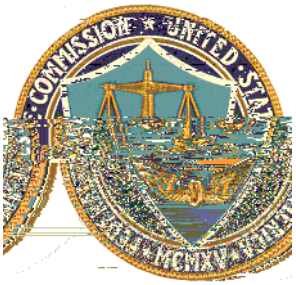
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models, and trends in provider consolidation.[9] We study emerging trends,[10] advocate for the adoption of healthcare policies that rely on competition as much as possible,[11] and investigate potential law violations.[12] From this continual cycle of learning and enforcement—or investment and consumption—we are in a position to provide guidance to courts, policymakers, and businesses whenever appropriate and 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 for deterring 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 $145 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.

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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.
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> Pharmaceutical firms should now be on notice, however, that arrangements comparable to those addressed in the present consent orders can raise serious-10(y)10(a)4(nc

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 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]

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 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

wrongfully listed that patent in the Orange Book in order to maintain its monopoly in the antihypertension drug Tiazac. Biovial 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 and Par Pharmaceutical, Inc. with

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

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 adrenocorticotropic 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

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]

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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 buff 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

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

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. 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.

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 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 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.

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[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

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 high 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 9–20%—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 T

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 collaboration 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, and 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