

Fostering Biologic Competition
(opening remarks as prepared for delivery*)

Remarks of Joe Simons
Chairman
March 9, 2020

Good morning. Please allow me to join Commissioner Hahn in welcoming you all today. Let me begin with a few thank you's. This workshop is part of the decades-long collaboration between the Federal Trade Commission and the Food & Drug Administration to promote competitive markets for pharmaceuticals. Today, our focus is on biologics markets and what can be done to spark competition for these innovative new treatments. I would like to thank former FDA Commissioner Scott Gottlieb for initiating this joint agency effort, and Commissioner Hahn for continuing it.

I also would like to thank the FDA for hosting this workshop, and the many FDA and FTC staff who made this workshop happen. An incredible amount of work went into planning and executing this event, and I'm grateful.

Biologics as we all know are innovative new treatments for serious and life-threatening diseases like cancer, diabetes, and Crohn's Disease. Often, biologics are the only effective treatments for these diseases. But biologics can be very expensive—some costing tens of thousands and others costing millions of dollars.¹ Total U.S. spending on biologics is growing rapidly, reaching \$125.5 billion in 2018.²

*As delivered by Tara Isa Koslov, Chief of Staff, Federal Trade Commission

¹ E.g., Christopher Rowland, *The FDA Approves a Gene Therapy that is the Most Expensive Drug in the World*, THE WASHINGTON POST, May 24, 2019, https://www.washingtonpost.com/business/economy/the-fda-approves-a-gene-therapy-that-is-the-most-expensive-drug-in-the-world/2019/05/24/57c66500-7e4a-11e9-8ede-f4abf521ef17_story.html; Danny Hakim, *Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.*, THE NEW YORK TIMES, Jan. 6, 2018, <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>.

² IQVIA, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*, at 26 (May 2019).

I'm going to provide some perspective from the FTC's viewpoint as a competition and consumer protection enforcement agency. As many in this room already know, the FTC has a broad mission to protect consumers and competition by preventing anticompetitive, deceptive, and unfair business practices. Because of the critical role that competition plays in reducing prices and fostering innovation, the FTC has always been interested in promoting competition in pharmaceutical markets.

One way the FTC promotes competition in pharmaceutical markets is by conducting industry studies. More than 40 years ago, for example, the FTC published a report on state laws preventing pharmacists from substituting branded drugs with generics.³ The FTC concluded that these laws imposed substantial unwarranted costs on consumers by unduly restricting price competition between generic and branded drugs.⁴ These findings helped pave the way for state laws that allow automatic substitution of the brand for the generic. Similarly, a 2002 Commission study on generic drug entry recommended that brand-name companies and generic applicants settling patent litigation under the provisions of the Hatch-Waxman Act submit those settlements to the FTC.⁵ This recommendation was incorporated into the Medicare Modernization Act of 2003⁶ and is now the primary means by which the FTC learns about potentially anticompetitive patent settlements between brand and generic drug manufacturers.

³ FTC, Drug Product Selection: Staff Report to the Federal Trade Commission, at 1 (1979), <https://www.ftc.gov/system/files/documents/reports/staff-report-drug-product-selection/790101drugproductrpt.pdf>.

⁴ *Id.*

⁵ FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study, at vi (July 2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

⁶ *E.g.*, Press Release, FTC, Bureau of Competition Issues FY 2005 Summary of Pharmaceutical Company Settlement Agreements (Apr. 24, 2006), <https://www.ftc.gov/news-events/press-releases/2006/04/bureau-competition-issues-fy-2005-summary-pharmaceutical-company>; Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (2003), Pub. L. No. 108-173, 117 Stat. 2066, <https://www.govinfo.gov/content/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf>.

Following the 2018 amendments to the Medicare Modernization Act, the FTC now also obtains and reviews biologic-biosimilar patent settlement agreements.⁷

Another way the FTC promotes competition in pharmaceutical markets is by vigorously combating anticompetitive conduct. The Commission for example has a long record of successful enforcement actions against brand and generic drug manufacturers seeking to game the Hatch-Waxman process by entering into anticompetitive reverse-payment agreements. The agency's victories include a landmark decision by the Supreme Court in *FTC v. Actavis* holding such agreements can create antitrust liability,⁸ favorable interpretations of *Actavis* in other federal courts,⁹ and sweeping settlements that prevent major manufacturers from entering into anticompetitive reverse-payment agreements.¹⁰ Perhaps as a result of these successes, the number of potentially anticompetitive reverse-payment agreements has dropped precipitously.¹¹

The FTC's experience with pharmaceuticals also extends to the biologics industry. In fact, the FTC brought its first enforcement action involving a biologic almost thirty years ago.¹² More recently, the FTC provided technical assistance as Congress developed the abbreviated pathway for biosimilars. In 2008 when Congress was weighing options for an abbreviated pathway, the House Subcommittee on Energy and Commerce requested, and the FTC provided,

⁷ E.g., FTC, Pharmaceutical Agreement Filing Procedures Updated: Modernized with Electronic Filings and Updated for Agreements Related to Biologics (June 6, 2019), <https://www.ftc.gov/news-events/press-releases/2019/06/pharmaceutical-agreement-filing-procedures-updated>; Patient Right to Know Drug Prices Act (2018), Pub. L. No. 115-263, 132 Stat. 3672, <https://www.congress.gov/bill/115th-congress/senate-bill/2554/text>.

⁸ *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

⁹ E.g., *In re AndroGel Antitrust Litig. (No. II)*, MDL Dkt. No. 2084, 2018 WL 2984873 (N.D. Ga. June 14, 2018); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F.Supp.3d 402 (E.D. Pa. 2015).

¹⁰ E.g., Stipulated Order for Permanent Injunction and Equitable Monetary Relief, Dkt. No. 405, *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141 (E.D. Pa. June 17, 2015); Stipulated Order for Permanent Injunction, Dkt. No. 4-2, *FTC v. Endo Pharms, Inc.*, No. 17-cv-00312 (N.D. Ca. Jan. 23, 2017).

¹¹ E.g., Press Release, FTC, FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors (May 23, 2019), <https://www.ftc.gov/news-events/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent>.

¹² Roche Holding Ltd./Genentech, Inc., FTC File No. 901-0072, 55 Fed. Reg. 53,191 (Dec. 27, 1990).

lessons learned from Hatch-Waxman to help structure the new pathway.¹³ And in 2009, the FTC testified before Congress about follow-on biologic drug competition to “inform the . . . debate” on the legislation that became the abbreviated pathway.¹⁴

Competition between reference biologics and biosimilars is just as important as competition between brand and generic small-molecule drugs. Biosimilars, which are as safe and effective as their reference biologics, hold the promise of reducing price and therefore increasing access to these treatments. This is because when given a choice between two highly similar products, well-informed consumers typically choose the less expensive option. This competition, in turn, drives prices down.

But competition only works when consumers have reliable and truthful information. In some instances, statements from reference biologic manufacturers and the groups they fund may mislead patients and physicians into believing the biosimilar is not as safe or as effective as the reference biologic. Such deception might violate both consumer protection and antitrust laws.

Although the Commission generally supports comparative advertising, that advertising must be truthful and not misleading. Advertising creating an impression of clinically meaningful differences between a reference biologic and its biosimilar is likely false or misleading and therefore constitutes an unfair or deceptive practice.

Similarly, from an antitrust perspective, maintaining or growing share by deceiving patients and physicians about competitors’ offerings is not competition on the merits. It also

¹³ Letter from C. Landis Plummer, Acting Sec’y, FTC, to Rep. Pallone (May 2, 2008).

¹⁴ *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, at 1, 111 Cong. (2009) (statement of Comm’r Pamela Jones Harbour, FTC), https://www.ftc.gov/sites/default/files/documents/public_statements/emerging-health-care-issues-follow-biologic-drug-competition/090611fobtestimony.pdf.

erects artificial barriers to entry and creates costs for biosimilar manufacturers to counter the deception. Such deception therefore likely constitutes an unfair method of competition.

The FTC is committed to taking appropriate enforcement action against false or misleading communications involving biologics and biosimilars.

But the FTC's enforcement priorities in this industry extend beyond deceptive conduct. The FTC will also deter behavior that impedes access to samples needed to develop biosimilars. In January of this year, for example, the FTC brought its first case alleging a restrictive distribution scheme that anticompetitively blocked competition for a small-molecule drug.¹⁵ The FTC will also continue to review patent settlement agreements involving biologics and biosimilars for, among other things, anticompetitive reverse-payment agreements.

In closing, I want to reiterate the importance of the more than 65-year history of collaboration between the FTC and the FDA. I believe this collaboration has benefitted American consumers in untold ways, but most concretely by making safe and effective treatments more widely available and at a lower price. I thank the FDA for its critical support of the FTC's investigations and industry studies, and look forward to continuing this legacy of collaboration.

Thank you all for your time this morning. I look forward to a productive and engaging day.

¹⁵ Press Release, FTC, FTC and NY Attorney General Charge Viera Pharmaceuticals, Martin Shkreli, and Other Defendants with Anticompetitive Scheme to Protect a List-Price Increase of More Than 4,000 Percent for Life-Saving Drug Daraprim (Jan. 27, 2020), <https://www.ftc.gov/news-events/press-releases/2020/01/ftc-ny-attorney-general-charge-viera-pharmaceuticals-martin>.