Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace
February 3, 2020

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have a long history of working collaboratively to protect American consumers. We have formally collaborated since 1954 to support the important missions of both FDA and FTC.[1]

Much of our collaborative work focuses on ensuring that advertising and other promotional communications for products subject both to FDA oversight and to FTC enforcement are truthful and non-misleading. Truthful and non-misleading advertising and promotional communications help foster competitive markets by allowing purchasers to compare products, prices, and benefits. In addition, ensuring that advertising and promotional communications about products subject to FDA regulation are truthful and non-misleading helps to protect and promote public health by enabling patients and health care providers to make decisions based on accurate information. This Statement details how FDA and FTC will work together to promote competitive markets for biological products and to take appropriate steps to address false or misleading statements and promotional communications by biological product (biologic) manufacturers.

Biologics have become a mainstay of modern medicine. These products are often more expensive than small molecule drugs, accounting for two percent of total prescription volume but 37 percent of total prescription drug spend in the United States.[2] Biologics comprise the fastest growing, and one of the most expensive, segments of prescription medicine spending.[3] Public and private insurers in the U.S. spent $125.5 billion on biologics in 2018 alone.[4]

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[1] The agencies updated and replaced the original 1954 Working Agreement between the FTC and the FDA in 1971 with a memorandum of understanding. *See* Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18, 539 (Sept. 16, 1971).

[2] *See* IQVIA Inst. for Human Data Sci., Medicine Use and Spending in the U.S. 6 (April 2018), https://www.iqvia.com/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf (discussing specialty drug prevalence and spending); *accord* Medicare Payment Advisory Commission, A Data Book: Health Care Spending and the Medicare Program, 150 (June 2018), http://medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf?sfvrsn=0; Congressional Budget Office, Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid (Mar. 2019), https://www.cbo.gov/system/files/2019-03/55011-Specialty_Drugs_WP.pdf.

[3] Scott Gottlieb, Comm'r, FDA, Speech at America's Health Insurance Plans' (AHIP) National Health Policy Conference: Capturing the Benefits of Competition for Patients (Mar. 7, 2018), https://www.fda.gov/news-events/speeches-fda-officials/capturing-benefits-competition-patients-03072018 ("Taken together, biologics now account for about 40% of all U.S. drug spending -- and 70% of spending growth. . . ."); *see also* IQVIA, *supra* note 2.

[4] *See* IQVIA Inst. for Human Data Sci., Medicine Use and Spending in the U.S. 26 (May 2019), https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.

Competition brings substantial benefits to consumers through lower prices, greater access to higher quality goods and services, and increased innovation. The 1984 Hatch Waxman Amendments created an abbreviated approval process for generic versions of small molecule drugs. Competition from generic drugs has saved Americans hundreds of billions of dollars in drug costs.[5] Similarly, with these benefits of competition in mind, in 2010 Congress enacted the Biologics Price Competition and Innovation Act (BPCI Act) to foster competition for biologics.[6] The BPCI Act created an abbreviated pathway for biological products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference product. A biosimilar is a biological product that is highly similar to its reference product, a biological medication already approved by FDA. Biosimilars have no clinically meaningful differences from the reference product in terms of safety or effectiveness. Generally described, an interchangeable is a biosimilar to the reference product that meets additional requirements outlined in the BPCI Act. Additional information is needed to show that an interchangeable is expected to produce the same clinical result as the reference product in any given patient. Also, for a biological product administered more than once to patients, FDA will have evaluated the risk in terms of safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product. An interchangeable product may be substituted for the reference product without the involvement of the prescriber.[7] The abbreviated pathway enables potentially shorter and less costly drug development programs for biosimilar and interchangeable products while maintaining FDA's high approval standards.

Biologics play a critical role in the treatment of many serious illnesses, including rare genetic disorders, autoimmune diseases, and cancer. For many of these conditions, there are no treatment alternatives. Supporting a competitive marketplace for biologics, including biosimilar and interchangeable products, is essential for improving patient access to medicines and potentially reducing health care costs. To date, FDA has approved twenty-six biosimilars, although business and intellectual property concerns have contributed to the delayed launch of some approved

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[5] *See Antitrust Concerns and the FDA Approval Process: Hearing Before the Subcomm. on Regulatory Reform, Commercial, and Antitrust Law of the H. Comm. on the Judiciary*, 115th Cong. (2017) (Prepared Statement of Markus H. Meier, Acting Director, Bureau of Competition, FTC at 5), https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf; Scott Gottlieb, *FDA Working to Lift Barriers to Generic Drug Competition*, FDA (June 21, 2017), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-working-lift-barriers-generic-drug-competition.

[6] Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (BPCI Act was enacted under Title VII of PPACA).

[7] More information about biosimilar and interchangeable products can be found at www.fda.hhs.gov/biosimilars.

products.[8] Biosimilars marketed in the United States typically launched with initial list prices 15 to 35 percent lower than the list prices of the reference products.[9]

While the U.S. market for biosimilars is still maturing, research suggests that after market entry, biosimilars can generate significant price competition and consumer savings.[10] FTC's analysis similarly concludes that competition generated by biosimilars could generate significant consumer benefit.[11] Basic economic principles support the analyses: more competition leads to price reductions, increased consumer access and choice, and innovation.

FDA issued a Biosimilars Action Plan (BAP) in July 2018 that outlines four key strategies to accelerate biosimilar competition.[12] One key goal in the BAP is to support market competition by reducing "gaming" and other attempts to unfairly delay competition. Strengthening the partnership and interagency coordination between FDA and FTC will help each agency address and deter anticompetitive behavior in the U.S. market for biological products. Such behavior might include anticompetitive reverse payment agreements, abusive repetitive regulatory filings, or misuse of restricted drug distribution programs.

To deter anticompetitive practices, FDA recently issued final guidance for industry related to certain types of citizen petitions intended to delay FDA action on a generic or other abbreviated application.[13] This guidance will help FDA allocate resources efficiently when addressing petitions likely to obstruct entry of generic and biosimilar medications. FDA will also refer to FTC and highlight in FDA's annual report to Congress its determinations of petitions submitted with the primary purpose of delaying an approval.

Both FDA and FTC support competitive markets for biologics and have serious concerns about false or misleading statements and their negative impacts on public health and competition. False

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[8] *See Biosimilar Product Information, FDA-Approved Biosimilar Products*, FDA (July 20, 2018), https://www.fda.gov/drugs/biosimilars/biosimilar-product-information (last visited Aug. 28, 2019); FTC, Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs 11 (July 16, 2018), https://www.ftc.gov/policy/advocacy/advocacy-filings/2018/07/statement-federal-trade-commission-department-health-human.

[9] *See* Mulcahy, *supra*, note 4; Gottlieb, *supra*, note 3; *see, e.g.*, *Merck's Biosimilar Debuts at a 35% List Price Discount to Remicade*, P&T Community (July 24, 2017), https://www.ptcommunity.com/news/20170724/merck-s-biosimilar-debuts-35-list-price-discount-remicade; *accord* Ameet Sarpatwari, et. al., *The US Biosimilar Market: Stunted Growth and Possible Reforms*, 105 Clinical Pharmacology & Therapeutics 92, 94 (2019) (as of Aug. 2018, biosimilar competition had resulted in discounts up to 57% off the reference biologic's list price).

[10] S*ee also* QuintilesIMS, The Impact of Biosimilar Competition in Europe (May 2017), https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf.

[11] *See* FTC, *supra* note 8, at 9.

[12] FDA, Biosimilars Action Plan: Balancing Innovation and Competition 5-9 (July 2018), https://www.fda.gov/media/114574/download.

[13] FDA, Docket No. FDA-2009-D-008, Final Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (Sept. 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/citizen-petitions-and-petitions-stay-action-subject-section-505q-federal-food-drug-and-cosmetic-act-0.

or misleading comparisons of reference products and biosimilars may constitute unfair or deceptive practices that undermine confidence in biosimilars. Both agencies want to ensure that health care professionals and patients receive truthful and non-misleading information about biological products. One focus of the agencies is false or misleading communications about biosimilars within their authorities. FDA will undertake efforts to educate health care professionals and patients about biosimilars and explain why people should have confidence in the safety and effectiveness of these FDA-approved products just as they would the reference products. The agencies believe these actions will facilitate a more competitive marketplace.

Joint Goals

FDA and FTC are collaborating to support appropriate adoption of biosimilars, deter false or misleading statements about biosimilars, and deter anticompetitive behaviors in this industry.

We jointly identified four goals to help in this effort:

1. **FDA and FTC will coordinate to promote greater competition in biologic markets.**

    - The agencies concur that more robust competition can help reduce the costs of biologics and facilitate increased patient access to important therapies.

    - FDA and FTC will cooperate in efforts to facilitate biologics competition to the extent possible.

    - FDA will develop materials to educate consumers and providers about biosimilars.

    - FDA and FTC will collaborate on future public outreach efforts, including sponsoring a public meeting to discuss competition for biologics.

2. **FDA and FTC will work together to deter behavior that impedes access to samples needed for the development of biologics, including biosimilars.**

    - FDA and FTC will collaborate to identify and deter tactics used to prevent or impede access to samples of the reference product that the prospective biosimilar applicant needs for testing to be licensed as a biosimilar or interchangeable biosimilar.

    - To facilitate such collaboration, FDA and FTC will evaluate whether additional information sharing arrangements are warranted.

3. **FDA and FTC intend to take appropriate action against false or misleading communications about biologics, including biosimilars, within their respective authorities.**

    - FDA and FTC, as authorized by their respective statutes, will work together to address false or misleading communications about biologics, including biosimilars. In particular, if a communication makes a false or misleading comparison between a reference product and a biosimilar in a manner that misrepresents the safety or efficacy of biosimilars, deceives consumers, or deters competition, FDA and FTC intend to take appropriate action within their respective authorities. FDA intends to take appropriate action to address such communications where those communications have the potential to impact public health.

    - FDA intends to use its authority under the Food, Drug, and Cosmetic Act to address false or misleading communications subject to FDA jurisdiction. FTC intends to use

its authority under the Federal Trade Commission Act to address unfair or deceptive acts or practices not subject to FDA jurisdiction.

- FDA is publishing a draft guidance outlining considerations for FDA-regulated advertisements and promotional labeling that contains information about biologic products.

4. FTC will review patent settlement agreements involving biologics, including biosimilars, for antitrust violations.

- Pursuant to the Patient Right to Know Drug Prices Act, Public Law No. 115-263 (Oct. 10, 2018), codified at 21 U.S.C.A. § 355, the FTC obtains and reviews patent settlement agreements between reference product and biosimilar manufacturers. This law extends a 2003 law requiring that drug manufacturers notify U.S. antitrust authorities of patent settlement agreements. This notification allows FTC to evaluate whether these agreements include, among other things, anticompetitive reverse payments that slow or defeat the introduction of lower-priced medicines, including biosimilars. Such review will occur in the same manner that FTC has been reviewing patent settlement agreements between brand and generic drug manufacturers.

- FDA and FTC will collaborate on efforts to ensure biosimilar development and uptake are not hindered by other anticompetitive practices.

We look forward to our continued work together to facilitate a more competitive biological product marketplace.

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs,
Food and Drug Administration

Joseph J. Simons,
Chair,
Federal Trade Commission

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The FTC is an independent agency charged by Congress with protecting the interests of consumers by enforcing competition and consumer protection laws. It exercises primary responsibility for civil antitrust enforcement in the pharmaceutical industry. The FTC also seeks to protect consumers by enforcing laws and rules that promote truth in advertising and fair business practices.