

Summary Report on the FDA/FTC Workshop on a Competitive Marketplace for Biosimilars

(March 9, 2020)



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I. Introduction

On March 9, 2020, the Food and Drug Administration (FDA), in collaboration with the Federal Trade Commission (FTC), held a public workshop entitled, *FDA/FTC Workshop on a Competitive Marketplace for Biosimilars* (hereafter, *the Workshop*).¹ The purpose of the Workshop was to discuss FDA's and FTC's collaborative efforts to support appropriate adoption of biosimilar products, discourage false or misleading communications about biosimilar products, and deter anticompetitive conduct in the biological product marketplace.

FDA plays a critical role facilitating access to biosimilar products, including interchangeable biosimilar (interchangeable) products² by, among other activities, promoting product development and efficiently reviewing applications for biosimilar and interchangeable products to support robust competition. Once marketed, the availability of these products can increase patient access and potentially reduce costs for patients and the healthcare system. FDA also helps to ensure the dissemination of truthful and non-misleading information on biological products through its oversight of prescription drug labeling and advertising by drug manufacturers, packers, distributors, and those acting on their behalf. FDA's external communications, including educational materials, aim to enhance understanding of biosimilar products by both patients and healthcare providers.

¹ This report reflects discussions, presentations, and docket submissions made in conjunction with the March 2020 public workshop and reflects the factual context that existed at that time. In particular, at the time of the workshop, no products had yet been licensed as interchangeable products.

² See section III.B for the definitions of biosimilar and interchangeable products.

In July 2018, FDA issued its *Biosimilars Action Plan*.³ The plan focuses on four FDA activities: (1) improving the efficiency of the biosimilar and interchangeable product development and approval process; (2) maximizing scientific and regulatory clarity for the biosimilar product development community; (3) developing effective communications to improve understanding of biosimilars among patients, clinicians, and payers; and (4) supporting market competition by reducing gaming of FDA requirements and other attempts to unfairly delay competition.

FTC protects Americans from unlawful business practices by, among other activities, enforcing laws and rules that promote truth in advertising and fair business practices. FTC has substantial experience in evaluating generic-drug and biosimilar marketplaces. Competition in healthcare markets benefits consumers by helping to: (1) control costs and prices; (2) improve quality of care; (3) promote innovation in products, services, and delivery models; and (4) expand access to healthcare goods and services. One of FTC's core missions is to ensure that advertising is both truthful and not misleading. FTC's law-enforcement efforts against deceptive advertising enable consumers to make well-informed decisions about how best to use their resources by deterring the dissemination of misleading information.

One month prior to the Workshop, FDA and FTC issued the *Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace* (hereafter, the *Joint Statement*).⁴ Among other things, the Joint Statement describes the agencies' shared commitment to support market competition, including the goal described in FDA's Biosimilars Action Plan, by reducing "gaming" and other attempts to unfairly delay competition. The Joint Statement also details how FDA and FTC will collaborate to promote competition in the market for biological products and take appropriate steps to address false or misleading statements and promotional communications by manufacturers of such products. Strengthening of interagency coordination better enables FDA and FTC to support public health and to address and deter deceptive, unfair, and anticompetitive behavior within their respective areas of authority.

3 U.S. Food & Drug Admin., *Biosimilars Action Plan: Balancing Innovation and Competition* (2018), <https://www.fda.gov/media/114574/download>.

4 U.S. Food & Drug Admin. & Fed. Trade Comm'n, *Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace* (2020), <https://www.fda.gov/media/134864/download>.



II. Background

A. FDA and FTC Collaboration: Shaping Regulatory Conditions for Competition

In 1954, FDA and FTC entered into a memorandum of understanding.⁵ Thus began their long history of collaboration in the interest of American consumers.

In 2010, Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which created an abbreviated pathway for biological products demonstrated to be biosimilar to, or interchangeable with, an FDA-licensed (approved) reference product.⁶ This pathway was established as a way to provide more treatment options, increase access to lifesaving medications, and potentially lower healthcare costs by fostering competition, which provides further opportunities for collaboration between FDA and FTC.

The most recently published collaboration between FDA and FTC—described in the Joint Statement—focuses on promoting competition in the biological product marketplace.⁷ The Joint Statement notes that biological products are a mainstay of modern medicine and are both the fastest growing and one of the most expensive segments of prescription medicine spending. The agencies expressed concern that deceptive advertising could hamper the introduction and promotion of biosimilars, suppressing competition and thus negatively affecting public health. As a result, FDA and FTC jointly identified specific goals to support appropriate adoption of biosimilars, deter false and/or misleading statements about biosimilars, and deter anticompetitive behavior.⁸

⁵ See generally Paul Rand Dixon, *Assuring Integrity Through Teamwork*, 22 Food Drug Cosm. L.J. 1, 54-56 (Jan. 1967).

⁶ Biologics Price Competition and Innovation Act of 2009 (BPCI Act), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (enacted under Title VII of the Patient Protection and Affordable Care Act).

⁷ FDA/FTC Joint Statement, *supra* note 4.

⁸ *Id.* at 4-5.

B. FDA Authority Regarding Biological Products, Including Biosimilar and Interchangeable Products

FDA regulates biological products under section 351 of the Public Health Service Act (PHS Act)⁹ and the Federal Food, Drug, and Cosmetic Act (FD&C Act).¹⁰ These statutes grant to FDA the authority to review proposed biosimilar and interchangeable products, and, if appropriate based on rigorous scientific review, approve such products pursuant to the abbreviated licensure pathway in section 351(k) of the PHS Act,¹¹ as added by the BPCI Act.¹² An applicant seeking licensure of a proposed biosimilar or interchangeable product pursuant to section 351(k) of the PHS Act¹³ can rely on FDA's previous determination of safety, purity, and potency for a reference product (i.e., a product licensed under section 351(a) of the PHS Act¹⁴), provided that the applicant can demonstrate biosimilarity to, or interchangeability with, the reference product. The BPCI Act was enacted with the intent to strike a balance between innovation and access to biological products.¹⁵

C. Federal Antitrust Statutes Concerning Fair Competition

FTC, in cooperation with the Department of Justice, enforces federal antitrust laws in the United States.¹⁶ These laws are designed to promote competition in the market for the benefit of consumers by facilitating lower prices, enhancing quality and choice, and increasing innovation.¹⁷ In addition to the Federal Trade Commission Act (FTC Act), which makes unlawful unfair methods of competition and unfair or deceptive acts or practices,¹⁸ the core antitrust laws are the Sherman Act¹⁹ and the Clayton Act.²⁰ The Sherman Act prohibits agreements “in restraint of trade” and

9 Public Health Service Act, 42 U.S.C. § 201 *et seq.*, § 262.

10 Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 301 *et seq.*

11 PHS Act, 42 U.S.C. § 262(k).

12 BPCI Act, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21.

13 PHS Act, 42 U.S.C. § 262(k).

14 *Id.*, 42 U.S.C. § 262(a).

15 BPCI Act, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804.

16 Aside from the Federal Trade Commission Act (FTC Act), 15 U.S.C. §§ 41-58, which FTC exclusively enforces, the agency shares enforcement authority of some antitrust laws with the Antitrust Division of the Department of Justice. State Attorneys General also enforce federal and state antitrust laws. See generally, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/enforcers>.

17 For a general discussion of the antitrust laws enforced by FTC, see Fed. Trade Comm'n, *Guide to Antitrust Laws*, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws>.

18 Section 5 of the FTC Act prohibits “unfair methods of competition” and “unfair or deceptive acts or practices.” 15 U.S.C. § 45(a). Section 12 of the FTC Act prohibits the false advertising of food, drugs, devices, cosmetics, and services. 15 U.S.C. § 52.

19 Sherman Antitrust Act of 1890 (Sherman Act), 15 U.S.C. §§ 1-38.

20 Clayton Antitrust Act of 1914 (Clayton Act), 15 U.S.C. §§ 12-27.

monopolization, including attempts or agreements to monopolize.²¹ The Clayton Act prohibits conduct that may substantially lessen competition or tends to create a monopoly.²² Because these statutes proscribe anticompetitive conduct generally, courts determine on a case-by-case basis whether conduct is unlawful.²³

One area in which FTC enforces these laws is healthcare, including anticompetitive and unfair and deceptive practices in the pharmaceutical and biological product markets.²⁴ For example, FTC has taken action against reverse-payment agreements, sham government petitioning designed to foreclose competition, and anticompetitive exclusive dealing.²⁵ FTC also provides advice on contemplated business actions,²⁶ conducts research studies, and engages in competition advocacy.²⁷

D. Federal Agency Authority Concerning False or Misleading Communications

1. FDA

FDA's Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion (OPDP) and Center for Biologic Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. This is accomplished through comprehensive surveillance, compliance, and education programs, and by fostering better communication of labeling and promotional information supplied to healthcare providers and consumers. Prescription drug promotion includes communications such as drug advertising or promotional labeling made by or on behalf of a drug manufacturer, packer, or distributor (hereafter, a *firm*).

The FD&C Act grants FDA authority over promotional communications about a prescription drug made by a firm. Specifically, the FD&C Act includes provisions addressing labeling for all drugs and advertisements for prescription drugs, including Section 502(a), which relates to false or misleading labeling, including

²¹ Sherman Act, 15 U.S.C. § 1.

²² Clayton Act, 15 U.S.C. §§ 13-14.

²³ Fed. Trade Comm'n, *Guide to Antitrust Laws*, *supra* note 17.

²⁴ For an overview of FTC's work to promote competition in the healthcare marketplace, see Fed. Trade Comm'n, *Competition in the Health Care Market*, <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care>.

²⁵ For a more detailed look at some of the pharmaceutical cases brought by FTC, see Markus H. Meier et al., Fed. Trade Comm'n, *Overview of FTC Actions in Pharmaceutical Products and Distribution* (July 2021), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_of_ftc_actions_in_pharmaceutical_products_and_distribution_updated_06302021.pdf.

²⁶ See Fed. Trade Comm'n, *Competition Advisory Opinions*, <https://www.ftc.gov/tips-advice/competition-guidance/competition-advisory-opinions>.

²⁷ For more information about FTC's engagement in the healthcare markets, see Fed. Trade Comm'n, *Competition in the Health Care Market*, *supra* note 24.



promotional labeling; and Section 502(n), which relates to prescription drug advertising.²⁸ FDA has promulgated several regulations related to drug labeling and prescription drug advertising in Parts 201 and 202 of Title 21 of the Code of Federal Regulations. OPDP, OCBQ, and other FDA offices rely on these statutes and regulations in the course of their work.

2. FTC

In addition to enforcing the antitrust laws, FTC serves as the nation's consumer protection agency. As noted above, it enforces laws, including the FTC Act, that prohibit unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce, and the false advertisement of foods, drugs, devices, services, or cosmetics.²⁹ FTC's authority over matters "in or affecting commerce" covers the vast majority of the U.S. economy, with few exceptions.³⁰

To protect consumers from misleading health-related claims, FTC monitors advertising, conducts investigations, and prosecutes law-enforcement actions in federal court or in adjudicative proceedings before an administrative law judge. Such activities, coupled with its rulemaking authority, enable FTC to prohibit and remedy unlawful practices, including, in appropriate cases, by seeking monetary relief and/or civil penalties.³¹

²⁸ FD&C Act, 21 U.S.C. §§ 352(a), (n).

²⁹ FTC Act, 15 U.S.C. §§ 41-58; *see generally*, <https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority>.

³⁰ Exceptions include banks, the business of insurance, and the common carrier activities of transportation and communications service providers. *See, e.g.*, FTC Act, 15 U.S.C. §§ 44, 45(a)(2), 57a(f)(2). FTC also does not have jurisdiction over bona fide nonprofits, except under certain consumer financial statutes and for purposes of the Clayton Act. *See, e.g.*, Truth in Lending Act, 15 U.S.C. §§ 1601-1667f; Clayton Act, 15 U.S.C. §§ 12-27.

³¹ FTC Act, 15 U.S.C. §§ 45, 52-54, 57a.

E. The 2020 FDA/FTC Joint Statement

On February 3, 2020, FDA and FTC issued the Joint Statement,³² which describes key steps the agencies plan to take to address false or misleading communications about biological products, including biosimilars, within their respective areas of authority and deter anticompetitive behavior.

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 fair competition. False 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.

As detailed in the Joint Statement, the agencies plan to collaborate on public outreach efforts, including bringing together representatives from industry, academia, and government agencies to discuss issues relating to competition in the market for biological products.

³² FDA/FTC Joint Statement, *supra* note 4.



III. The 2020 Joint FDA/FTC Biosimilars Workshop

FDA and FTC held the Workshop in March 2020. The Workshop comprised six panel discussion sessions and a public comment session. Below are summaries of the points made by panelists during each of these sessions.

A. Panel 1: FDA Licensure Process and the U.S. Biosimilar Markets

This panel discussed FDA’s licensure and approval process for biological products. Most biological products are manufactured by biotechnological means and generally are structurally more complex, and consist of larger molecules, than conventional, small-molecule drugs.

The panel first discussed FDA approval of a biological product. “Standalone” biologics license applications (BLAs) licensed under section 351(a) of the PHS Act must include all information necessary to demonstrate that the proposed products are safe, pure, and potent (safe and effective). An abbreviated pathway to licensure under section 351(k) of the PHS Act exists for biological products that are biosimilar to, or interchangeable with, a U.S.-licensed reference product.³³

The panel then discussed FDA approval of biosimilar and interchangeable products. A biosimilar is a biological product that is highly similar to the reference

³³ PHS Act, 42 U.S.C. § 262(k). A reference product means the single biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in an application submitted under section 351(k) of the PHS Act. *Id.*, 42 U.S.C. §§ 262(a), (i), (k).

product, notwithstanding minor differences in clinically inactive components, and that has no clinically meaningful differences from the reference product in terms of safety, purity, and potency.³⁴

An interchangeable product is a product that is biosimilar to the reference product and meets the following additional statutory requirements: (1) the product can be expected to produce the same clinical result as the reference product in any given patient; and (2) for a biological product administered more than once to patients, the risk in terms of safety or diminished efficacy from alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch³⁵ An interchangeable product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.³⁶

As the panel noted, the goal of a biosimilar development program is to demonstrate biosimilarity and/or interchangeability between the proposed product and the reference product, not to establish the safety and effectiveness of the proposed product independently. Generally, manufacturers engaged in such a development program will not need to conduct as many expensive and lengthy clinical trials, providing the potential for shorter development programs and faster access to these products. Biosimilarity is generally demonstrated by data from analytical studies, animal studies, and a clinical study or studies.³⁷ A demonstration of interchangeability generally will also include a switching study or studies to demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between use of the proposed interchangeable product and the reference product is not greater than the risk of using the reference product without such alternation or switch.³⁸

Panelists noted that biosimilars are not generic drugs—these products are approved through a different pathway. However, these products use abbreviated approval pathways that can avoid duplicating certain costly clinical trials.³⁹ The objective of the BPCI Act is to increase competition in the medical marketplace, which in turn will increase treatment options for patients and, potentially, reduce health-care costs. This is conceptually similar to the success of generic drugs in lowering cost and increasing access. From the first approval of a biosimilar product in 2015 to the date of the FDA/FTC workshop in March 2020, FDA approved a total of 26

³⁴ *Id.*, 42 U.S.C. § 262(i)(2).

³⁵ *Id.*, 42 U.S.C. § 262(k)(4).

³⁶ *Id.*, 42 U.S.C. § 262(i)(3).

³⁷ U.S. Food and Drug Admin., *Guidance for Industry, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (Apr. 2015), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product>.

³⁸ U.S. Food and Drug Admin., *Guidance for Industry, Considerations in Demonstrating Interchangeability with a Reference Product* (May 2019), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry>.

³⁹ U.S. Food and Drug Admin., *Review and Approval* (Dec 13, 2022), <https://www.fda.gov/drugs/biosimilars/review-and-approval>



biosimilars (to nine reference products). Biosimilars' potential to increase access to therapeutic options, and thereby lower healthcare costs, continues to grow.

Panelists discussed the challenges of developing the U.S. biosimilar market, including patent abuse and patent thickets, exclusionary contracting practices, rebate traps, misinformation, and reimbursement and formulary placement. These were also the subjects of more-detailed discussions in later panels. With respect to biosimilar development, panelists discussed potential legislation to require patents for biological products to be listed in the Purple Book.⁴⁰ Patent settlements can be helpful to bring biosimilars to market sooner, and FTC is actively working to ensure that such settlements are not anti-competitive.

Panelists noted that biosimilar use and uptake can be affected by several factors. Rather than focusing on the uptake rates of biosimilars approved for treating an acute or chronic condition, some panelists suggested considering the formulary status of the product and the type of health care benefit under which a biosimilar is covered. For example, panelists opined that a biosimilar that can be physician-administered or self-administered and may be eligible for coverage under either a medical or pharmacy benefit can be more complicated from the standpoint of utilization and formulary management compared to a biosimilar that may be eligible for payment solely under medical benefit. The financial aspect of biosimilar utilization and uptake is also important, given the ongoing debate on drug pricing in the U.S.

⁴⁰ The Biological Product Patent Transparency (BPPT) section of the Consolidated Appropriations Act of 2021, Pub. L. 116-260 (enacted Dec. 27, 2020), requires, among other things, publication in the Purple Book of patent lists provided by reference product sponsors (i.e., BLA holders) to FDA for certain licensed biological products. See U.S. Food & Drug Admin., Purple Book FAQs 5-7 at <https://purplebooksearch.fda.gov/faqs>.

Panelists also suggested that biosimilar uptake is generally less about the specifics of the products and more about where the existing launched products sit within the healthcare system. Provider incentives to use biosimilars vary, and legislative proposals aiming to increase provider incentives could promote the use of biosimilars. Additionally, panelists noted that insurers are increasingly using their leverage to drive their preferred product strategy, such as in allowing pharmacy adjudication of some drugs, supplying through an affiliated or network specialty pharmacy, or using prior authorization before approving payment of a prescribed drug.

Unlike other countries with approval pathways for biosimilar products, the U.S. is the only jurisdiction with an abbreviated pathway for both biosimilars and interchangeable products. The panel noted that in the U.S., the value of being approved as an interchangeable can differ depending on whether the product is physician-administered and covered under a medical benefit, or a self-administered product that can be covered under a pharmacy benefit. Panelists commented that approval as an interchangeable product is expected to have more impact on utilization in a retail or specialty pharmacy setting than in a physician-administered or hospital setting where products are typically dispensed at the point of care. If permitted by state law, a pharmacist may substitute an interchangeable product for the reference product without intervention of the prescribing healthcare provider.

The panel also discussed parallels to, and lessons learned from, the generic drug industry as well as the European experience with biosimilars. There are parallels between the early days of generic drugs and biosimilars, including slow uptake and misinformation. A biosimilar pathway has existed for longer in the European Union than in the U.S., and the members of the European Union have taken various actions to ensure a robust and sustainable biosimilar marketplace. The panel noted that FDA has provided guidance on a variety of topics to support biosimilar and interchangeable product development and provide regulatory clarity to reduce the number of review cycles for applicants to reach approval. FDA has also sought the advice of industry and other stakeholders on what additional information it could provide to further support product development. Panelists emphasized the need for additional educational information from FDA for patients and providers, especially on what it means for a biosimilar product to also meet the standard of interchangeability. FDA recognized the issues and understood the importance of educational outreach and the need for incentives to create a robust market for biosimilar and interchangeable products.



B. Panel 2: FDA and FTC Approaches to Ensure Truthful and Non-Misleading Advertising and Promotional Communications

Members of this panel opined that the significant benefits of biosimilar products will not be fully realized unless patients, healthcare providers, and others in the health-care system have accurate information on biosimilar products and their roles as therapeutic options. Panelists noted that incomplete and misleading communications that suggest to patients and healthcare providers that biosimilar products are less safe or less effective than their reference products, or that there are clinically meaningful differences between a biosimilar and its reference product, can deter the adoption of biosimilar products.

1. FDA and CDER's Office of Prescription Drug Promotion

The panel discussed the role of OPDP in helping to ensure that prescription drug communications are truthful, balanced, and accurately communicated.⁴¹ This is accomplished through comprehensive surveillance, compliance, and education programs, and by fostering better communication of labeling and promotional information to healthcare providers and consumers. FDA's communications with stakeholders include OPDP's responses to industry's voluntary requests for comment on draft promotional communications. This process enables firms to receive

41 Note that while CDER's Office of Compliance and Biologics Quality was not part of the panel, they share CDER OPDP's mission and engage in many of the activities described in this section.

OPDP feedback on draft promotional communications before they are made available to the public.

The panel noted that FDA also provides guidance for industry in areas related to promotional communications. Guidances, such as the draft guidance *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar—Products Questions and Answers*,⁴² provide firms with FDA's thinking on particular topics. Many of these guidance documents are informed in part by OPDP's social science research program. OPDP's research program provides scientific evidence to help ensure that FDA's policies on prescription drug communications will have the greatest possible benefit to public health. As always, FDA invites the public to visit OPDP's website to learn more about its social science research program and the studies conducted, and to review research in progress.

Panelists further discussed OPDP's robust surveillance and compliance program to monitor compliance with applicable FDA-administered laws and regulations. For example, OPDP regularly attends conferences and other events to observe industry promotion, and OPDP reviews many promotional communications submitted to FDA by firms pursuant to post-marketing reporting requirements. OPDP also reviews and investigates complaints from healthcare providers, consumers, competitors, and others regarding potentially violative promotional materials. Through its surveillance activities, OPDP frequently identifies common concerns in promotional communications. Although not an exhaustive list, the areas of concern OPDP most often identifies in promotional communications relate to omitting risk information, minimizing risk information, overstating the effectiveness of a drug, and misleading drug comparisons.

When potential violations of the FD&C Act are identified by OPDP's surveillance of industry promotion, depending on the nature of that violation and other public protection considerations, FDA may notify a firm of FDA's concerns and provide them an opportunity to take voluntary and prompt corrective action to avoid the potential for enforcement action. As one panelist stated, FDA's application of its authority on such matters is fact specific, so the details of a particular promotional communication, including both its content and presentation, are important when FDA considers whether to notify the firm. If efforts to obtain voluntary compliance are not successful, FDA can work with the Department of Justice to pursue enforcement actions, including those seeking seizures or injunctions, to address violations of the FD&C Act.

42 U.S. Food & Drug Admin., Draft Guidance for Industry, *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers Guidance for Industry* (Feb. 2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/promotional-labeling-and-advertising-considerations-prescription-biological-reference-and-biosimilar>. When finalized, this guidance will represent FDA's current thinking on this topic.

2. FTC

The panel also discussed FTC's jurisdiction over prescription drug advertising, including promotional material that may or may not refer to a manufacturer's or distributor's drug by name, and promotional communications created by surrogates for drug manufacturers and distributors.⁴³ A panelist noted that a threshold question for FTC is whether the communication is considered commercial speech.⁴⁴ Determining if a communication constitutes commercial speech requires examination of several factors. Panelists considered communications promoting the demand for a particular product or service generally as commercial speech.⁴⁵ Demand can be generated by positive statements about one's product as well as by negative statements on a competitor's product.⁴⁶ Panelists identified additional factors including whether the communication references a specific product or service or its attributes (such as type, price, quality, or associated health benefits), the means used to publish the communication, and the use of a traditional paid format that consumers would recognize as advertising.⁴⁷ The panel noted that FTC may also consider the speaker's economic interest in disseminating the communication.⁴⁸ No single factor is determinative.⁴⁹ For example, a peer-reviewed scientific article or a press release may be considered commercial speech depending on how it is disseminated and used.

The panel discussed FTC's authority under Sections 5 and 12 of the FTC Act, which prohibit false and unsubstantiated claims and the deceptive failure to disclose material facts in drug advertising, including advertising for biological products, whether reference, biosimilar, or interchangeable.⁵⁰ A firm is responsible for both express and implied claims.⁵¹ In express claims, the statement is the message. However, as noted by the panel, advertising claims can range from express claims to virtually express claims to reasonably implied claims, to claims that few consumers would consider to convey a particular message. The last category of

43 See generally FTC Act, 15 U.S.C. §§ 45, 52; Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971), <https://www.ftc.gov/policy/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug>.

44 See, e.g., FTC Act, 15 U.S.C. § 45 (Section 5 prohibits "unfair or deceptive acts or practices in or affecting commerce"); see generally *R.J. Reynolds*, 111 F.T.C. 539, 544-547 (1988) (discussing factors the Supreme Court has determined characteristic of commercial speech); *POM Wonderful*, 155 F.T.C. 1, 73-76 (2013), *aff'd*, 777 F.3d 478 (D.C. Cir. 2015) (rejecting the premise that only paid advertisements, not deceptive commercial speech more broadly, can form the basis for liability under Section 5 and discussing the *R.J. Reynolds* commercial speech factors).

45 *R.J. Reynolds*, 111 F.T.C. at 544; *POM Wonderful*, 155 F.T.C. at 74.

46 *R.J. Reynolds*, 111 F.T.C. at 545.

47 *R.J. Reynolds*, 111 F.T.C. at 544-45; *POM Wonderful*, 155 F.T.C. at 74-76.

48 *R.J. Reynolds*, 111 F.T.C. at 545-46; *POM Wonderful*, 155 F.T.C. at 75-76.

49 *R.J. Reynolds*, 111 F.T.C. at 544; *POM Wonderful*, 155 F.T.C. at 76.

50 FTC Act, 15 U.S.C. §§ 45, 52.

51 See generally Fed. Trade Comm'n, *FTC Policy Statement on Deception* at 1-3 (Oct. 1983), *appended to Cliffdale Associates, Inc.*, 103 F.T.C. 110, 174 (1984), <https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception>.

claims generally is not considered actionable. When determining the meaning of an advertisement, extrinsic evidence (such as copy testing or expert testimony) is not necessary if the meaning can be reasonably determined from its content.

Advertisements are interpreted based on their net impression from the viewpoint of a reasonable person in the target audience.⁵² A panelist mentioned that as interpreted by FTC, “net impression” does not require that consumers read everything in an advertisement. Consumers read the headlines; they may read some of the text. It is rare that a footnote in an advertisement will be considered to alter the net impression. The net impression of an advertisement may also differ depending on whether the advertisement targets, for example, persons suffering from diabetes or physicians treating diabetic patients.

One member of the panel noted that where an advertisement conveys more than one message, the advertisement is deceptive if a significant minority of the target audience will take away a deceptive message even though a non-deceptive interpretation is possible. For example, the general statement that a biosimilar is not interchangeable with a reference product can be interpreted in several ways. A consumer who is aware that ‘interchangeable’ is a term of art when applied to biological products might understand the statement that the product is ‘not interchangeable’ to mean that the biosimilar cannot be substituted for the reference product without the intervention of the prescribing healthcare provider; instead, the healthcare provider must write a prescription specifically for the biosimilar. However, another consumer applying the common meaning of interchangeable might interpret ‘not interchangeable’ to mean that the biosimilar could not be used in place of the reference product.

The panel discussed the FTC’s role in more detail: the FTC potentially could challenge as false or unsubstantiated, or for failing to disclose material information, a variety of claims made about biological products, including that there are clinically meaningful differences between reference and biosimilar products; that reference and biosimilar products are not highly similar; that even though the reference and biosimilar products may be highly similar, there are nonetheless clinically meaningful differences; or that biosimilar products are less safe or effective than reference products. These claims could result in cease-and-desist demands or formal law-enforcement actions, whether in federal court or by means of administrative procedures.

⁵² *Id.* at 3-4.



3. FDA and FTC are Working Collaboratively to Protect the Public Health, Foster Competition, and Level the Playing Field in the Biological Product Marketplace

Panelists confirmed that FDA and FTC work within two different, but complementary, frameworks to help ensure that labeling, advertising, and promotional communications about drugs, including biological products, are truthful and not misleading. As set forth in the Joint Statement on their collaboration to advance competition in the biological product marketplace, the agencies are continuing and extending their decades-long partnership to protect the public with respect to prescription biological products. Both agencies have serious concerns when false or misleading statements are made about biological products because of the potential negative effects of such statements on public health and competition. With these shared concerns in mind and using their respective authorities, FDA and FTC will work to ensure that healthcare professionals and patients receive truthful and non-misleading information about biological products and have the opportunity to benefit from vigorous and fair competition. Panelists agreed that the agencies intend to continue to work in concert to support biosimilar uptake and facilitate a more competitive marketplace.

C. Panel 3: FDA Draft Guidance for Industry: Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers

Panel 3 discussed the FDA Draft Guidance entitled *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers*, which was made available for public comment in February 2020. As reflected in that draft guidance document, as the number of licensed biosimilar products increases, FDA has started seeing promotional communications for some of these products and receiving questions from firms on promotional issues related to biosimilar and reference products. FDA is particularly concerned about promotional claims and presentations that make false or misleading comparisons between a reference product and a biosimilar product in a way that misrepresents the safety or efficacy of either.

To address questions firms may have when developing FDA-regulated promotional communications for prescription reference products and biosimilar products, in 2020 FDA published a draft guidance that discusses considerations for presenting data and information about reference or biosimilar products in promotional communications in a truthful and non-misleading way.⁵³ Although the draft guidance covers promotional issues involving both reference and biosimilar products, some questions and answers focus only on biosimilar product promotional communications. The draft guidance does not discuss considerations unique to promotional communications for interchangeable products. FDA is reviewing comments received from the public on the draft guidance.

The draft guidance and the ongoing collaboration with FTC are part of FDA's continuing work to help ensure truthful and non-misleading prescription drug promotion and serves as another example of FDA's commitment to public health by addressing anti-competitive tactics that aim to undermine confidence in the safety and effectiveness of FDA-approved products.

⁵³ U.S. Food & Drug Admin., Draft Guidance for Industry *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers*, *supra* note 42.

D. Panel 4: What's at Stake? The Benefits of Competition

This panel first discussed the increasing economic impact of biological products, including biosimilars, on the U.S. pharmaceutical industry. Biological products comprise a large and growing proportion of total U.S. spending on pharmaceuticals. While accounting for only 2% of prescriptions, biological products, as of March 2020, accounted for 42% of the total net spending on prescription drugs in the U.S., up from 30% in 2014.⁵⁴ As described by a panelist, about 40% of new drugs are biological products; the remaining 60% are small-molecule drugs.⁵⁵

The panel noted that growth in U.S. spending on prescription drugs is largely driven by biological products. Per capita spending on small-molecule drugs has decreased by 12% since 2014 whereas spending on biological products has increased by 50%.⁵⁶ This is in part a result of competitive dynamics. Forty percent of total sales of small-molecule pharmaceuticals are subject to competition from a generic, and where generics are available, on average they represent 97% of total small-molecule sales for a particular product.⁵⁷ However, at the time of the FDA/FTC workshop only 17.5% of total biological product sales were subject to competition from a biosimilar product, and biosimilars on average accounted for only about 20% of sales of biological products.⁵⁸

Panelists explained that although limited data exist to evaluate the competitive impact of biosimilar entry, initial research suggests a decrease in the net price, but not the list price, of the reference product. They note that net price decreases are driven by discounting after biosimilar entry. Panelists indicated these dynamics may suggest competition between reference products and biosimilars resembles small-molecule brand-brand competition more than brand-generic competition or may be a function of different payor types and drug channels.

Panelists identified two types of barriers for biosimilars: barriers to entry and barriers to utilization of approved biosimilars. Examples of barriers to entry are exclusivities that prohibit FDA acceptance or approval of an application for a biosimilar product, or a determination of interchangeability, for a period of time, and approval processes designed to ensure safety and efficacy that can be costly and time consuming. Examples of barriers to utilization are insufficient education on the

54 Murray Aitken, *Biologics Market Dynamics: Setting the Stage for Biosimilars*, Presentation at the Workshop (Mar. 9, 2020), <https://www.regulations.gov/document/FDA-2019-N-6050-0002>, slideshow at 46.

55 Murray Aitken, *Biologics Market Dynamics: Setting the Stage for Biosimilars*, Presentation at the Workshop (Mar. 9, 2020), <https://www.fda.gov/media/136791/download>, transcript at 130.

56 Aitken, *supra* note 54, at 47.

57 *Id.* at 51.

58 *Id.* at 52.

relationship between biosimilars and their reference products and “rebate traps,” defined by one panelist as an incumbent manufacturer using existing market power to secure preferred formulary access for its drug by offering volume-based rebates to PBMs (pharmacy benefit managers) and plans on the condition that they deny or limit the formulary access of rival drugs. The manner in which biosimilars are reimbursed may also affect their adoption. In some state Medicaid programs, for example, managed-care organizations pay the list prices, but states receive the rebates. In those states that use preferred drug lists, higher-list-price reference products may be preferred over lower-list-price biosimilars because higher list prices generate larger rebates, thus benefitting the states.

Panelists suggested that policies aimed at addressing these barriers should focus on ensuring that biosimilar manufacturers can anticipate the barriers that they’re going to face; streamlining the approval process to reduce costs; and educating healthcare providers, patients, and payors about the relationship between biosimilars and their reference products.

E. Panel 5: Improving Stakeholder Engagement: Education and Understanding

Panelists noted that healthcare providers’ and patients’ knowledge, awareness, and perceptions regarding biosimilar and interchangeable products can influence their uptake and acceptance. Education to improve understanding of these products not only increases acceptance but also helps combat misinformation and other means of disparaging biosimilar and interchangeable products. During this panel, FDA described educational materials and information for healthcare providers and patients it had developed to increase knowledge related to biosimilarity and interchangeability. Panelists were clear that stakeholder groups, including patient advocacy and professional associations, also play an important role in enhancing awareness of biosimilar products by educating their members and constituents with truthful, non-misleading, and unbiased information.

Panelists acknowledged, however, that both healthcare providers and patients may have concerns and uncertainty related to biosimilar products. For example, patients are worried that if they switch from a reference product to a biosimilar their condition will worsen or that the products will not work the same way. They are also concerned about whether the biosimilar is as safe as the reference product. Pharmacy substitution, medication coverage, and cost are additional concerns. Healthcare providers share many of these concerns, e.g., about the safety and efficacy of biosimilars, whether the approval process is sufficiently rigorous, and whether clinical studies were conducted for all approved indications. Disparagement and misinformation can increase healthcare-provider and patient mistrust and confusion over biosimilar and interchangeable products.

Panelists stated that healthcare providers and patient advocacy organizations are trusted resources for patients. As a result, panelists noted that when provider and



patient advocacy organizations educate the community about biosimilar products, they should disclose all sources of funding and consult credible, independent clinicians and researchers to develop accessible, research-based information that does not confuse or create unfounded concern over biosimilar and interchangeable product safety and efficacy. Coordinated education efforts and use of consistent terminology on biological products can reduce confusion over biosimilar product safety and efficacy. Therefore, it is important that all members of the broader healthcare community—including FDA, healthcare providers, and patient advocacy organizations—use unbiased, accurate language when discussing biosimilar treatment options with patients. Also, it is important to simplify messaging and test communications for comprehension and bias to avoid unintended negative impacts, such as the nocebo effect,⁵⁹ of such education and outreach efforts.

Panelists were clear that healthcare systems also have a role in ensuring their staff are educated about biosimilar and interchangeable products. This includes general and product-specific education so that healthcare providers and, in turn, patients are aware of biosimilar treatment options. Peer-to-peer conversations between healthcare providers who prescribe and those considering prescribing biosimilars can also promote education and uptake. Educating patients is vital to increase medication compliance and uptake. Healthcare systems can assist education efforts by creating electronic medical records systems for use by prescribers and pharmacists, that follow patients, monitor outcomes, and generate data that can increase healthcare-provider confidence in biosimilar products.

59 See Luana Colloca & Franklin G. Miller, *The Nocebo Effect and Its Relevance for Clinical Practice*, 73 *Psychosom. Med.* 598-603 (2011), <https://pubmed.ncbi.nlm.nih.gov/21862825/>.

F. Panel 6: Biosimilar Disparagement as an Antitrust or Consumer Protection Cause of Action

Disparaging statements can take many forms. Panelists noted that such statements could suggest that: (1) the biosimilar does not, in fact, meet the statutory standard for biosimilarity; (2) although the biosimilar is highly similar to its reference product, a patient may react differently to the biosimilar than to the reference product; (3) only interchangeable products provide the same degree of safety and efficacy as the reference product; or (4) the biosimilar has different effects than the reference product.

In private actions, the Lanham Act enables competitors to sue those who make disparaging statements that are false or misleading.⁶⁰ However, panelists noted that the burden of proof is higher to prove misleading claims than under the FTC Act and that the Lanham Act offers few options for consumer plaintiffs. They also noted consumers could sue under state consumer-protection laws, either individually or as a class, but there are many challenges to doing so.

An antitrust claim grounded in Section 2 of the Sherman Act⁶¹ may provide an alternative, although courts do not adopt a consistent approach. Some courts reason that false statements increase competition in advertising markets, so disparagement cannot violate the antitrust laws. Other courts adopt a *de minimis* presumption, under which the plaintiff has the burden to rebut a presumption that any exclusionary effects of disparaging statements are *de minimis*. Yet other courts adopt a case-by-case approach, under which the factfinder considers the entirety of the evidence without employing any presumptions.

Panelists advocated for a new approach: If a plaintiff establishes both that the defendant has monopoly power in the relevant market and that the defendant's disparaging statements are false or misleading under the Lanham Act standard, those findings create a rebuttable presumption that the defendant has violated the antitrust laws.

⁶⁰ Lanham Act, 15 U.S.C §§ 1051-1141.

⁶¹ Sherman Act, 15 U.S.C. § 2.



G. Public Comments

1. Open Forum Comments

The *Federal Register* notice announcing the Workshop⁶² provided individuals an opportunity to register on a first-come, first-served basis to give a short oral presentation. Of the 19 registered speakers, 17 gave oral presentations during the Open Public Workshop Speaker session. The speakers represented organizations such as consumer, patient, and healthcare advocacy groups, industry and industry trade organizations, consultants, and public standards. Most comments made by the speakers concerned topics discussed during the Workshop.

Several speakers addressed regulatory requirements and processes. These included a request for FDA to consider the need for switching studies to support a demonstration of interchangeability⁶³ and the identification of certain biological products for which comparative effectiveness studies would not be necessary to support a demonstration of biosimilarity. FDA was asked to consider shortening the review clock to less than 6 months for supplements where biosimilar product applicants are seeking to add to an already approved application a condition of use that has been previously approved for the reference product.⁶⁴ FDA was also asked

⁶² 85 Fed. Reg. 6203 (Feb. 4, 2020).

⁶³ U.S. Food and Drug Admin., Guidance for Industry, *Considerations in Demonstrating Interchangeability with a Reference Product* (May 2019), *supra* note 38.

⁶⁴ U.S. Food and Drug Admin., Draft Guidance for Industry, *Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed* (February 2020), <https://www.fda.gov/media/134932/download>. When finalized, this guidance will represent FDA's current thinking on this topic.

to provide further guidance on use of the CBE-0 supplement⁶⁵ process for adding to the biosimilar labeling safety information recently approved for the reference product labeling.

In addition, FDA was asked to consider the need to add to the nonproprietary names of biological products a distinguishing suffix that is devoid of meaning and composed of four lowercase letters.⁶⁶ One speaker recommended that certain patent information for biological products be made publicly available, consistent with certain patent information for drug products being available in the Orange Book. Another speaker asked that information on manufacturing changes to U.S.-licensed biological products be publicly available to increase awareness that monitoring of biologic variation by analytical means is not a new concept for biological products.

Regarding FDA's draft guidance for industry, *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers*,⁶⁷ a speaker asked how the guidance would apply to Internet-marketing platforms and “brand-connected ads.”⁶⁸

Several speakers requested consideration of anticompetitive practices, such as non-medical switching of patients by payers, step-therapy practices, variable coverage and payment policies, rebate walls, and patent litigation and settlements. Speakers recommended that FDA and FTC support the growing biosimilar market through patient-centric policy decisions and efforts to safeguard competitive market dynamics.

Some speakers expressed the belief that currently available biosimilars and interchangeable products are, and those that become available in future will be, accepted by the healthcare community. A few speakers addressed the enhancement of stakeholder confidence in biosimilars by means of educational outreach. Negative information about biosimilar and interchangeable products could be combatted by an FDA educational program targeting healthcare professionals and patients. Such an educational program would promote the adoption of such products.

65 A supplement, changes-being-effected (CBE-0), proposes changes that do not require FDA approval prior to distribution of the product; for such changes, the application holder may distribute the product with the changes upon FDA's receipt of the supplement and before FDA has reviewed or approved the supplement. See 21 C.F.R. §§ 314.70(c)(6), 601.12(f)(2).

66 U.S. Food and Drug Admin., *Guidance for Industry, Nonproprietary Naming of Biological Products* (January 2017), <https://www.fda.gov/media/93218/download>; Draft Guidance for Industry, *Nonproprietary Naming of Biological Products: Update* (March 2019), <https://www.fda.gov/media/121316/download>. When finalized, the draft guidance will represent FDA's current thinking on this topic.

67 U.S. Food & Drug Admin., Draft Guidance for Industry, *Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers* Guidance for Industry, *supra* note 42.

68 The speaker described “brand-connected ads” as “ads that do not mention any brand within the ad itself but then link directly to a brand.com website.” See page 299 of the workshop transcript (<https://www.fda.gov/media/136791/download>).

2. Written Comments

FDA and FTC staff read and considered the 17 written public comments submitted to the docket for the Workshop.⁶⁹ Public comments were submitted by a range of stakeholder organizations, including health insurance plans, biopharmaceutical companies, employer groups, unions, and consumer advocates. The comments focused on the benefits of robust competition and factors that can impact market acceptance and competition from biosimilar and interchangeable products. Generally, the commenters urged greater FTC enforcement to stop or deter the various market abuses, as well as proactive guidance from FDA on interchangeability, the use of real-world evidence, and study waivers.

All of the commenters recognized that competition from a robust biosimilar industry can improve Americans' access to affordable biological products while generating tens of billions of dollars in savings over the next decade.⁷⁰ Most commenters urged FDA and FTC to continue working on issues of disparagement and misinformation that impact biosimilar uptake and competition. Other commenters urged the agencies to consider the impacts of business strategies that increase barriers to entry to biosimilar competition and do more to address these barriers. They encouraged action to reduce these barriers, including by 1) clarifying regulatory approval standards for interchangeable products, 2) addressing patent litigation considerations, 3) eliminating drug rebating linked to formulary access strategies, and 4) addressing the confusion generated by labeling carve-outs and the utility of adding a distinguishing suffix that is devoid of meaning and composed of four lowercase letters to the nonproprietary names of biological products. A comment submitted by a consortium of consumer groups emphasized the commercial barriers to biosimilar competition created by rebate walls or traps, sample blockage, patent thickets, pay-for-delay agreements, prior authorization, and formulary placement issues.⁷¹

69 U.S. Food & Drug Admin., FDA/FTC Workshop on a Competitive Marketplace for Biosimilars; Public Workshop; Request for Comments, Dkt. No. FDA-2019-N-6050, <https://www.regulations.gov/docket/FDA-2019-N-6050>.

70 *Id.*

71 Public comment filed jointly by the U.S. PIRG Education Fund, Services Employees International Union, American Federation of State, County, and Municipal Employees, American Federation of Teachers, UNITE HERE, Consumer Action, Doctors for America, Social Security Works, Treatment Action Group, and Coalition to Protect Patient Choice (April 9, 2020).



IV. Conclusion

The FDA/FTC workshop highlighted serious concerns about false or misleading communications regarding reference, biosimilar, and interchangeable products, and the potential for such communications to negatively affect public health, patient access, and competition. False or misleading comparisons of reference products and biosimilar products may constitute unfair or deceptive practices that undermine confidence in biosimilar products. Educational resources directed to consumers, patients and healthcare providers, among others, were identified as a key means to help counter false or misleading communications. Both agencies strive to ensure that all Americans have affordable access to the medications they need, and that healthcare providers, patients, payers, and others receive truthful and non-misleading information about biological products.

V. Appendix

A. Joint Statement

Joint Statement of the Food & Drug Administration and the Federal Trade Commission regarding a collaboration to advance competition in the biological product marketplace. February 3, 2020: <https://www.fda.gov/media/134864/download> or https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdaftcbiologicsstatement.pdf.

B. Workshop Materials

1. Workshop materials—including the Federal Register notice, agenda, speaker biographies, transcript, and webcast recording—can be found at the following websites:
 - a) <https://www.ftc.gov/news-events/events-calendar/fda-ftc-workshop-competitive-marketplace-biosimilars>
 - b) <https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020-03092020>
2. Presentations
 - a) The presentations are available for download as a single file at: <https://www.regulations.gov/document/FDA-2019-N-6050-0002>.

C. Public Comments

1. Comments submitted to the docket can be found at www.regulations.gov, docket number FDA-2019-N-6050.
2. Public comments presented at the Workshop can be found in the meeting transcript beginning on page 255. The transcript has been posted to the FDA website at: <https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020-03092020>.



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