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“To Know Where You’re Going, Look at Where You’ve Been”

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I am pleased to be here today to discuss the FTC’s recent competition enforcement work in the healthcare sector. Healthcare policy is a hot topic these days and will likely continue to be. Vigorous competition is not the answer to every challenge in healthcare policy, but it can mitigate the need for more intrusive regulatory solutions aimed at controlling the exercise of market power.

The past few years under Chairwoman Ramirez leadership—and with the bipartisan support of the other Commissioners—have been especially busy with litigation on many fronts. Last year, the FTC conducted two hospital merger trials—FTC v. Penn State Hershey Medical Center, which we won on appeal, and FTC v. Advocate Health Care Network, where we wait for the district court to issue its decision following the Seventh Circuit’s remand order. Currently, we have four actions pending in federal court, and one in administrative litigation, which involve anticompetitive conduct by pharmaceutical manufacturers. Soon, we hope to have a final divestiture order in St. Alphonsus/St. Luke’s Health System, more than a year after the Ninth Circuit upheld the district court’s finding that the transaction was illegal after a full trial on the merits.² Looking back past last year, the Commission also obtained a significant victory at the Supreme Court in *North Carolina Dental*.³ That case established a role for federal antitrust enforcement to stop anticompetitive conduct when a state fails to supervise regulatory boards comprising active market participants.

Of course, outside of the litigation spotlight, the Commission also has obtained significant settlements that achieve important outcomes for consumers. For instance, a district court recently approved a settlement to resolve our claims that a branded drug maker maintained

¹ The views stated here are my own and do not necessarily reflect the views of the Commission or of any Commissioner. I would like to thank Kelly Signs for her invaluable assistance on this speech.

² *St. Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke’s Health Sys.*, 778 F.3d 775 (9th Cir. 2015).

³ *N.C. State Bd. of Dental Exam’rs v. FTC*, 135 S. Ct. 1101 (2015).

its monopoly by acquiring the rights to develop a lower-priced synthetic version. The Commission also brought several exclusive dealing cases that were settled when the companies agreed not to enter into exclusivity agreements that block competition.

Some might look at all this litigation and wonder if the FTC has succumbed to the lure of big headlines and suddenly embarked on an aggressive healthcare enforcement agenda. As former Chairman Bill Kovacic noted recently, government agencies face a perennial choice between consuming and investing. He warned against the tendency to prioritize consumption—in the form of bringing more cases—while deferring investments in infrastructure and knowledge necessary to bring the next generation of cases.⁴ It is probably not a surprise to most of you, however, that he pointed to the FTC’s healthcare program as an example of “the importance and benefits of sustained investments in capability.”

These investments began in the 1970s, when the FTC undertook strategic planning with a particular focus on healthcare.⁵ This and other early investments in policy R&D laid the foundation for the FTC’s ground-breaking case against American Medical Association; that case led to many more.⁶ To sustain the work, in the 1980s the Bureau of Competition formed a special division to investigate potential antitrust violations in the healthcare sector. I am proud to say that some of those dedicated pioneers in healthcare antitrust are still at the FTC and many other dedicated attorneys and economists who are truly experts in the field have joined them. Sadly, the FTC family recently lost a key figure from those early days of the Health Care Division. Art Lerner skillfully led the shop as it embarked on a series of foundational cases, including the FTC’s first hospital merger challenge and its first antitrust case against a state licensing board. And just as important, he was a master at explaining to skeptics—and rest assured there were many—why applying antitrust law to the health care sector is good public policy that should enjoy bipartisan support.

Even as the FTC was bringing cases, it also provided antitrust guidance to those in the healthcare sector. In the 1990s, the FTC and the Department of Justice issued a series of Health Care Statements to provide guidance about how antitrust analysis applies to various types of health care arrangements.⁷ Just as important, the FTC continued to gain knowledge and track trends in health care markets. In 2003, the FTC and the DOJ held 27 days of hearings, covering a wide variety of topics, and issued a seminal report, *A Dose of Competition*.⁸ More recently, the FTC hosted several days of workshops on healthcare competition topics such as innovations in health care delivery, price transparency, alternatives to traditional fee-for-service payment

⁴ William E. Kovacic & David A. Hyman, *Consume or Invest: What Do/Should Agency Leaders Maximize?*, 91 WASH. L. REV. 295 (2016).

⁵ *Id.* at 298.

⁶ *Am. Med. Ass’n*, 94 F.T.C. 701 (1979), *aff’d sub nom. Am. Med. Ass’n v. FTC*, 638 F.2d 443 (2d Cir. 1980), *aff’d by an equally divided Court*, 455 U.S. 676 (1982); see CARL F. AMERINGER, *THE HEALTH CARE REVOLUTION: FROM MEDICAL MONOPOLY TO MARKET COMPETITION* (2008).

⁷ FED. TRADE COMM’N AND DEPARTMENT OF JUSTICE, *Statements of Antitrust Enforcement Policy In Health Care* (1996), https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf.

⁸ FED. TRADE COMM’N AND DEPARTMENT OF JUSTICE, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION* (2004).

models, and trends in provider consolidation.⁹ We study emerging trends,¹⁰ advocate for the adoption of healthcare policies that rely on competition as much as possible,¹¹ and investigate potential law violations.¹² From this continual cycle of learning and enforcement—or investment and consumption—we are in a position to provide guidance to courts, policymakers, and businesses whenever appropriate to advocate for the benefits of competition in healthcare markets and ensure good outcomes for consumers.

Today I want to talk about some of our recent enforcement actions, showing how they draw upon prior cases, research, and policy work. As former Chairman Tim Muris first noted in a speech entitled “Everything Old is New Again: Health Care and Competition in the 21st Century,” FTC enforcement actions in the healthcare sector often have precursors in decades past.¹³ To that I would add, if you want to know where the FTC is going, look at where we’ve been. My aim is to remind readers that competition continues to play an important role in healthcare markets, and antitrust enforcement is essential to ferreting out anticompetitive conduct and preventing mergers that create market power.

Pharmaceuticals: A Case of FTC Investment and Consumption

In 2015, Americans spent an estimated \$324 billion on prescription drugs, with individuals paying more than \$45 billion out-of-pocket and federal programs such as Medicare, Medicaid and the Veterans Administration paying for another \$127 billion.¹⁴ The percentage of U.S. spending on pharmaceuticals has slowly been on the rise, and spending on pharmaceuticals continues to drive healthcare cost increases.¹⁵ Given the direct impact of high drug costs on both

⁹ FTC Workshop, *Examining Health Care Competition* (Mar. 20-21, 2014, and Feb. 24-25, 2015), <https://www.ftc.gov/news-events/events-calendar/2015/02/examining-health-care-competition>.

¹⁰ Recent research topics for Bureau of Economics staff include health outcomes associated with physician acquisitions by hospitals; the accuracy of hospital merger screening methods; and the impact of market structure on patient care quality.

¹¹ The FTC has an active advocacy program. Recent comments address policy proposals related to scope of practice regulations, licensing requirements, and telehealth. A complete list of FTC advocacy filings related to health care is available at <https://www.ftc.gov/policy/advocacy/advocacy-filings>.

¹² The Bureau of Competition maintains two indices cataloging the FTC’s competition enforcement and advocacy efforts, including industry guidance and amicus briefs: *Overview of FTC Actions in Health Care Services and Products* (Jan. 2017), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_health_care_january_2017.pdf, and *Overview of FTC Actions in Pharmaceutical Products and Distribution* (Jan. 2017), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_january_2017.pdf. A third resource is a Topic Index of Advisory Opinions, also updated in January 2017, https://www.ftc.gov/system/files/attachments/competition-policy-guidance/topic_and_yearly_indices_of_health_care_advisory_opinions_january_2017.pdf.

¹³ Timothy J. Muris, Chairman, Federal Trade Commission, *Everything Old is New Again: Health Care Competition in the 21st Century*, Speech before the 7th Annual Competition in Health Care Forum (Nov. 7, 2002), <https://www.ftc.gov/public-statements/2002/11/everything-old-new-again-health-care-competition-21st-century>.

¹⁴ U.S. Dep’t of Health & Human Servs., Ctr. for Medicare & Medicaid Servs., *Prescription Drug Expenditures*, National Health Expenditures by Type of Service and Source of Funds, CY 1960-2015, lines 283, 284, 312, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

¹⁵ See U.S. Dep’t of Health & Human Servs., Office of the Assistant Sec’y for Planning and Evaluation, *Observations on Trends in Prescription Drug Spending*, at 1 (Mar. 8, 2016), <https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending>.

consumers and taxpayers, the FTC devotes significant resources to promoting competition in pharmaceutical markets.

The FTC's work in the pharmaceutical sector began with an ambitious research agenda, as the FTC conducted industry-wide studies and issued public reports that involved detailed examinations of the functioning of pharmaceutical markets.¹⁶ Of course, a key development that facilitated competition from generic drugs came in 1984, when Congress enacted the Hatch-Waxman Act. The Act established an abbreviated regulatory pathway for approval of generic drugs to foster the speedy market entry of these lower-cost alternatives. By the late 1990s, however, there were indications that aspects of the Hatch-Waxman regulatory framework might also be facilitating anticompetitive behavior aimed at delaying the entry of generic products. In particular, it became apparent that the very mechanism that Congress created to encourage generic drug firms to challenge invalid or narrow patents on brand name products—a reward to the first patent challenger of 180 days of market exclusivity—could also be used to create a barrier to competition. Armed with the knowledge of which firm was eligible for first-filer rights, branded companies could trade a share of the profits that would be lost once entry occurred in return for a promise not to enter.

The FTC's first two enforcement actions against reverse payment agreements between brand and generic drug firms were ultimately resolved with consent orders. In the first case, filed in 2000, the FTC charged that Abbott Labs paid Geneva Pharmaceuticals \$4.5 million per month in exchange for not bringing to market a generic alternative to Abbott's brand-name hypertension and prostate drug, Hytrin. At the time of the agreement, Geneva had received FDA approval as the first filer, which entitled it to 180 days of market exclusivity. Both parties settled the charges with a consent order that prohibited each company from entering into agreements in which a generic firm (1) gave up or transferred its 180-day exclusivity rights, or (2) agreed not to enter the market with a non-infringing product.¹⁷ In 2002, the FTC filed an administrative complaint charging Hoechst and Andrx with entering an agreement whereby Andrx would not enter with a generic version of Cardizem CD in exchange for millions of dollars and a commitment by Andrx not to transfer its 180-day exclusivity rights as a first-filer or even to market a non-infringing generic version of the drug.¹⁸

¹⁶ One early study examined the effects of state laws barring pharmacists from advertising the prices of prescription drugs, a study cited by the Supreme Court in striking down such laws under the First Amendment. *See Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 754 n.11, 765 n.20 (1976) (citing *Staff Report to the Federal Trade Commission on Prescription Drug Price Disclosure* (1975)). Another study examined the effects of state "anti-substitution" laws, which prevented pharmacists from dispensing a lower-cost generic drug unless the physician specifically prescribed the drug by its non-proprietary name. In this instance, the FTC published the staff's empirical findings, along with a model state law FTC staff developed with the Food and Drug Administration, to assist states in reforming their regulations to promote competition and facilitate consumer access to lower cost generic drugs. *See Staff Report to the Federal Trade Commission on Drug Product Selection* (1979), <https://www.ftc.gov/reports/staff-report-drug-product-selection>. *See also Staff Report of the Bureau of Economics, Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985), <https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf>.

¹⁷ *Abbott Labs.*, Dkt. C-3945, and *Geneva Pharms., Inc.*, Dkt. C-3946 (final orders issued May 22, 2000).

¹⁸ *Hoechst*, Dkt. 9293 (complaint issued Mar. 16, 2000; consent order issued May 11, 2001).

In announcing these cases, the Commission (at the time, Chairman Pitofsky and Commissioners Anthony, Thompson, Swindle and Leary) issued a statement with the following counsel:

These consent orders represent the first resolution of an antitrust challenge by the government to a private agreement whereby a brand name drug company paid the first generic company that sought FDA approval not to enter the market, and to retain its 180-day period of market exclusivity. Because the behavior occurred in the context of the complicated provisions of the Hatch-Waxman Act, and because this is the first government antitrust enforcement action in this area, we believe the public interest is satisfied with orders that regulate future conduct by the parties. We recognize that there may be market settings in which similar but less restrictive arrangements could be justified, and each case must be examined with respect to its particular facts.

Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious antitrust issues, with a potential for serious consumer harm. Accordingly, in the future, the Commission will consider its entire range of remedies in connection with enforcement actions against such arrangements, including possibly seeking disgorgement of illegally obtained profits.¹⁹

Other cases would not be resolved so quickly. In 2001, the FTC filed an administrative case against Schering-Plough, alleging that the company had entered into anticompetitive agreements in which it paid two generic firms millions of dollars to forgo launching a competitive alternative to K-Dur 20, an extended release potassium chloride supplement manufactured by Schering. The case proceeded into administrative litigation against Upsher, one of the generic firms, after American Home Products settled.²⁰ After the ALJ dismissed the complaint, the Commission reversed, but then the Eleventh Circuit set aside the Commission's decision, holding that the Commission did not establish that the challenged agreements restricted competition beyond the exclusionary effects of Schering's patent. In 2006, the Supreme Court denied the Commission's petition for certiorari.²¹

Undeterred, in 2008 the Commission, led by Chairman Majoras, filed a federal court complaint against Cephalon, Inc. relating to agreements it made to prevent generic competition to its blockbuster drug, Provigil. The following year, with Bill Kovacic at the helm, the agency challenged two patent settlements involving the testosterone replacement drug AndroGel in a case that would eventually make it to the Supreme Court. While these cases were pending, the Commission under Chairman Leibowitz released an FTC staff report estimating that reverse payment settlements cost consumers, businesses and taxpayers \$3.5 billion a year in higher drug

¹⁹ Statement of the Commission, *Abbott Labs.*, Dkt. C-3946 (Mar. 16, 2000), https://www.ftc.gov/sites/default/files/hoeschtandrxcommstmt_0.htm.

²⁰ *Am. Home Prods.*, Dkt. 9297, 133 F.T.C. 611 (final order issued Apr. 2, 2002).

²¹ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). Note that the Third Circuit's decision in the private K-Dur litigation adopted the "presumptively unlawful" analysis urged in our amicus brief and created the circuit split that led the Supreme Court to grant cert in the *Actavis* case. See *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012).

prices.²² But it wasn't until 2013 that the Supreme Court weighed in on this issue, rejecting the scope-of-the-patent test and permitting antitrust scrutiny for reverse payment agreements—giving the FTC its first favorable ruling from a federal court.²³

The Supreme Court's decision in *FTC v. Actavis* was a watershed moment in the FTC's efforts to combat anticompetitive brand-generic agreements that undermine the Hatch-Waxman framework. That decision was announced just a few weeks before I came back to the FTC to serve as Bureau Director. Since then, there have been many other successes in the Commission's long-running effort. In May of 2015, Teva, by then Cephalon's owner, agreed to settle the FTC's charges by paying \$1.2 billion in ill-gotten Provigil profits and refraining from entering into various types of reverse payment agreements for any of its other products.²⁴ More recently, branded drug maker Endo agreed to settle FTC claims that it entered into anticompetitive agreements with several generic companies not to enter the market in exchange for a promise not to market an authorized generic.²⁵ Under the stipulated order entered by the federal court, Endo—another large pharmaceutical company with a broad range of products—is barred for ten years from entering into reverse payment agreements that contain certain provisions, including no-AG commitments. The FTC first signaled its concern about no-AG commitments in amicus briefs in private actions,²⁶ and the First and Third Circuits have now held that patent litigation settlements containing these provisions can raise the same competitive concerns the Supreme Court addressed in *Actavis*.²⁷

The Commission can leverage its knowledge and resources by filing amicus briefs in private cases to help advance the development of post-*Actavis* case law. For instance, we urged the Third Circuit to correct several errors in the district court's antitrust analysis of the reverse payment settlement in *In re Wellbutrin Antitrust Litigation*.²⁸ Specifically, the amicus brief

²² *Pay-for-Delay: How Drug Company Pay-offs Cost Consumers Billions*, FTC Staff Report (2010), <https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff>.

²³ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

²⁴ *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141, 2015 WL 4395566 (E.D. Pa. 2015).

²⁵ Joint Motion for Entry of Stipulated Order for Permanent Injunction, *FTC v. Allergan plc*, No. 17-cv-00312 (N.D. Cal. Jan. 23, 2017). The stipulated order, filed in federal court in California, settles separate charges against Endo in three separate proceedings, including *FTC v. Actavis* (Endo is the parent of defendants Par Pharmaceuticals Companies, Inc. and Paddock Laboratories). At the same time as its original complaint against Endo, the Commission also filed a stipulated order for permanent injunction against Teikoku Seiyaku Co., Ltd. and Teikoku Pharma USA, Inc., settling charges for those two defendants. See Stipulated Order for Permanent Injunction, *FTC v. Teikoku Pharma USA, Inc.*, No. 16-cv-01440 (E.D. Pa. Mar. 30, 2016).

²⁶ Brief of Federal Trade Commission as Amicus Curiae, supporting Plaintiffs-Appellants, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 14-1243 (3d Cir. Apr. 28, 2014),

https://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf; Brief of Federal Trade Commission as Amicus Curiae, supporting Plaintiffs-Appellants, *Sales Co. v. Warner-Chilcott Co.*, No. 14-2071 (1st Cir. June 16, 2015), https://www.ftc.gov/system/files/documents/amicus_briefs/american-sales-co.et-al.plaintiffs-appellants-v.warner-chilcott-co.llc-et-al.defendants-appellees/1506warner-chilcottamicusbrief.pdf.

²⁷ *King Drug Co. of Florence Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015); *In re Loestrin 24 FE Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016).

²⁸ Brief of Federal Trade Commission as Amicus Curiae in Support of No Party, *In re Wellbutrin XL Antitrust Litig.*, Nos. 15-3559, 15-3591, 15-3681 & 15-3682 (3d Cir. Mar. 11, 2016), https://www.ftc.gov/system/files/documents/amicus_briefs/re-wellbutrin-antitrust-litigation/160311wellbutrinbrief.pdf.

focuses on errors made in assessing the anticompetitive harm that gives rise to a reverse payment claim and on possible justifications a defendant can offer in the rule-of-reason analysis. With respect to the anticompetitive harm, the brief explains that a reverse payment from a brand-name drug maker can violate the antitrust laws by eliminating the risk of generic competition regardless of whether the settlement fully resolves the patent litigation. Paying to eliminate the possibility of an at-risk launch during the pendency of an infringement action raises the same type of competitive harm at issue in *Actavis*. Further, the brief cautions against confusing antitrust liability, which requires a general showing of harm to the competitive process, with antitrust injury, which requires a specific showing that a party has suffered threatened harm or damages because of the antitrust violation.²⁹ A reverse payment settlement can violate the antitrust laws regardless of whether the generic definitively would have otherwise entered the market sooner than permitted by the settlement. On justifications, the brief explains that a reverse payment is not justified by a procompetitive benefit unless the defendant shows how the payment directly promotes that benefit and explains the presence of the reverse payment. For example, the two justifications specifically identified in *Actavis*—saved litigation expenses and compensation for other services—indicate that the generic company’s decision not to market its product was based on “traditional settlement considerations,” not a sharing of monopoly profits preserved by avoiding competition.

Arguments made in amicus briefs also can signal new areas of concern. For instance, two recent FTC amicus briefs outline potential concerns that branded firms may use FDA-mandated REMS distribution restrictions or other closed distribution systems to deny generic drug makers the samples they need to conduct bioequivalence tests, which they must do before they can enter the market.³⁰ Given the number and complexity of private actions in the pharmaceutical space, FTC staff will continue to look for opportunities to shape antitrust law for the benefit of consumers and competition.

Following the same timeline as the efforts on reverse payment settlements, the Commission initiated what former Chairman Tim Muris referred to as “second generation” cases, those involving unilateral conduct by branded drug manufacturers to abuse the Hatch-Waxman process in order to restrain competition.³¹ Although the Commission had examined the potential for competitors to abuse a judicial process in order to limit competition in cases outside

²⁹ In a separate action, the First Circuit accepted the FTC’s distinction between an antitrust violation and injury-in-fact. See *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 59-60 (1st Cir. 2016); Brief of Amicus Curiae Federal Trade Commission in Support of No Party, *In re Nexium (Esomeprazole) Antitrust Litig.*, Nos. 15-2005, 15-2006, & 15-2007 (1st Cir. Feb. 12, 2016), https://www.ftc.gov/system/files/documents/amicus_briefs/re-nexium-esomeprazole-antitrust-litigation/160212nexiumbrief.pdf.

³⁰ Federal Trade Commission’s Brief as Amicus Curiae, *Mylan v. Celgene*, No. 2:14-CV-2094 (D.N.J. June 17, 2014), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf; Brief of Federal Trade Commission as Amicus Curiae, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743 (D.N.J. Mar. 11, 2013), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf.

³¹ Statement of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, (Apr. 23, 2002) at 5, *available at* https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-pharmaceutical-industry/pharmtestimony.pdf.

the healthcare sector,³² the Commission began to focus during this period on the practice of some pharmaceutical companies to improperly list patents in the FDA’s “Orange Book.”³³ Once listed in the Orange Book, these patents triggered the Hatch-Waxman provision granting an automatic 30-month stay of any ANDA approval, thereby delaying generic entry. Filings made in bad faith had the same exclusionary effect as properly listed patents, because the FDA took the listings at face value, without any further inquiry.

Antitrust violations relying on an abuse of government processes implicate the scope of the *Noerr-Pennington* doctrine.³⁴ Another project Chairman Muris launched—which Acting Chairman Ohlhausen spearheaded during her time as head of the Office of Policy Planning—was a study of the proper scope of *Noerr* immunity, which prevents antitrust liability for individual petitioning activity that is protected by the First Amendment. The staff’s 2006 Report specifically addressed the proper application of *Noerr* protection for three scenarios in which competitors could use government processes to seek anticompetitive rewards: 1) requests for ministerial government acts; 2) misrepresentations to a government decision maker in a non-political context; and 3) repetitive requests for government action filed regardless of merit solely to use the government process to suppress competition.³⁵

The Commission first signaled its concerns about this type of conduct related to pharmaceutical products in amicus briefs filed in two private actions, arguing that Orange Book filings are not protected petitioning under *Noerr* because the government performs no independent review, but rather acts solely in reliance on the private party’s representations.³⁶ Then, in 2002, the Commission brought its first enforcement action involving *Noerr* issues, alleging that Biovail Corporation illegally acquired the exclusive license to a drug patent and

³² See *AMERCO*, Dkt. 9193, 109 F.T.C. 135 (consent order entered May 18, 1987); *FTC v. Superior Ct. Trial Lawyers Ass’n*, 493 U. S. 411 (1990).

³³ Under the provisions of the Hatch-Waxman Act, a company may obtain approval to make and sell a generic version of a branded drug by filing an Abbreviated New Drug Application (ANDA) with the FDA. If a company seeks to market a generic version of a branded drug prior to the expiration of one or more of the patents listed in the Orange Book as relating to that drug, the generic applicant must provide a certification to the FDA with respect to each such patent. One type of certification a generic applicant may make to the FDA is a “Paragraph IV certification,” in which the applicant claims that the branded-drug company’s patent is invalid or will not be infringed by the manufacture, use, or sale of the generic product. The Hatch-Waxman Act allows a branded-drug company to delay the entry of a generic drug for which Paragraph IV certification has been filed by filing a patent infringement suit against the generic drug applicant. If such a suit is filed, the FDA stays final approval of the ANDA until the earliest of: 1) patent expiration; 2) a final determination by a court of non-infringement or patent invalidity; or 3) the expiration of a 30-month period from the time the ANDA filer notifies the patent holder of a Paragraph IV certification. An ANDA filer must notify each patent owner and branded-drug company listed in the Orange Book when the ANDA filer makes its Paragraph IV certification.

³⁴ See *E. R.R. Presidents’ Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).

³⁵ FTC Staff Report, *Enforcement Perspectives on the Noerr-Pennington Doctrine*, at 4 (2006), <https://www.ftc.gov/sites/default/files/documents/reports/ftc-staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf>.

³⁶ Brief for Federal Trade Commission as Amicus Curiae, opposing Defendant’s Motion to Dismiss, *Am. Bioscience, Inc. v. Bristol-Myers Squibb Co.*, No. CV-00-08577 (C.D. Cal. Sept. 7, 2000), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf; Brief for Federal Trade Commission as Amicus Curiae, opposing Defendant’s Motion to Dismiss, *In re Buspirone Patent Litig.*, MDL No. 1410 (S.D.N.Y. Jan. 8, 2002), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-buspirone-antitrust-litigation/buspirone.pdf.

wrongfully listed that patent in the Orange Book in order to maintain its monopoly in the antihypertension drug Tiazac. Biovail settled the charges by divesting part of the exclusive rights back to the original owner and agreeing to a prohibition on wrongfully listing patents in the Orange Book.³⁷

I mention these origin cases not out a sense of nostalgia, but more out of a sense of déjà vu. Look closely at recent FTC enforcement actions in this area and you will see how our work relies on areas of interest identified years ago. For instance, the Commission has always been concerned about agreements not to compete that are not part of a patent settlement but nonetheless have the effect of reducing generic competition. In 2004, Perrigo and Alpharma, the only two manufacturers of over-the-counter store-brand children's liquid ibuprofen, agreed to pay \$6.25 million in illegal profits generated from their illegal agreement not to compete.³⁸ In 2015, the FTC charged Concordia Pharmaceuticals, Inc. and Par Pharmaceutical, Inc. with entering into an unlawful agreement not to compete in the sale of generic versions of Kapvay, a prescription drug used to treat Attention Deficit Hyperactivity Disorder.³⁹

Similarly, competitive issues continue to arise from unilateral conduct to abuse governmental processes. The Commission's recent unanimous decision to charge Shire ViroPharma with illegal monopolization via a campaign of sham citizen petitions harkens back to the original Orange Book cases.⁴⁰ In that case the Commission alleges that ViroPharma maintained its monopoly over Vancocin Capsules by filing 43 repetitive and unsupported petitions with the FDA, as well as three lawsuits, between 2006 and 2012, all in an effort to obstruct and delay approval of a generic version. Even after a panel of 16 independent scientific and medical experts considered and rejected ViroPharma's unsupported arguments, ViroPharma continued to repeat its rejected arguments, the complaint alleges. Because of the FDA's policy not to approve any generic applications until it resolves any pending citizens' petitions, we allege that ViroPharma's conduct delayed the FDA approval of a generic, at a significant cost to those who take this medicine.

Other good news on the reverse payment agreement front comes from FTC staff's review of agreements filed with the antitrust agencies under the Medicare Prescription Drug,

³⁷ *Biovail Corp.*, Dkt. C-4060 (final order issued Oct. 2, 2002).

³⁸ *FTC v. Perrigo Co.*, No. 1:04CV01397 (D.D.C. 2004) (final order and stipulated permanent injunction approved Aug. 24, 2004; modified June 23, 2006).

³⁹ *Concordia Pharms, Inc. and Par Pharm., Inc.*, Dkts. C-4553 and C-4554 (final orders issued Oct. 30, 2015).

⁴⁰ The Commission also has charges pending in federal court against AbbVie, Inc. and its partner, Besins Healthcare Inc., alleging that the companies filed baseless infringement lawsuits to delay consumers' access to lower-priced versions of Androgel. *FTC v. Abbvie Inc.*, 107 F. Supp. 3d. 428 (E.D. Pa. 2015), *reconsideration denied*, No. 14-cv-5151, WL 5025438 (E.D. Pa. Aug. 25, 2015) (complaint seeking a permanent injunction and other equitable relief filed September 8, 2014, <https://www.ftc.gov/enforcement/cases-proceedings/121-0028/abbvie-inc-et-al>). The complaint had two principal counts: (1) baseless patent infringement lawsuits by AbbVie Defendants against potential generic competitors to trigger the automatic 30-month stay and delay generic entry; and (2) while these lawsuits were pending, the AbbVie Defendants entered into an anticompetitive settlement with Teva to delay launching its alternative to Androgel in exchange for a highly profitable authorized generic deal for another product. In May 2015, the district court granted defendants' motion to dismiss, ruling that the patent settlement agreement was not anticompetitive under *FTC v. Actavis*, that Teva could not plausibly know the patent infringement case was groundless and therefore that its agreement to settle that action was not a restraint of trade. At the appropriate time, the Commission may consider whether to appeal that ruling; the case is proceeding on the sham litigation count.

Improvement and Modernization Act, also known as MMA filings. Based on our most recent annual report—which includes the first full year of filings since the Court’s ruling in *Actavis*—the number of potentially unlawful reverse payment agreements appears to be falling, reversing what had been a steady upward trend in the number of those agreements since 2005.⁴¹ It has always been true that the majority of patent settlements do not include payments to generic companies, proving that reverse payment compensation to the generic company is not a necessary feature of settling patent litigation. The recent data reinforce that conclusion.

Let me turn for a moment to another area of concern to the Commission—ensuring that transactions involving pharmaceutical companies do not lead to less competition and higher prices. Here again, the Commission’s expertise in reviewing competition in pharmaceutical mergers is deep and wide. The FTC has a well-developed analytical approach to examining the likely competitive effects in pharmaceutical markets that considers not only on-market products, but also products in development where a merger might eliminate one of only a few likely entrants. Starting in 1995 with cases that required divestitures involving potential competition,⁴² Commission staff has routinely investigated not only products where there are existing product overlaps between the merging parties, but also markets in which one firm has a product and the other has a product in development, as well as future markets in which there is no generic version available but both firms are two of only a few firms likely to develop a generic product in the near future.

During my time at the Bureau, the Commission has required divestitures in connection with 18 transactions involving generic pharmaceutical products. But we are aware of concerns that, in light of the number and size of pharmaceutical mergers, increasing levels of concentration may be adversely affecting current levels of competition as well as the development of new branded and generic drugs. In light of these concerns, during our review of Teva’s proposed acquisition of Allergan—two firms with extensive generic portfolios—FTC staff looked beyond individual product overlaps to investigate three additional potential theories of harm. First, we considered whether the merger would likely lead to anticompetitive effects from the bundling of generic products. Second, we examined whether the merger would likely decrease incentives to challenge the patents held by brand name pharmaceutical companies and bring new generic drugs to market. Finally, we analyzed whether the proposed transaction might dampen incentives to develop new generic products generally rather than with respect to specific overlapping products, especially for difficult-to-develop products such as sterile injectables. In each instance, however, the Commission concluded that there were unlikely to be additional competitive effects beyond those arising from direct product overlaps.⁴³

Nonetheless, the consent order in Teva/Allergan represents the largest divestiture order in a pharmaceutical merger in the Commission’s history. It remedies the competitive concerns in 79 markets including oral contraceptives, steroidal medications, and mental health drugs. In

⁴¹ BUREAU OF COMPETITION, FED. TRADE COMM’N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, OVERVIEW OF AGREEMENTS FILED IN FY 2014, <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf>.

⁴² *Am. Home Prods.*, Dkt. C-3557, 119 F.T.C. 217 (1995); *Hoechst*, Dkt. C-3629, 120 F.T.C. 1010 (1995).

⁴³ Statement of the Commission, *Teva Pharm. Indus. Ltd.*, Dkt. C-4589 (July 27, 2016), https://www.ftc.gov/system/files/documents/public_statements/973673/160727tevaallergan-statement.pdf.

order to address the potential effects in an additional 15 products for which Teva supplies the active ingredients to current or future Allergan competitors, the Commission required Teva to offer existing API customers the option of entering into long-term supply contracts. In addition, the Commission took steps to structure the divestitures to minimize the risk that the buyer would not maintain the competitive status quo. First, we separated the products into smaller divestiture packages so that no one buyer would take on too many products. Second, we required Teva to divest the easier-to-divest product, such as one that was made by a contract manufacturer where the contract could be assigned. Third, we brought specialist interim monitors on board early in the divestiture negotiation process to oversee the technology transfers, and required Teva to take additional steps to dedicate resources to ensure a smooth transfer. Finally, we carefully vetted the eleven buyers to ensure each one had the resources to take the assets and compete in the market at issue.

Many of the improvements incorporated into the Teva/Allergan order reflect learning gained during the recently concluded Merger Remedy Study.⁴⁴ The Remedy Study examined 89 merger orders issued between 2006 and 2012, including 24 orders involving pharmaceutical divestitures. The study confirmed that Commission's practices related to designing, drafting and implementing its merger remedies are generally sound, but it also identified areas for improvement. Specifically with regard to pharmaceutical merger remedies, the Study offers the following Best Practices:

To ensure the success of divestitures in the pharmaceutical industry, the respondent should:

- divest the easier-to-divest product wherever possible, such as products already made at a third-party manufacturing site;
- provide complete information upfront to the proposed buyer so that the buyer can be prepared to step into the respondent's place with key customers, including regarding any production problems or supply chain issues and more in-depth sales and costs figures;
- work with the proposed buyer to develop a comprehensive technology transfer plan and identify specific employees to oversee respondent's transfer to the new manufacturing facility; and
- retain a Commission-approved monitor prior to entry of the order to facilitate development of the technology transfer plan.

The proposed buyer should identify any necessary third-party contract manufacturers for divested products that the buyer will not manufacture in its own facilities, and provide detailed business plans for investment in products in development, including internal hurdle rates.⁴⁵

Going forward, a divestiture order for pharmaceutical products will follow these principles whenever appropriate to ensure that it prevents competitive harm from the merger.

⁴⁴ FTC Staff Report, *The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics* (2017), https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf.

⁴⁵ *Id.* at 36-37.

I also want to briefly address the issue of high drug prices. We are often asked what the FTC can do about the high cost of prescription drugs, especially when there are sudden and dramatic increases. My answer, not surprisingly, is that it depends. I always start by cautioning that it is not an antitrust violation if a firm—even a monopolist—charges a high price or increases prices without warning. A pharmaceutical company with a patented product may charge a high price for that product—that is an essential feature of our patent system. Moreover, sudden price changes are often the result of normal market forces, such as ingredient shortages or manufacturing disruptions. But there can be situations where a company with market power in a pharmaceutical product engages in conduct that restrains competition—reverse payment agreements, for instance. Or garden variety agreements not to compete, like the one I discussed earlier involving Concordia and Par. Or conduct that effectively excludes potential rivals.

Earlier this year, the Commission alleged that Questcor Pharmaceuticals, Inc. (acquired by Mallinckrodt ARD Inc., after the conduct at issue), engaged in illegal monopolization when it acquired the rights to a drug that threatened its monopoly in the U.S. market for adrenocorticotrophic hormone (ACTH) drugs.⁴⁶ Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants. In other parts of the world, doctors treat patients with Synacthen Depot at a fraction of the price of Acthar. The FTC’s complaint alleges that, while benefitting from an existing monopoly over Acthar, the only U.S. ACTH drug, Questcor illegally acquired the rights to develop Synacthen Depot in the United States. The acquisition stifled competition by preventing other bidders interested in acquiring these assets from using them to develop a competing synthetic ACTH drug. This conduct preserved Questcor’s monopoly and allowed it to maintain extremely high prices for Acthar. Under a stipulated settlement filed in federal court, Mallinckrodt agreed to pay \$100 million in equitable monetary remedies and grant a license to another company to develop Synacthen Depot to treat certain conditions.⁴⁷

The Questcor case is not the first time the FTC has targeted exclusionary conduct by a monopolist where the effect was to stave off nascent competition and keep prices high. In 1998, the Commission filed charges in federal court alleging that Mylan Laboratories, Inc. and three other companies conspired to create a monopoly for Mylan over two generic anti-anxiety medications. Along with 32 state attorneys general, the FTC alleged that in exchange for signing 10-year exclusive licensing agreements to supply only Mylan with the raw materials necessary to make lorazepam and clorazepate, Mylan agreed to pay the manufacturers a percentage of its gross profits on sales. Mylan promptly raised its price for the two products as much as 3,000%. After the district court denied the defendants’ motion to dismiss and ruled that the Commission has the authority to seek disgorgement in antitrust actions brought in federal court under Section

⁴⁶ Complaint for Injunctive and Other Equitable Relief, *FTC v. Mallinckrodt ARD Inc.*, No. 1:17-cv-00120 (D.D.C. Jan. 25, 2017).

⁴⁷ Stipulated Order for Permanent Injunction and Equitable Monetary Relief, *FTC v. Mallinckrodt ARD Inc.*, No. 1:17-cv-00120 (D.D.C. Jan. 30, 2017).

13(b) of the FTC Act,⁴⁸ Mylan settled the charges and paid \$100 million, money that was returned to consumers and state agencies that had overpaid for the drugs.⁴⁹

The Commission also obtained a 2015 settlement that included disgorged profits after charging Cardinal Health with coercing the only two suppliers of a critical input into exclusive supply agreements that denied these inputs to other radiopharmacies that might compete with Cardinal. At the time, Cardinal was the largest operator of radiopharmacies in the U.S. and the only operator in 25 metropolitan areas. The FTC's complaint set out a variety of coercive tactics Cardinal allegedly used to obtain exclusive rights to heat perfusion agents sold by General Electric and Bristol-Myers-Squibb, leading to inflated prices for the drugs.⁵⁰ The Commission's order bars Cardinal from entering into simultaneous exclusive deals with manufacturers of the same radiopharmaceutical product, or coercing suppliers into *de facto* exclusive distribution agreements. The order also contains provisions designed to facilitate entry in certain markets, for instance by granting Cardinal customers the option to terminate contracts and find another supplier. Cardinal also paid \$26.8 million into a fund for distribution to injured customers.

The Commission is also attentive to exclusionary conduct by pharmaceutical companies that inhibits innovation that could increase competition and lead to lower prices. Last year, the Commission voted unanimously to charge Invibio, the first company to sell implant-grade polyetheretherketone (PEEK), with using exclusive supply contracts to lock up customers and box out rivals. When two other companies developed a competing PEEK product, Invibio adopted an "all-or-nothing" strategy with medical device customers that not only kept PEEK prices high, but also stifled incentives to develop new and improved forms of PEEK. In pursuing and enforcing exclusivity, Invibio prevented the newcomers from establishing a reputation with medical device companies that would validate their status as an effective PEEK supplier, leading to lower prices and other benefits of competition, such as future investments in innovative technologies. The Commission's order was designed to prevent Invibio from establishing *de facto* exclusivity, but allows the company to continue to engage in procompetitive collaborations with customers.⁵¹

The FTC is continually trying to better understand market behavior, including when and how pricing practices in the pharmaceutical sector might impede competition on the merits. For instance, at a June 2014 workshop, the FTC and the DOJ brought together academics and practitioners to consider economic learning related to pricing practices such as loyalty and bundled discounts, and to assess the proper treatment of these practices under the antitrust laws.⁵² While the antitrust laws were not designed to regulate prices, antitrust enforcement can prevent exclusionary conduct that allows a firm to raise prices without fear of inducing entry.

⁴⁸ *FTC v. Mylan Labs, Inc.*, 62 F. Supp. 2d 25, 37 (D.D.C. 1999).

⁴⁹ FTC News Release, *FTC Reaches Record Financial Settlement to Settle Charges of Price-fixing in Generic Drug Market* (Nov. 29, 2000), <https://www.ftc.gov/news-events/press-releases/2000/11/ftc-reaches-record-financial-settlement-settle-charges-price>.

⁵⁰ Complaint for Injunctive and Other Equitable Relief, *FTC v. Cardinal Health, Inc.*, No. 15-cv-3031 (S.D.N.Y. Apr. 20, 2015), <https://www.ftc.gov/system/files/documents/cases/150420cardinalcmpt.pdf>.

⁵¹ *Victrex plc*, Dkt. C-4586 (final order issued July 14, 2016).

⁵² FTC/DOJ workshop, *Conditional Pricing Practices: Economic Analysis & Policy Implications* (June 23, 2014), <https://www.ftc.gov/news-events/events-calendar/2014/06/conditional-pricing-practices-economic-analysis-legal-policy>.

High prices alone will not trigger antitrust condemnation, but high prices plus exclusionary conduct might.

Provider Mergers: Clear Guidance from Litigated Cases

Provider mergers constitute one area of FTC antitrust enforcement that stands out for the sheer number of recent litigated decisions. Since July 2013, there have been four appellate court decisions validating the Commission’s approach to analyzing virtually every aspect of provider combinations, from market definition to competitive effects, failing firms, and efficiencies.⁵³ Coupled with the two recent district court opinions blocking the Aetna/Humana and Anthem/Cigna insurance mergers on antitrust grounds,⁵⁴ there should be little question as to how the antitrust agencies are likely to view the benefits of competition in nearly every aspect of negotiating for healthcare services—from both sides of the bargaining table.

Most FTC observers are familiar with the backstory on the Commission’s efforts to retool its hospital merger analysis. Over a decade ago, it turned to its economists to study consummated hospital mergers after several federal courts relied on overly broad geographic markets and other arguments not likely to pass muster today to rebuff FTC (and DOJ) merger challenges.⁵⁵ In particular, several federal courts had rejected the agencies’ proffered geographic markets in part based on evidence (or belief) that patients would simply drive to other hospitals if the hospitals in the FTC’s proffered market tried to raise prices.⁵⁶ In published retrospectives, economists from the Bureau of Economics compared price changes post-merger with those in a control group of hospitals, and found that the consummated hospital mergers resulted in competitive harm, including higher prices.⁵⁷ The findings also showed that hospital competition tends to be highly localized, with price effects even in a city with many other hospitals.

As a result of these studies, the Commission retooled its analysis. Specifically, the Commission began to focus on whether a merger is likely to affect the ability of an *insurer*—the company directly paying for the services—to avoid a price increase by excluding the hospitals in

⁵³ *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559 (6th Cir. 2014), *cert. denied*, 135 S. Ct. 2049 (2015); *St. Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke’s Health Sys.*, 778 F.3d 775 (9th Cir. 2015); *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016); *FTC v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016).

⁵⁴ *United States v. Aetna Inc.*, No. 16-1494, 2017 WL 325189 (D.D.C. Jan. 23, 2017); *United States v. Anthem, Inc.*, No. 16-1493 (D.D.C. Feb. 21, 2017).

⁵⁵ For example, some courts considered arguments that the non-profit ownership structure of the hospitals should alter the Merger Guidelines analysis. *See, e.g., FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1302 (W.D. Mich. 1996), *aff’d per curiam*, 121 F.3d 708 (6th Cir. 1997); *FTC v. Freeman Hosp.*, 911 F. Supp. 1213, 1222-23 (W.D. Mo. 1995), *aff’d*, 69 F.3d 260 (8th Cir. 1995).

⁵⁶ *See FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1052-54 (8th Cir. 1999); *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 981-85 (N.D. Iowa 1995).

⁵⁷ Steven Tenn, *The Price Effects of Hospital Mergers: A Case Study of the Sutter-Summit Transaction*, 18 INT’L J. ECON. BUS. 65 (2011); Christopher Garmon & Deborah Haas-Wilson, *Two Hospital Mergers on Chicago’s North Shore: A Retrospective Study*, 18 INT’L J. ECON. BUS. 17 (2011); Aileen Thompson, *The Effect of Hospital Mergers on Inpatient Prices: A Case Study of the New Hanover-Cape Fear Transaction*, 18 INT’L J. ECON. BUS. 91 (2009). *See also* Michael G. Vita & Seth Sacher, *The Competitive Effects of Not-for-Profit Hospital Mergers: A Case Study*, 49 J. INDUS. ECON. 63 (2001); David J. Balan & Patrick S. Romano, *A Retrospective Analysis of the Clinical Quality Effects of the Acquisition of Highland Park Hospital by Evanston Northwestern Healthcare* (FTC Bureau of Economics, Working Paper No. 307, 2010), <http://www.ftc.gov/be/workpapers/wp307.pdf>.

a given geographic area from its network of providers. The reality of how hospital prices are set, coupled with the commercial reality that most patients receive care close to where they live, led to smaller geographic markets. Another significant finding of two of the studies (including the retrospective review of Evanston Northwestern Healthcare’s 2000 acquisition of Highland Park Hospital) was that non-profit hospitals do not necessarily abstain from exercising market power gained from a merger, as evidenced by the large price increases that occurred post-merger.⁵⁸ Starting with the administrative case against the consummated Evanston/Highland Park merger,⁵⁹ the Commission has relied on the learning from these studies with good results. That is until last year, when the district courts in both *FTC v. Penn State Hershey Medical Center*⁶⁰ and *FTC v. Advocate Health System*⁶¹ rejected our proposed geographic markets on grounds similar to those courts relied on prior to the hospital merger retrospective project.

In both cases, the Commission acted quickly and obtained stays pending appeal. The FTC has learned the hard way that it is very difficult to unwind a hospital merger once the operations have been integrated.⁶² From our perspective, the effort certainly paid off, with two strong appellate decisions that we hope will put to rest market definition arguments that rely on the Elzinga-Hogarty test—or what the Third Circuit called a “discredited economic theory” in analyzing hospital mergers. (I should also point out that we had incredible support from many quarters, including amicus support from more than a dozen states attorneys general as well as an impressive group of economics professors, including Professor Elzinga himself.) Importantly, the Third and Seventh Circuit decisions refute the “silent majority” fallacy, that is, the argument that patients who travel long distances to obtain care constrain the prices at closer hospitals for those patients who use those local hospitals.⁶³

It is hard not to compare the two decisions, which we litigated on roughly parallel tracks after filing the complaints within two weeks of each other in December 2015. At the most basic level, the two cases tell the tale of hospitals serving patients in two very different geographies—Harrisburg, Pennsylvania and environs, and the urban areas of Chicago’s North Shore. In *Advocate*, the appellate court remanded the case to the district court for further proceedings; currently, we are waiting for rulings from the district court. Thus, I will focus on the Third Circuit decision in *Penn State Hershey* because the court addressed several issues that arise frequently in hospital merger reviews.

From the beginning of our Penn State Hershey litigation, it was clear that the contours of the relevant geographic market could determine the outcome. In our complaint, we alleged that the geographic market was a four-county area near Harrisburg (the counties of Dauphin,

⁵⁸ Michael G. Vita & Seth Sacher, *The Competitive Effects of Not-for-Profit Hospital Mergers: A Case Study*, *supra* note 57; Steven Tenn, *The Price Effects of Hospital Mergers: A Case-Study of the Sutter-Summit Transaction*, *supra* note 57.

⁵⁹ *Evanston Nw. Healthcare Corp.*, 2007 WL 2286195, at *64 (F.T.C. 2007).

⁶⁰ *FTC v. Penn State Hershey Med. Ctr.*, 185 F. Supp. 3d 552 (M.D. Pa. Feb. 29, 2016).

⁶¹ *FTC v. Advocate Health Care*, No. 15-CV-11473, 2016 WL 3387163 (N.D. Ill. June 20, 2016).

⁶² See *Evanston Nw. Healthcare Corp.*, 2007 WL 2286195, at *77-78 (F.T.C. 2007); Statement of the Commission, *Phoebe Putney Health System, Inc.*, Dkt. 9348 (Mar. 31, 2015),

https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf.

⁶³ *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 340-41 (3d Cir. 2016); *FTC v. Advocate Health Care Network*, 841 F.3d 460, 474-76 (7th Cir. 2016).

Cumberland, Perry, and Lebanon). Our evidence focused on the commercial reality that insurers seeking to sell policies in that four-county area must include hospitals located within that area in order to have a marketable product. At trial, our expert testified that a hypothetical owner of all Harrisburg-area hospitals could successfully demand a price increase from insurers, and thereby established a properly defined antitrust market using the hypothetical monopolist test.

The district court rejected our geographic market definition, citing as a key fact that 43.5% of Hershey’s patients travel from outside the proffered geographic market. But as detailed in the Third Circuit’s opinion, the interpretation of patient flow data has been the source of much confusion in hospital merger litigation over the years. The Third Circuit determined that “the silent majority fallacy renders the test employed by the district court unreliable,” and “relying solely on patient flow data is not consistent with the hypothetical monopolist test.”⁶⁴ It also noted that the District Court did not consider undisputed evidence that 91% of patients who live in the Harrisburg area receive their hospital services from Harrisburg-area hospitals. The Third Circuit explained that such a high number of patients who do not travel long distances for healthcare supported our contention that hospital services are inherently local, and, in turn, that insurers would not be able to market a healthcare plan to Harrisburg area resident that did not include Harrisburg-area hospitals.

The Third Circuit also found error in the district court’s failure to consider the likely response of insurers to a price increase in hospital services. As the Third Circuit noted, ignoring the commercial realities *faced by insurers* results in a misapplication of the hypothetical monopolist test. The correct formulation of the hypothetical monopolist test in the case of hospital services is whether insurers, in the face of a small but significant non-transitory price increase, could avoid the price increase by excluding all the hospitals in the proposed geographic market and relying on those outside the market. According to the Third Circuit, without answering this question, there is no basis to conclude that the market is too narrow.⁶⁵

The Third Circuit also rejected the notion that private agreements between the merging hospitals and two payors to maintain existing rate structures for multi-year periods had any bearing on the analysis to determine the relevant geographic market. The district court had used the price agreements in its assessment of the relevant geographic market. After noting that the two payors could not raise their rates for at least five years, the district court stated it could not “be blind to this reality when considering the import of the hypothetical monopolist test advanced by the Merger Guidelines.” On appeal, the Third Circuit explained that the hypothetical monopolist test is a construct for delineating the relevant market. It made clear that the test is a theoretical exercise unaffected by a promise not to raise prices. According to the Third Circuit, “if we allowed such private contracts to impact our analysis, any merging entity could enter in to similar agreements—that may or may not be enforceable—to impermissibly broaden the scope of the relevant geographic market.”⁶⁶

⁶⁴ *FTC v. Penn State Hershey Med. Ctr.*, *supra* note 63.

⁶⁵ *Id.* at 341-43.

⁶⁶ *Id.* at 344.

Another aspect of the Third Circuit decision that merits a close read is the discussion of two of the hospitals' rebuttal arguments, which the court referred to as efficiency-based.⁶⁷ The hospitals put forth two main arguments that the merger would produce procompetitive effects. First, they claimed that, in view of Pinnacle's excess capacity, the merger would allow Hershey to avoid construction of a new \$277 million bed tower that otherwise would have been needed to alleviate capacity constraints at the hospital because Pinnacle had excess capacity. The Third Circuit was willing to credit, in theory, potential capital cost savings as a cognizable efficiency. However, it found—as we argued—that the combined firms' decision not to expand as a result of the merger was not a cognizable efficiency nor verifiable under the Horizontal Merger Guidelines.

Recent developments support the Third Circuit's rejection of the parties' arguments. Contrary to its claims of excess capacity, Pinnacle announced recently that it is building out its space because it cannot meet current demand. Because of the build-out, Harrisburg area patients will have access to an additional 32 large, private rooms for oncology, urology, and medical/surgical patients, including additional space for visitors with private consultation rooms, spacious bathrooms, and flat-screen televisions.

Finally, the Third Circuit found the very high level of post-merger concentration would require extraordinarily great cognizable efficiencies to prevent the merger from being anticompetitive, a high standard that the hospitals had not met. Similarly, the Third Circuit rejected the hospitals' argument that the merger would improve their combined ability to engage in risk-based contracting. Among other reasons, the court concluded that there was no proof in the record that the benefits of this practice would be passed on to consumers. Importantly, the court reiterated that “[a]n efficiencies analysis requires more than speculative assurances that a benefit enjoyed by the Hospitals will also be enjoyed by the public.”

I would point out that there are many ways to integrate care without mergers or acquisitions—and of most importance, in ways that do not raise antitrust concerns. It is the parties' burden to explain why a merger is necessary to achieve these goals. Some may remember that around the time of passage of the Affordable Care Act, the agencies were pressed to provide guidance for Accountable Care Organizations that some claimed would otherwise not be formed out of concerns over antitrust scrutiny. In response, in 2011 the FTC and DOJ issued an ACO Policy Statement to clarify our analysis of collaborations such as ACOs.⁶⁸ Since that time, hundreds of ACOs have been formed and the agencies have not challenged any ACO for violations of the antitrust laws.

⁶⁷ Like other courts, the Third Circuit expressed skepticism that precedents support an efficiencies defense. *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d at 348. Nonetheless, as stated in the *Horizontal Merger Guidelines*, “the antitrust agencies will not challenge a merger if cognizable efficiencies are of a character and magnitude such that the merger is not likely to be anticompetitive in any relevant market. . . . The greater the potential adverse competitive effect of a merger, the greater must be the cognizable efficiencies, and the more they must be passed through to customers, for the Agencies to conclude that the merger will not have an anticompetitive effect in the relevant market.” FED. TRADE COMM’N AND DEPARTMENT OF JUSTICE, *Horizontal Merger Guidelines* § 10.

⁶⁸ FED. TRADE COMM’N AND DEPARTMENT OF JUSTICE, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011).

Given the high profile of litigated cases, it would be easy to get the false impression that the FTC will challenge any combination of providers that results in a higher level of concentration. In fact, over the past decade, the FTC has challenged a very small fraction—roughly 1%—of hospital mergers. Often, the competitive dynamics of the market make clear that anticompetitive effects are unlikely. Further, we routinely consider efficiency arguments, especially with respect to quality improvement claims, as well as claims that the acquired hospital is in dire financial condition. In a prior speech, I described how we view efficiency claims and failing firm arguments in the healthcare context, including what courts have said when the issue has arisen in the context of merger litigation.⁶⁹ Suffice it to say that although it is a high bar to show in court that either efficiencies or financial distress will cause a merger to be on balance procompetitive, the FTC does decide *not* to pursue cases based on our assessment of these claims during our investigation.

Some have suggested that these latest decisions merely reflect that the pendulum has swung back in favor of the government, as though there may come a time when hospital merger enforcement will once again become an exercise in futility. But underlying the recent favorable decisions are new economic learning and established facts based on broad research into the price effects associated with hospital mergers.⁷⁰ In fact, the Seventh Circuit took note that after NorthShore was created by a merger in 2000, the Commission’s retrospective study found that prices increased 9-10%—and that was according to the testimony of the hospital’s expert.⁷¹ As former Commissioner Josh Wright recently suggested, “Sometimes, a concentrated industry is noncompetitive. Consider hospitals, where the Federal Trade Commission has successfully challenged proposed mergers with convincing economic evidence that greater concentration would lead to increases in price and reduced quality of service.”⁷² It is hard to imagine that this is just a phase we are going through.

Taking the long view, the FTC’s recent litigation successes demonstrate that the Commission’s approach to analyzing the likely effects of a provider merger is sound. It has been tested in a variety of settings and found to be reliable for describing how to apply the hypothetical monopolist test in a provider transaction. Because it rests on a firm foundation of empirical work and well-tested economic theories, providers considering mergers in the future should look closely at the FTC accepted approach as reflected in these litigated decisions.

⁶⁹ “Antitrust Enforcement in Health Care: Proscription, not Prescription,” Remarks of Deborah L. Feinstein before the 5th National Accountable Care Organization Summit, Washington, D. C. (June 19, 2014) at 11-14, https://www.ftc.gov/system/files/documents/public_statements/409481/140619_aco_speech.pdf. See also “Power shopping for an alternative buyer,” Debbie Feinstein and Alexis Gilman, *FTC Competition Matters* blog, Mar. 31, 2015.

⁷⁰ Cory Capps & David Dranove, Hospital Consolidation and Negotiated PPO Prices, 23 *Health Affairs* 175, 179 (2004); Leemore S. Dafny, Estimation and Identification of Merger Effects: An Application to Hospital Mergers 26 (Nat’l Bureau of Econ. Research, Working Paper No. 11673, 2005); Martin Gaynor & Robert Town, The Impact of Hospital Consolidation — Update, Technical Report (Robert Wood Johnson Foundation/The Synthesis Project, Princeton, N.J.), June 2012, at 2.

⁷¹ *Advocate*, 841 F.3d at 472-3.

⁷² Joshua Wright, *Concentration in an Industry Does Not Mean It Lacks Competition*, New York Times Room for Debate (Nov. 14, 2016), <http://www.nytimes.com/roomfordebate/2016/11/14/should-the-government-bring-back-trust-busting>.

No Need for Special Rules for Healthcare Markets.

In closing, I want to lay down a familiar marker from the antitrust enforcer playbook: There is no basis to suspend the antitrust laws as they apply to mergers or conduct in healthcare markets. The FTC generally opposes exemptions from the antitrust laws because they typically result in higher prices and reduced quality.⁷³ As I have said many times, the antitrust laws permit procompetitive collaborations among healthcare participants, whether they are related horizontally as competitors or they are in a vertical relationship. I believe that antitrust rules strike the right balance between conduct and alliances that promote competition and those that do not. Creating antitrust exemptions invariably leads to combinations or alliances that by definition would not pass antitrust review, meaning they are likely to result in a worse outcome for consumers (although they may well benefit those whose actions are exempted).

I offer the following mostly out a sense of nostalgia, but also because, as is often the case with FTC work, someone has said something thoughtful before that simply cannot be improved upon. Here are remarks circa 1995 from one of my mentors, former Chairman Janet Steiger. These remarks continue to ring true today:

Before I close, I would like to make one final point on the proposed special antitrust rules and exemptions for physicians. At its core, the proposed special rules and exemptions from traditional antitrust enforcement standards for physicians may be based on faulty premises about the nature of competition in health care and how antitrust law applies to physicians. We also saw this when there was a proposal for the exemption of hospitals just a few years ago. One premise is that due to market imperfections, competition in health care does not work to contain costs and ensure quality. The other premise is that the antitrust laws are unable to deal with markets, such as health care, that do not resemble perfect competition. In my view, however, the record of antitrust enforcement in the health care field shows that competition is important to containing costs and ensuring quality, and that antitrust enforcement is able to prevent harmful conduct without interfering with joint conduct that is truly justified.⁷⁴

⁷³ See, e.g., Statement of the Federal Trade Commission before the Subcommittee on Consumer Protection, Product Safety, and Insurance, Committee on Commerce, Science & Transportation, United States Senate (July 16, 2009), https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-importance-competition-and-antitrust-enforcement-lower/090716healthcaretestimony.pdf.

⁷⁴ Janet D. Steiger, Chairman, *Health Care Antitrust Enforcement Issues*, Remarks before The Health Trustee Institute (Nov. 9, 1995), <https://www.ftc.gov/public-statements/1995/11/health-care-antitrust-enforcement-issues>.