITAL CARE (Feb. 2006). Simulation studies show increases of 53%; event studies, 40%; and structure-conduct performance studies, 4% – 6%. *Id.* (summarizing studies).

⁶⁹ Center for Studying Health Systems Change, <http://www.hschange.com/index.cgi?data=06> (periodic survey of competitive conditions in 12 markets).

⁷⁰ For an interesting illustration of the risks of the interaction of hospital market power and physician contracting through managed care entities controlled by hospitals, see *Abraham v. Intermountain Health Care, Inc.*, 461 F.3d 1249 (10th Cir. 2006).

⁷¹ See Jeff Miles, *The Nursing Shortage, Wage Information Sharing Among Hospitals, and the Antitrust Laws: The Nurse Wage Cases*, 7 HOUS. J. HEALTH L. & POL'Y 305 (2007).

gone further and engaged in outright collusion or strategies to raise rivals' costs to thwart competition from doctor-owned facilities. Inasmuch as enhanced competition from new entry is one of the few avenues for undoing the effects of lax enforcement in hospital markets, agencies should be vigilant to prevent efforts that would deter new forms of competition from arising.

VI. Regulation and Government as a Purchaser

In evaluating efforts to improve competition in healthcare, it is important to remember that the “industry” (physicians, insurers, hospitals, and pharmaceutical companies, to name a few) ranks among the most highly regulated sectors of the American economy. In a number of important arenas that are largely outside the reach of antitrust law, regulation directly influences whether competition will exist at all or whether it will be effective in improving consumer welfare. More importantly, because the government as purchaser and regulator has such a central role, its decisions necessarily affect the efficacy of competition policy in private purchasing. While antitrust litigation can help in some limited areas (e.g., challenging state regulations that do not meet the state action or *Noerr* defenses), in many other areas, active competition advocacy by antitrust agencies can help assure that competitive forces work effectively.

Regulations and payment policies that inhibit competition should be closely examined, and state and federal antitrust enforcers should be active in advocating repeal or rejection of legislation that limits entry. For example, certificate of need (CON) laws have been shown to reduce competition without achieving lower costs and rationalized delivery of care. Indeed, recent cases suggest that these laws provide an opportunity for anticompetitive abuse as providers have used the CON process to collude and divide markets. In addition, competition might be improved by removing unnecessary competitive obstacles from nonphysician providers, such as nurse practitioners, nurse midwives, and physician assistants. Given forecasts of physician shortages and the existence of monopolies or oligopolies in some physician markets, reducing barriers to competition from alternative care providers should be an important item on the health care competition policy agenda.

Because the government is a major purchaser of health services, it exerts an extraordinary influence on the delivery of health services that spills over into the private sector. To the extent that these programs rely on administered pricing, they distort the market and

strongly influence practice patterns that often undermine the benefits of competition in those markets. Through competition advocacy and involvement in the policy decisions of the Centers for Medicare and Medicaid Services (CMS), the agencies can exert influence that will improve the workings of competition in the private sector. Efforts to expand reliance on competition in Medicare are therefore vitally important to improving the functioning of health care markets. Unfortunately, the Medicare Modernization Act of 2003 was deeply flawed, giving enormous, unjustified subsidies to managed care (through Medicare Advantage plans), including some that do next to nothing to efficiently manage care (the so-called “private fee for service plans”). Nevertheless, it is important that CMS continue to provide market incentives even where it is the sole purchaser of care. For example, its demonstration project in competitive bidding for durable medical equipment provides a useful model for incorporating competition into the procurement process.

Appendix — Patents

To receive a patent, an inventor files an application with the U.S. Patent and Trademark Office (PTO). The application is assigned to an examiner who specializes in the field of invention.⁷² The examiner then searches for printed publications and previously issued patents that help determine whether the application meets the requirements of patentability. In particular, the examiner determines if the invention is novel, useful, and not obvious to a person in the relevant field and if it would enable others to create the invention.

These tasks have become more difficult in recent years. In the 1980s and 1990s, courts dramatically expanded the range of patentable subject matter by holding that inventions related to biotechnology, computer software, and methods for doing business were all patentable.⁷³ As a consequence, by 2007, the PTO suffered under a backlog of more than 760,000 applications.⁷⁴

⁷² DONALD S. CHISUM, 4 CHISUM ON PATENTS § 11.01 (2005).

⁷³ See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (biotechnology); *Diamond v. Diehr*, 450 U.S. 175 (1981) (software); *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) (business methods).

⁷⁴ U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2007, available at <http://www.uspto.gov/web/offices/com/annual/2007/2007annualreport.pdf>.

The length and complexity of patent applications have increased in the past quarter-century. Despite this development, as well as the increase in literature that must be reviewed, production quotas have not been updated since 1976.⁷⁵ On average, each patent examiner is expected to process 87 applications per year at a rate of 19 hours per application.⁷⁶ Within this period, examiners must read the application, search for related inventions (known as prior art), communicate with the applicant, evaluate patentability, and reach and write up conclusions.⁷⁷

The effect of these workload increases is exacerbated by the *ex parte* nature of the process, with only the applicant communicating with the examiner. To invalidate a patent, the examiner or applicant must discover prior art. But because the applicant has no duty to search for prior art, the PTO ultimately grants some patents that are not novel.

The objective of issuing valid patents has come under additional pressure from the system's pro-patent bias. Examiners receive bonus points only for final allowances or rejections of patents.⁷⁸ But since even "final" rejections can be appealed, examiners who wish to receive bonuses (and who often face significant backlogs) are more likely to grant applications.⁷⁹

⁷⁵ U.S. GOV'T ACCOUNTABILITY OFFICE, REPORT TO CONGRESSIONAL COMMITTEES, INTELLECTUAL PROPERTY: USPTO HAS MADE PROGRESS IN HIRING EXAMINERS, BUT CHALLENGES TO RETENTION REMAIN, GAO-05-720, at 29 (June 2005), *available at* <http://www.gao.gov/new.items/d05720.pdf>.

⁷⁶ *Id.* at 28.

⁷⁷ FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, EXEC. SUMMARY 9 – 10 (2003), <http://www.ftc.gov/os/2003/10/innovationrptsummary.pdf>.

⁷⁸ Robert P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 607 (1999).

⁷⁹ *Id.* See generally U.S. DEP'T OF COMMERCE, OFFICE OF INSPECTOR GENERAL, USPTO SHOULD REASSESS HOW EXAMINER GOALS, PERFORMANCE APPRAISAL PLANS, AND THE AWARD SYSTEM STIMULATE AND REWARD EXAMINER PRODUCTION 24-28 (Sept. 2004), *available at* <http://www.oig.doc.gov/oig/reports/2004/USPTO-IPE-15722-09-04.pdf>; Randolph A. Smith, *USPTO Examiners Performance System and Strategy Tips for Improving the Value of Your Inventions* (Nov. 22, 2005), *available at* <http://www.miyoshipat.co.jp/seminar/pdf/seminar051122.pdf>.

These difficulties are not theoretical. Courts analyzing patents often conclude that they should not have been granted. Empirical studies have consistently shown that a significant percentage of granted patents are invalid. Surveys have found that:

- courts invalidated 46% of patents between 1989 and 1996;⁸⁰
- the alleged infringer prevailed in 42% of the patent cases that reached trial between 1983 and 1999;⁸¹ and
- in patent cases between 2000 and 2004, courts found that 43% of patents were invalid and 75% were not infringed.⁸²

In the context of generic challenges to drug patents in particular, the invalidity rate appears to be even higher. In a study of paragraph IV challenges between 1992 and 2000, the FTC found that the generic producer prevailed in 73% of the cases and that brand name firms won only 27% of the time.⁸³ These figures are consistent with a survey of Federal Circuit decisions from 2002 through 2004 that found that pharmaceutical patentees were successful on the merits in 30% of the cases.⁸⁴

This invalidity rate is particularly troubling, and the potential anticompetitive effects especially staggering, given the importance of the drugs that have been the subject of lawsuits. In the FTC study of challenges between 1992 and 2000, sales were far higher in the cases in which brand name firms sued generics.⁸⁵

⁸⁰ John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (survey limited to cases resulting in a final judgment of validity).

⁸¹ Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000).

⁸² UNIV. HOUS. LAW CTR., INST. FOR INTELLECTUAL PROP. & INFO. LAW, PATSTATS: U.S. PATENT LITIGATION STATISTICS, DECISIONS FOR 2000 – 2004, ¶¶ 1 – 16, 23 – 24 (2000 – 04).

⁸³ See GENERIC DRUG STUDY, *supra* note 41, at 10, 16.

⁸⁴ Janicke & Ren, *supra* note 42, at 20.

⁸⁵ GENERIC DRUG STUDY, *supra* note 41, at 14 (noting that, for the 75 drug products subject to litigation, the first generic applicant gained \$190 million in median net sales the year it filed its application, while most of the 29 new drug applications not subject to suit had net sales of less than \$100 million).

Lawsuits have been particularly prevalent on blockbuster drugs such as Cipro, Claritin, Paxil, Pravachol, Prilosec, Prozac, and Zoloft.⁸⁶ In fact, of the ten top-selling brand name drugs in the United States in 2006, at least six (Nexium, Prevacid, Singulair, Effexor XR, Plavix, and Lexapro) were the subject of litigation under the Hatch-Waxman Act in 2008.⁸⁷

⁸⁶ *Id.* at 10 – 11. See generally Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309, 331 (2005).

⁸⁷ Corrected Brief of Amicus Curiae Fed. Trade Comm'n in Support of Appellants, *In re Ciprofloxacin Hydrochloride Antitrust Litig.* at 9 (Fed. Cir. Jan. 25, 2008) (No. 2008-1097).