The FTC: A Framework for Promoting Competition and Protecting Consumers

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Introduction

Over the course of the last 100 years, the Federal Trade Commission ("FTC" or "Commission") has successfully tackled complex and often politically charged economic issues by elevating reason over rhetoric and consensus over contention. It has a history of bipartisan and effective action that promotes competition and protects consumers. In my view, much of its success is a product of the way the agency was designed by its Progressive Era founders.

North Carolina State Board of Dental Examiners v. FTC[1] is a good recent illustration. In that case, the Commission defended its view that professional licensing bodies comprised of market participants cannot shield their activities from antitrust scrutiny using the state-action doctrine in the absence of active state supervision.[2]

The editorial boards of the *New York Times* and *Wall Street Journal*, which typically agree on little, both supported the FTC's position while the matter was pending before the Supreme Court. The *Times*

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* Chairwoman of the Federal Trade Commission. This Essay is adapted from the opening address Chairwoman Ramirez delivered at *The George Washington Law Review* Symposium, *The FTC at 100*, held on November 8, 2014. The views expressed here are her own and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner. Chairwoman Ramirez is grateful to Jon Nathan, Liz Hilder, and Kelly Signs for their assistance in preparing this Essay.

1 N.C. State Bd. of Dental Examiners v. FTC (*North Carolina Dental*), 135 S. Ct. 1101 (2015).

2 *Id.* at 1108–09.

concluded that, while "[s]tates have the right to regulate competition in the public interest . . . they cannot blindly outsource that responsibility to professionals who stand to benefit from such restrictions."[3] The *Wall Street Journal* credited the FTC with being on "the right side" and urged the Supreme Court "to pull the dentists' rules against competition."[4] Ultimately, the Supreme Court also sided with the FTC, noting that, without neutral supervision, there is always a risk that market participants serving on state licensing boards will confuse their own interests with the policy goals of the state.[5]

The two newspapers also endorsed the FTC's decision in 2012 not to challenge Express Script, Inc.'s acquisition of Medco Health Solutions, a transaction that combined two of the country's largest pharmacy benefit managers.[6] The *Wall Street Journal* hailed the FTC's approval of the deal as "a win for competition and consumer choice,"[7] while the *New York Times* declared that it was "persuaded that the commissioners made the right choice."[8]

Matters like *North Carolina Dental* and *Express Scripts/Medco* show the FTC at its best: an agency engaging in thorough, fact-intensive antitrust investigations and making decisions backed by sound factual, legal, and economic analysis that benefit competition and consumers. At the FTC, results like these are the rule, not the exception.

This Essay focuses on certain core features of the FTC that have contributed significantly to its consistent and successful pursuit of the agency's dual mission to promote competition and protect consumers: the FTC's institutional structure and the variety of tools it has at its disposal. In particular, I will highlight the agency's role as an expert administrative body and the importance of the agency's combination of enforcement, research, and advocacy work. To illustrate how these attributes have helped the FTC achieve its mission, I present as a case study one of the agency's longest-running campaigns—its fight against unlawful reverse payment patent settlements.

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3 Editorial, *The White Teeth Monopoly*, N.Y. TIMES, Oct. 18, 2014, at A22.

4 Editorial, *Smile and Say Price-Fixing*, WALL ST. J., Oct. 14, 2014, at A14.

5 *North Carolina Dental*, 135 S. Ct. at 1114.

6 Press Release, Fed. Trade Comm'n, *FTC Closes Eight-Month Investigation of Express Scripts, Inc.'s Proposed Acquisition of Pharmacy Benefits Manager Medco Health Solutions, Inc.* (Apr. 2, 2012), https://www.ftc.gov/news-events/press-releases/2012/04/ftc-closes-eight-month-investigation-express-scripts-incs.

7 Editorial, *Antitrust Enlightenment*, WALL ST. J., Apr. 3, 2012, at A14.

8 Editorial, *Costs, Benefits and Your Drug Plan*, N.Y. TIMES, Apr. 5, 2012, at A22.

I. Core FTC Strengths

A. *Institutional Design*

The FTC was the product of a distinct moment in our nation's history. At the turn of the twentieth century, the United States was struggling to overcome major financial shocks and the impact of rapid industrialization.[9] The public was losing faith in government's ability to respond to the economic and social challenges of the time.

By 1914, however, Progressive movement leaders had begun to develop and put in place a public policy framework based on the dispassionate decisions of experts in the new social sciences.[10] The FTC's founders, very much a part of this movement, sought to create an independent agency that could rise above the political fray by applying its expertise to economic markets to ensure they worked for the benefit of consumers.[11] As Justice Sutherland wrote in *Humphrey's Executor v. United States*,[12] the aim was for the FTC to "exercise the trained judgment of a body of experts" when "dealing with these special questions concerning industry that comes from experience."[13]

To do this, the FTC was vested with both administrative and prosecutorial functions. President Wilson, Justice Brandeis, and Congress shared a vision of an expert administrative agency capable of both investigating and analyzing markets, and adjudicating cases in order to shape antitrust doctrine and policy.[14] At the same time, however, they sought to imbue the product of the agency's administrative process with the credibility and precedential effect of judicial oversight by the federal appellate courts.[15]

Judicial supervision cabins the FTC's lawmaking and policymaking within the bounds of our common-law tradition. But it also leaves room for the FTC to bring its expertise to bear on novel issues of antitrust and consumer protection law. The sheer number of FTC cases taken up by the Supreme Court over the last twenty-five years, including three in the last three terms alone, shows that the agency regularly addresses significant and often unsettled questions of law

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9 *See, e.g.*, Richard Hofstadter, The Progressive Movement: 1900-1915 2 (1963).

10 *Cf.* Walter Lippmann, Drift and Mastery: An Attempt to Diagnose the Current Unrest 42, 62 (1914).

11 *See* Marc Winerman, *The Origins of the FTC: Concentration, Cooperation, Control, and Competition*, 71 Antitrust L. J. 1, 1–6 (2003).

12 Humphrey's Ex'r v. United States, 295 U.S. 602 (1935).

13 *Id.* at 624 (quoting Ill. Cent. R.R. v. Interstate Commerce Comm'n., 206 U.S. 441, 454 (1907); S. Rep. No. 63-597, at 10–11 (1914)).

14 *See generally* Winerman, *supra* note 11, at 32–92.

15 *See id.* at 90–91.

meriting the Court's time and attention.[16] We have often seen the FTC incorporate into its decisions new ideas and modes of analysis that have yet to be accepted widely by courts.

Examples include the novel merger policy issues addressed by the Commission in *Chicago Bridge & Iron*,[17] *Polypore*,[18] and *ProMedica*,[19] as well as the application of the truncated or "quick look" rule of reason analysis in *Polygram*,[20] *North Texas Specialty Physicians*,[21] and *RealComp*,[22] in which the Commission concluded that the conduct at issue was "inherently suspect." Although the courts of appeal in each of these cases affirmed and adopted the FTC's analysis, federal district courts might well have been reluctant to apply novel approaches had the courts ruled in the first instance given their institutional preference for precedent. As an expert body, the FTC is well positioned to advance antitrust doctrine provided its reasoning and conclusions are backed by rigorous analysis and grounded in the administrative record.

Another institutional feature that has proven important to the agency's success is the FTC's governing structure—a five-member bipartisan commission serving seven-year staggered terms.[23] The FTC's architects believed that decisions made by consensus through a collective body, rather than by a single agency head, would make for better

16 N.C. State Bd. of Dental Examiners v. FTC, 135 S. Ct. 1101 (2015); FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013); FTC v. Phoebe Putney Health Sys., Inc., 133 S. Ct. 1003 (2013); Cal. Dental Ass'n v. FTC, 526 U.S. 756 (1999); FTC v. Ticor Title Ins. Co., 504 U.S. 621 (1992); FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990).

17 Opinion of the Commission, Chi. Bridge & Iron Co., FTC Docket No. 9300 (Jan. 6, 2005), http://www.ftc.gov/sites/default/files/documents/cases/2005/01/050106opionpublicrecordversion9300_0.pdf (addressing scope of relief in consummated merger), *aff'd*, Chi. Bridge & Iron Co. v. FTC, 534 F.3d 410 (5th Cir. 2008).

18 Opinion of the Commission, Polypore Int'l, Inc., FTC Docket No. 9327 (Dec. 13, 2010), http://www.ftc.gov/sites/default/files/documents/cases/2010/12/101213polyporeopinion.pdf (addressing issues of potential competition), *aff'd*, 686 F.3d 1208 (11th Cir. 2012).

19 Opinion of the Commission, ProMedica Health Sys., Inc., FTC Docket No. 9346 (June 25, 2012), https://www.ftc.gov/sites/default/files/documents/cases/2012/06/120625promedicaopinion.pdf (discussing "cluster markets"), *aff'd*, 749 F.3d 559 (6th Cir. 2014), *cert. denied*, 135 S. Ct. 2049 (2015).

20 Opinion of the Commission, Polygram Holding, Inc., FTC Docket No. 9298 (July 28, 2003), https://www.ftc.gov/sites/default/files/documents/cases/2003/07/polygramopinion.pdf, *aff'd*, 416 F.3d 29 (D.C. Cir. 2005).

21 Opinion of the Commission, N. Tex. Specialty Physicians, FTC Docket No. 9312 (Dec. 1, 2005), https://www.ftc.gov/sites/default/files/documents/cases/2005/12/051201opinion.pdf, *aff'd*, 528 F.3d 346 (5th Cir. 2008).

22 Opinion of the Commission, Realcomp II, Ltd., FTC Docket No. 9320 (Nov. 2, 2009), https://www.ftc.gov/sites/default/files/documents/cases/2009/11/091102realcompopinion.pdf, *aff'd*, 635 F.3d 815 (6th Cir. 2011).

23 15 U.S.C. § 41 (2012).

policy. Significant social science research today supports the view that collective decisionmaking has certain important benefits, especially when it comes to resolving complex matters requiring predictive analysis.[24]

Five independent decisionmakers, with a diversity of views and experiences, help ensure that the main issues in FTC matters are fully explored and weaknesses fully debated. It reduces the likelihood that key questions are overlooked, or that action is taken or avoided for any reason other than the public interest. It also imposes analytical discipline on the agency as whole. Staff recommendations to the Commission require thorough, rational arguments based on compelling facts and strong legal analysis that will withstand deliberative scrutiny from a variety of angles. The Commission in turn must reach a consensus decision of at least a majority of commissioners to authorize, or forbear from, action.

This process forces the agency to grapple with a wide spectrum of arguments and develop responses during the investigation phase rather than confronting them for the first time in litigation. In addition to preparing the agency for the rigors of litigation, this iterative process also produces well-informed decisions.

Further, the staggered, seven-year terms for commissioners provide institutional stability that leads to continuity of policy and the tempering of swings in priorities across administrations. This structure fosters consistency and allows the agency to make investments in research and analysis with respect to specific issues and industries over time. That in turn contributes to the development and implementation of long-term strategies for confronting anticompetitive harms.[25]

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24 *See, e.g.*, Stephen M. Bainbridge, *Why a Board? Group Decisionmaking in Corporate Governance*, 55 VAND. L. REV. 1, 54 (2002); Alan S. Blinder & John Morgan, *Are Two Heads Better Than One?: An Experimental Analysis of Group vs. Individual Decisionmaking* 47 (Nat'l Bureau of Econ. Research, Working Paper No. 7909, 2000), http://www.nber.org/papers/w7909.pdf.

25 For example, the Commission has focused on the proper application of the state action doctrine for years, including issuing a report on the subject in 2003. *See* FED. TRADE COMM'N, OFFICE OF POLICY PLANNING, REPORT OF THE STATE ACTION TASK FORCE (2003), http://www.ftc.gov/sites/default/files/documents/advocacy_documents/report-state-action-task-force/stateactionreport.pdf. On the enforcement front, in addition to the recently decided *North Carolina Dental* case, the Commission also prevailed before the Supreme Court in *FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003 (2013). In that case, a unanimous Court ruled that the granting of general corporate powers to government entities under state law does not provide blanket immunity from the antitrust laws. *Id.* at 1011–12.

Perhaps the strongest evidence of the benefits of the agency's expertise and intensive deliberative process is the agency's administrative appellate record. Over the last two decades, appellate courts have affirmed ten out of thirteen Commission administrative competition decisions.[26] That number increases to eleven wins out of thirteen cases once one considers that the Commission's 2003 ruling in *Schering-Plough*, reversed by the Eleventh Circuit in 2005,[27] was ultimately vindicated by the Supreme Court's 2013 decision in *FTC v. Actavis*.[28] In *Actavis*, the Supreme Court agreed with the principles set forth by the Commission in *Schering-Plough*, holding that reverse payment patent settlements are subject to antitrust scrutiny even if they fall within the scope of the patent.[29]

It is an impressive record, particularly given that many of those opinions have involved novel questions of law on which the Commission is given no deference,[30] as well as the fact that respondents have the ability to choose the most favorable appellate forum.[31] This record affirms the virtues of the FTC's role as an expert arbiter of anticompetitive mergers and business practices in an administrative setting.[32]

B. Agency Tools

The advantages of the FTC's institutional structure are complemented by the unique combination of tools the agency employs.

As shown by the cases addressed above, law enforcement functions as the core of the FTC's dual mission to protect consumers and maintain competition. The agency has two enforcement bureaus dedi-

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26 Only three Commission decisions have been reversed in the last twenty years. *See* Rambus, Inc. v. FTC, 522 F.3d 456, 466–67 (D.C. Cir. 2008); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1073–76 (11th Cir. 2005); Cal. Dental Ass'n v. FTC, 224 F.3d 942, 957–58 (9th Cir. 2000). As noted above, see *supra* note 21, the only aspect of the Commission's opinion in *North Texas Specialty Physicians* that was reversed and remanded concerned the issue of appropriate relief. *See* N. Tex. Specialty Physicians v. FTC, 528 F.3d 346, 352 (5th Cir. 2008).

27 *Schering-Plough*, 402 F.3d at 1073–76.

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

29 *Id.* at 2234–37.

30 *See, e.g.*, Chi. Bridge & Iron Co. v. FTC, 534 F.3d 410, 422 (5th Cir. 2008) ("We review de novo all legal questions pertaining to Commission orders.").

31 The FTC Act authorizes respondents to appeal Commission orders to any regional court of appeals where the challenged method of competition was used or where the respondent would otherwise be subject to personal jurisdiction. 15 U.S.C. § 45(c) (2012).

32 *See, e.g.*, ProMedica Health Sys., Inc. v. FTC, 749 F.3d 559,573 (6th Cir. 2014) (affirming the Commission's determination that a proposed hospital merger in Toledo, Ohio was anticompetitive and praising its analysis as "comprehensive, carefully reasoned, and supported by substantial evidence in the record").

cated to carrying out this mission. In 2014, for instance, the agency brought 130 consumer protection and 25 competition enforcement actions.[33]

But while they may garner fewer headlines, the FTC's other tools also play a crucial role in cementing the agency's continuing relevance and impact on the daily lives of consumers. The agency's research efforts include more formal studies facilitated by its ability to compel the production of information under Section 6(b) of the FTC Act as well as workshops.[34] These efforts help ensure that the Commission has the data and information needed to track market developments and chart future priorities. They also allow the agency to play an active role in the development of relevant legal standards and policies.

To give a recent example, in 2014, the FTC conducted a workshop examining emerging competition issues involving the introduction of biosimilars and interchangeable biologic drugs.[35] We convened relevant experts and interested parties, including consumer groups, academics, pharmacists, health insurers, and biosimilar and biologics companies, to explore various issues, among them how naming conventions may affect the development of biosimilar competition.[36] Based in part on the information obtained through this workshop, the FTC has urged the development of policies that protect patient health and safety, but without unnecessarily chilling competition and deterring investment in follow-on biologics.[37]

Another example is the FTC's 2003 report on balancing competition policy and patent law and policy.[38] This report resulted from a

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33 *Stats & Data 2014*, FED. TRADE COMM'N, https://www.ftc.gov/annual-highlights-2014/stats-data-2014 (last visited Oct. 6, 2015).

34 15 U.S.C. § 46(b) (2012).

35 Press Release, Fed. Trade Comm'n, *FTC to Host Workshop on the Competitive Impacts of State Regulations and Naming Conventions Concerning Follow-on Biologics* (Nov. 8, 2013), https://www.ftc.gov/news-events/press-releases/2013/11/ftc-host-workshop-competitive-impacts-state-regulations-naming.

36 FED. TRADE COMM'N, FOLLOW-ON BIOLOGICS WORKSHOP 12 (2014) (opening remarks of Chairwoman Edith Ramirez), https://www.ftc.gov/system/files/documents/public_events/171301/140204biologicstranscript.pdf.

37 FTC Staff Comment to the Food & Drug Admin. In Response to a Request for Comments on Its Guidance for Industry on the "Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability," (Oct. 27, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-submitted-food-drug-administration-response-fdas-request-comments-its-guidance/151028fdabiosimilar.pdf.

38 FED. TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003) [hereinafter TO PROMOTE INNOVATION], https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf.

series of hearings that the agency held in 2002 and 2003 to study patent quality and its impact on competition in our knowledge-based economy.[39] Although the report's recommendations focused on suggested changes to patent law, rather than antitrust law,[40] it has been widely influential.[41] More recently, in 2011, the FTC issued a report examining patent notice and remedies.[42]

Research has also improved the agency's own performance. In 1999, the FTC conducted a remedy study to evaluate the effectiveness of Commission-ordered divestitures and understand why certain divestitures had not achieved their remedial objectives.[43] Drawing on information gathered during the study, the FTC adopted a number of changes to its divestiture policies that have proven effective in maintaining competition in affected markets.[44] The agency is currently engaged in a follow-up and more expanded remedy study.[45]

Another example of the role of research in improving agency outcomes is the FTC's hospital merger retrospective project, announced in 2002,[46] which made significant contributions to the agency's enforcement efforts in healthcare provider markets. Those efforts, which included retrospective studies of several hospital mergers as well as a series of workshops focusing on healthcare markets, led to a shift in the FTC's litigation approach to hospital mergers.[47] The new approach led to a winning streak that now includes four successfully litigated merger challenges[48] and a growing number of transactions

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39 *See id.* at 3–4.

40 *See id.* at 7–18.

41 *See, e.g.*, Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2252 n.11 (2011) (citing TO PROMOTE INNOVATION, *supra* note 38); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 134 (2006) (Breyer, J., dissenting) (same); eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396 (2006) (Kennedy, J., concurring) (same).

42 FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION (2011), https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf.

43 BUREAU OF COMPETITION, FED. TRADE COMM'N, A STUDY OF THE COMMISSION'S DIVESTITURE PROCESS (1999), https://www.ftc.gov/sites/default/files/documents/reports/study-commissions-divestiture-process/divestiture_0.pdf.

44 *Id.* at iv–v.

45 Notice and Request for Comment, Agency Information Collection Activities, 80 Fed. Reg. 34,415, 34,416–18 (June 16, 2015).

46 For a general discussion of the FTC's hospital merger retrospective efforts, see Joseph Farrell et. al., *Economics at the FTC: Retrospective Merger Analysis with a Focus on Hospitals*, 35 REV. INDUS. ORG. 369 (2009).

47 *See id.* at 373–76.

48 *See* ProMedica Health Sys., Inc. v. FTC, 749 F.3d 559, 573 (6th Cir. 2014); St. Alphonsus Med. Ctr.-Nampa, Inc. v. St. Luke's Health Sys., Ltd., Nos. 1:12-CV-00560-BLW, 1:13-CV-00116-

abandoned after the FTC raised competitive concerns and had either decided to challenge or was close to doing so.[49] In light of the significant costs of health care and strong evidence that hospital consolidation can lead to higher prices without corresponding quality improvements,[50] the FTC's recent success in blocking anticompetitive hospital mergers has provided significant benefits to consumers.

The FTC's advocacy efforts—aimed at Congress, state legislatures, state and federal policymakers, and courts—also complement our law enforcement and other policy work.[51] Advocacy can be especially effective in helping to address government restraints, which are often imposed for reasons unrelated to competition and without due consideration for their impact on consumers. For instance, the FTC has been active in encouraging the removal of unnecessary scope of practice restrictions that prevent healthcare professionals from being able to take full advantage of their training and expertise.[52] Through these efforts, the FTC seeks to enhance competition, expand access to qualified providers, and encourage new, innovative models of care.

Filing amicus briefs in private litigation is another common route for the Commission to share its experience and expertise where it may prove helpful.[53] One notable example of this form of advocacy is the amicus brief the FTC submitted in *Leegin Creative Leather Products v.*

BLW, 2014 WL 407446, at *1–2 (D. Idaho Jan. 24, 2014), *aff'd*, 778 F.3d 775 (9th Cir. 2015); FTC v. OSF Healthcare Sys., 852 F. Supp. 2d 1069, 1071 (N.D. Ill. 2012) (transaction abandoned following grant of preliminary injunction); Opinion of the Commission Evanston Nw. Healthcare Corp., FTC Docket No. 9315, (Aug. 6, 2007), https://www.ftc.gov/sites/default/files/documents/cases/2007/08/070806opinion.pdf.

49 *See, e.g.*, Order Dismissing Complaint, Reading Health Sys., FTC Docket No. 9353 (Dec. 7, 2012), https://www.ftc.gov/sites/default/files/documents/cases/2012/12/121207readingsircmpt.pdf; Order Dismissing Complaint, Inova Health Sys. Found., FTC Docket No. 9326 (June 17, 2008 https://www.ftc.gov/sites/default/files/documents/cases/2008/06/080617orderdismisscmpt.pdf.

50 *See, e.g.*, Eduardo Porter, *Health Care's Overlooked Cost Factor*, N.Y. TIMES, June 12, 2013, at B1; MARTIN GAYNOR & ROBERT TOWN, ROBERT WOOD JOHNSON FOUND., THE SYNTHESIS PROJECT: THE IMPACT OF HOSPITAL CONSOLIDATION—UPDATE (2012), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261.

51 *See* Tara Isa Koslov, Fed. Trade Comm'n, *Competition Advocacy at the Federal Trade Commission: Recent Developments Build on Past Successes*, CPI ANTITRUST CHRON., Aug. 2012, at 2, 4–6, https://www.competitionpolicyinternational.com/competition-advocacy-at-the-federal-trade-commission-recent-developments-build-on-past-successes. FTC advocacy efforts are identified at the following link: http://www.ftc.gov/policy/advocacy.

52 *See, e.g.*, FED. TRADE COMM'N STAFF, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES 3–4 (2014), http://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf.

53 FTC amicus briefs are available at *Amicus Briefs*, FED. TRADE COMMISSION, http://www.ftc.gov/policy/advocacy/amicus-briefs (last visited Oct. 6, 2015).

PSKS.[54] Faced with the weighty decision about whether to overturn *Dr. Miles* and the per se rule against vertical price restraints, the Court took comfort in the fact that both the FTC and the Department of Justice ("DOJ")—"the antitrust enforcement agencies with the ability to assess the long-term impacts of resale price maintenance—ha[d] recommended that [it] replace the per se rule with the traditional rule of reason."[55]

II. The FTC's Efforts to Combat unlawful Reverse-Payment Patent Settlements

An FTC effort in which the institutional design and tools I have just discussed have proven key is the Commission's long-running fight against unlawful reverse payment patent settlements in the pharmaceutical industry (referred to colloquially as "pay-for-delay" agreements).

The Supreme Court's *Actavis* ruling, in which the Court overturned the so-called "scope-of-the-patent" test and held that pay-for-delay patent settlements are subject to antitrust scrutiny,[56] was a significant victory for consumers and a vindication of basic antitrust principles. But the road to *Actavis* began decades ago for the FTC. It involved a long-term effort consisting not only of enforcement, but also of extensive research, advocacy, interagency collaboration, and engagement from the Bureaus of Competition, Consumer Protection, and Economics. *Actavis* is a story that showcases the many strengths of the FTC and its ability to use its broad expertise and unique authority to drive real change for the benefit of competition and consumers.

The FTC's efforts to address concerns about impediments to generic competition began the way that many important FTC initiatives do—with research. In the mid-1970s, the Commission tasked the staff of the Bureau of Consumer Protection with a series of industry-wide studies of emerging issues in the distribution of pharmaceuticals.[57] One of the studies examined state "anti-substitution" laws, which prevented pharmacists from dispensing a lower-cost generic drug unless a physician specifically prescribed the drug by its nonproprietary

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54 Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877 (2007); Brief for the United States as Amici Curiae Supporting Petitioner, Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877 (2007) (No. 06-480), 2007 WL 173650.

55 *Leegin*, 551 U.S. at 900.

56 FTC v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013).

57 Health Care Div., Bureau of Competition, Fed. Trade Comm'n, Overview of FTC Antitrust Actions in Pharmaceutical Services and Products 1 (2013), https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/rxupdate.pdf.

name.[58] Another study led to a model state law, developed by the FTC in cooperation with the FDA, to help states reform their regulations to promote competition and facilitate consumer access to lower-cost generic drugs.[59] Today, laws permitting pharmacists to substitute generics, many of which were modeled on the FTC template, exist in every state and help consumers save millions on their medications.[60]

In 1984, Congress passed the Hatch-Waxman Act,[61] which established an abbreviated regulatory pathway for generic drugs to enter the market.[62] By the late 1990s, however, there were indications that aspects of this regulatory framework—the promise of 180 days of market exclusivity for the first patent challenger,[63] for example—could also be used to prevent or impede generic competition.[64]

At that time, the FTC began to observe that brand-name drug firms, guided by judicial interpretations of the Hatch-Waxman market exclusivity provisions, were paying generic competitors to settle their patent challenges and defer generic entry.[65] Supported by staff research showing the clear benefits of generic competition, the FTC responded by opening a number of law enforcement investigations.

Using its authority under Section 6(b), the FTC also completed another industry-wide study to examine whether certain features of the Hatch-Waxman framework facilitated strategies to delay generic

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58 BUREAU OF CONSUMER PROTECTION, FED. TRADE COMM'N, DRUG PRODUCT SELECTION 1–2 (1979).

59 *See* ALISON MASSON & ROBERT L. STEINER, BUREAU OF ECONOMICS, FTC, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 219–21 (1985) ("The FTC/FDA Model State Act"), http://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf.

60 *See* OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS 3, app. A (2010), http://aspe.hhs.gov/sites/default/files/pdf/76151/ib.pdf.

61 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355, 35 U.S.C. §§ 156, 271(e)(1) (2012)).

62 *See id.* at sec. 101, § 505, 98 Stat. 1585–92.

63 35 U.S.C. § 156(d)(2)(B)(i).

64 In April 1998, two federal appellate courts invalidated an FDA regulation that limited the award of 180-day exclusivity to first filers that successfully defended a patent infringement suit. Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066–74 (D.C. Cir. 1998); Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL 153410, at *6–7 (4th Cir. Apr. 3, 1998). In defending its rule, the FDA noted the risk under the statute that "the first applicant colludes with the pioneer drug company to eliminate generic competition." *Mova Pharm.*, 140 F.3d at 1067.

65 FED. TRADE COMM'N, GENETIC DRUG ENTRY PRIOR TO PATENT EXPIRATION vi–vii (2002) [hereinafter GENETIC DRUG ENTRY], https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

competition.[66] It would be hard to overstate the impact of the FTC's empirical findings and the recommendations contained in the resulting report. Perhaps most significantly, Congress adopted reforms to the Hatch-Waxman framework in 2003 with the Medicare Modernization Act based on FTC recommendations.[67] One central reform was the requirement that drug companies file various types of agreements, including settlements between brands and generics, with the FTC and DOJ,[68] thereby enabling the examination of agreements that might otherwise escape review. This notification program provides the FTC with a unique source of data on the nature and extent of brand-generic patent settlements, which has proven to be instrumental in monitoring the evolution of reverse payment patent settlement agreements.[69]

In March 2000, the FTC filed its first two pay-for-delay cases: a proposed administrative consent agreement involving Abbott's brand name hypertension and prostate drug, Hytrin,[70] and an administrative complaint involving Cardizem CD.[71] The proposed settlement provided immediate guidance to the drug industry and the antitrust bar, as well as an opportunity for public comment. Meanwhile, the administrative action afforded the Commission an opportunity to consider the relevant competition issues in the context of an extensive factual record developed during an administrative proceeding. This action was ultimately resolved with a consent order.[72]

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66 *See* GENETIC DRUG ENTRY, *supra*, note 65, at 1–3.

67 Medicare Prescription Drug, Improvement, and Modernization Act § 1112, Pub. L. No 108-173, 117 Stat. 2066, 2461–63 (2003) (codified in scattered sections of 21 U.S.C., 26 U.S.C., & 42 U.S.C.).

68 *See id*.

69 *See, e.g.*, 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 FISCAL YEAR 2013 1–2 (2014) [hereinafter PAY FOR DELAY REPORT 2013], https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf.

70 *See* Decision and Order, Abbott Labs., FTC Docket No. C-3945 (May 22, 2000), https://www.ftc.gov/sites/default/files/documents/cases/2000/05/c3945.do_.htm; *see also* Complaint, Abbott Labs., FTC Docket No. C-3945 (Mar. 16, 2000), https://www.ftc.gov/sites/default/files/documents/cases/2000/05/c3945complaint.htm.

71 *See* Complaint, Hoechst Marion Roussel, Inc., FTC Docket No. 9293 (Mar. 16, 2000), http://www.ftc.gov/sites/default/files/documents/cases/2000/03/hoechstandrxcomplaint.htm.

72 *See* Decision and Order, Hoechst AG, FTC Docket No. 9293 (May 11, 2001), https://www.ftc.gov/sites/default/files/documents/cases/1999/12/hoechst.do_.htm.

In 2001, the FTC filed an administrative complaint against brand manufacturer Schering-Plough and two generics.[73] Following an administrative hearing, the Commission concluded Schering-Plough had entered into an unlawful reverse payment settlement agreement.[74] That determination, which was appealed by Schering-Plough to the Eleventh Circuit, became the first FTC pay-for-delay case to be considered by a federal court.

In 2005, the Eleventh Circuit reversed the Commission decision,[75] dealing the FTC the first of several setbacks on the pay-for-delay battlefront. The Eleventh Circuit adopted the so-called scope-of-the-patent test,[76] effectively immunizing pay-for-delay deals from antitrust scrutiny.[77] The Second Circuit and the Federal Circuit followed suit soon after.[78] All told, the Supreme Court denied certiorari three times in the late 2000s leaving in place appellate rulings that disfavored the FTC position.[79] As the defeats mounted, internally, senior Commission officials took to quoting the classic rallying cry often cited when facing near impossible odds—the St. Crispin's Day speech from Shakespeare's *Henry V*.[80]

Following the Eleventh Circuit's ruling in *Schering-Plough*, reverse payment patent settlements increased dramatically.[81] The FTC, with the unanimous support of all Commissioners—Republicans, Democrats, and Independents alike—redoubled its efforts on three fronts. The agency first went back to the data. Drawing from the pool of patent settlement agreements filed with the antitrust agencies, the FTC published details about the proliferation of reverse payment pat-

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73 *See* Complaint, Schering-Plough Corp., FTC Docket No. 9297 (Mar. 30, 2001), http://www.ftc.gov/sites/default/files/documents/cases/2001/04/scheringpart3cmp_0.pdf.

74 Opinion of the Commission, Schering-Plough Corp., FTC Docket No. 9297, at 86–87 (Dec. 18, 2003), http://www.ftc.gov/sites/default/files/documents/cases/2003/12/031218commissionopinion.pdf.

75 Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076–77 (11th Cir. 2005).

76 *Id.* at 1066.

77 Michael A. Carrier, *Why the "Scope of the Patent" Test Cannot Solve the Drug Patent Settlement Problem*, 16 STAN. TECH. L. REV. 1, 5–8(2012).

78 *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008), *abrogated by* FTC v. Actavis, 133 S. Ct. 2223 (2013); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212–13 (2d Cir. 2006), *abrogated by* FTC v. Actavis, 133 S. Ct. 2223 (2013).

79 Ark. Carpenters Health & Welfare Fund v. Bayer AG, 557 U.S. 920 (2009), *denying cert. to* 544 F.3d 1323 (Fed. Cir. 2008); Joblove v. Barr Labs, Inc., 551 U.S. 1144 (2007), *denying cert. to* 466 F.3d 187 (2d Cir. 2006); FTC v. Schering-Plough Corp., 548 U.S. 919 (2006), *denying cert. to* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005).

80 WILLIAM SHAKESPEARE, HENRY V act 4, sc. 3 ("We few, we happy few, we band of brothers . . . .").

81 *See* PAY FOR DELAY REPORT 2013, supra note 69, at 4.

ent deals.[82] In addition, FTC economists examined a range of data and calculated that these payments led to billions of dollars a year in higher prescription drug costs.[83]

The FTC also identified other relevant agreements for investigation and potential enforcement action. In 2008, the FTC filed a federal lawsuit against Cephalon alleging that it had entered into agreements to prevent generic competition to its leading product, Provigil.[84] In 2009, the FTC challenged two patent settlements involving the testosterone replacement drug AndroGel in the federal district court lawsuit that eventually went up to the Supreme Court.[85]

Finally, the FTC turned to advocacy. It publicized its findings about the extent of the pay-for-delay problem.[86] The agency testified before Congress about its research and enforcement efforts, advocating for federal legislation to protect consumers from anticompetitive reverse payment patent settlements.[87] The FTC also continued to file amicus briefs in private actions to explain to courts why pay-for-delay settlements are anticompetitive, urging the application of traditional antitrust standards.[88] This effort eventually bore fruit in 2012 when the Third Circuit rejected the scope-of-the-patent test in *In re K-Dur*

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82 *Id.*

83 FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 5–6 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (estimating consumer harm at $35 billion over a ten-year period).

84 Complaint at 1–2, FTC v. Cephalon, Inc., No. 2:08-cv-2141 (D.D.C. 2008), https://www.ftc.gov/sites/default/files/documents/cases/2008/02/080213complaint.pdf. The FTC recently settled its litigation against Cephalon and its parent Teva Pharmaceutical Industries, Ltd. for a payment of $1.2 billion, as well as significant injunctive relief. Press Release, Fed. Trade Comm'n, *FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics* (May 28, 2015), https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill.

85 Complaint at 2–3, FTC v. Watson Pharm., Inc., 2:090-CV-00598-MRP (PLA) (C.D. Cal. Jan. 27, 2009), 2009 WL 761167.

86 *See, e.g.*, *supra* notes 69, 83.

87 *See, e.g.*, *Pay-for-Delay Deals: Limiting Competition and Costing Consumers: Hearing Before the Subcomm. on Antitrust, Competition Policy & Consumer Rights of the S. Comm. on the Judiciary*, 113th Cong. 5–7 (2013) (statement of Edith Ramirez, Chairwoman, Fed. Trade Comm'n); *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 1–4 (2009) (statement of Richard A. Feinstein, Director, Bureau of Competition, Fed. Trade Comm'n).

88 *See, e.g.*, Brief of the Fed. Trade Comm'n as Amicus Curiae Supporting Appellants and Urging Reversal, *In re* K-Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012), 2011 WL 2115235.

Antitrust Litigation.[89] That ruling, which interestingly involved the same agreements that the Commission had unsuccessfully challenged in 2001 in *Schering-Plough*, set the stage for Supreme Court review and eventual FTC victory in *Actavis*.

Despite the success in *Actavis*, the FTC's effort to combat illegal reverse payments is not over. The agency continues to litigate on multiple fronts. In fact, the Commission filed its most recent pay-for-delay case in September 2014.[90] But this long-term effort highlights how the agency can use its expertise and unique authority effectively, sometimes over the course of decades, in an effort to stop anticompetitive conduct that causes substantial consumer harm. It is an important example to revisit as one examines the agency's accomplishments and the role it can play in the future.

Conclusion

The FTC's founders wisely designed an agency that would operate in accordance with principles of bipartisan consensus, rational analysis, careful research, and thoughtful enforcement and advocacy. The FTC has adhered to those principles, remaining useful and relevant for 100 years—even as the U.S. economy has undergone successive and dramatic transformations. I believe continued adherence to these principles will keep the FTC useful and relevant in its next century.

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89 *In re* K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), *vacated sub nom.* Upsher-Smith Labs, Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013) (mem.) (remanded for further consideration in light of *Actavis*).

90 Complaint, FTC v. AbbVie, Inc., No. 14–5151, (E.D. Pa. Sept. 16, 2014), 2015 WL 2114380.