UNITED STATES
FOOD AND DRUG ADMINISTRATION

Considerations in Demonstrating Interchangeability with a Reference Product: Update; Draft Guidance for Industry	Docket No. FDA-2017-D-0154

COMMENT OF THE UNITED STATES
FEDERAL TRADE COMMISSION

I. Introduction

The Federal Trade Commission ("FTC" or "the Commission") and the Food and Drug Administration ("FDA") have a long history of collaborative efforts to support competition and non-deceptive advertising in pharmaceutical markets upon which American consumers depend for life-saving treatments.[1] The FTC is an independent agency charged by Congress with enforcing competition and consumer protection laws.[2] The FTC exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry and it has substantial experience evaluating generic drug and biosimilar marketplaces.[3]

In 2010, Congress enacted the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") to provide more treatment options, increase access to lifesaving medications, and lower healthcare costs by fostering competition among biologic treatments.[4] Since that time, biologics have transformed the treatment of many illnesses, including chronic bowel diseases, kidney diseases, arthritis, and cancer, and they are the fastest growing class of medications in the United States. The FDA has approved many biosimilar drugs, increasing patient access to lifesaving medications at potentially lower costs and saving the U.S. healthcare system and the patients it serves over $24 billion since 2015.[5]

Despite these gains, biologics remain expensive and biosimilar uptake remains low, with the average market share for biosimilars hovering below 20% in many markets following biosimilar entry.[6] Increasing the number of biologics that are designated as "interchangeable" could improve competition and uptake for biosimilars. When the FDA designates a biosimilar product as "interchangeable," pharmacists can substitute that product for a biologic without

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[1] *See* FDA & Fed. Trade Comm'n, *Summary Report on the FDA/FTC Workshop on a Competitive Marketplace for Biosimilars* (March 9, 2020), at 3, https://www.ftc.gov/system/files/ftc_gov/pdf/fda-ftc-workshopbiosimilars-summaryreport.pdf.

[2] 15 U.S.C. §§ 41–58.

[3] For a summary of FTC's enforcement actions in the pharmaceutical industry, *see* Bradley S. Albert, et al., Overview of FTC Actions in Pharm. Products and Distrib., Fed Trade Comm'n (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.

[4] Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010).

[5] Association for Accessible Medicines, *The U.S. Generic and Biosimilar Medicines Savings Report*, (Sept. 2023) at 27, https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[6] *Id.* at 29; *see also* IQVIA, *Biosimilars in the United States 2020-2024:Competition, Savings and Sustainability*, at 2 (Oct. 2020), https://www.fdanews.com/ext/resources/files/2020/iqvia-biosimilars-in-us.pdf?1602088219 ("Biologics represent 43% of invoice-level medicine spending in the United States, reaching $211 billion in 2019, and growing at a 14.6% compound annual growth rate (CAGR) over the past five years. This compares to a 6.1% CAGR for the total market comprising small molecules, biologics, and biosimilar competitors.").

prescriber intervention, consistent with state law.[7] Yet, of the 56 biosimilar products approved by the FDA as of July 1, 2024, only 13 are designated as interchangeable.[8]

On June 21, 2024, the FDA issued a Federal Register Notice requesting public comment on updated draft guidance to industry regarding considerations in demonstrating interchangeability with a reference product ("Draft Guidance").[9] The Draft Guidance removes the recommendation that a biosimilar applicant submit clinical switching studies to demonstrate that a biosimilar is interchangeable with the reference product.[10] Instead, the applicant may submit a statement explaining why the existing data in the biologic license application supports the FDA designation of "interchangeable."[11]

As discussed below, the FDA's Draft Guidance would provide flexibility to expedite the approval process. The Commission believes that, if the FDA's guidance is implemented, the guidance would likely have a positive impact on the number of biosimilars designated as interchangeable and on the uptake of biosimilar products by reducing barriers to entry and increasing competition among biologic products. In addition, the Draft Guidance provides welcome clarity surrounding interchangeable designations to reduce marketplace confusion about the safety and efficacy of interchangeable biosimilars as compared to other biologic products.[12]

II. The FTC's Interest in the Draft Guidance

Competition brings substantial benefits to consumers through lower prices, greater access to higher quality goods and services, and increased innovation. In healthcare markets, competition benefits patients 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

[7] *See* Sophia Humphreys, *Understanding Interchangeable Biosimilars at the Federal and State Levels*, 29 Evidence-Based Oncology 7 at SP545 (Aug 16, 2023) https://www.ajmc.com/view/understanding-interchangeable-biosimilars-at-the-federal-and-state-levels ("In total, 47 of the 50 states allow pharmacist substitution of the prescribed reference product to an interchangeable biosimilar without the authorization of the physician, provided that this is communicated back to the prescribing physician and/or patient.").

[8] *See* U.S. Dep't Health & Hum. Servs., Food & Drug Admin. [hereinafter "FDA"], *Biosimilar Product Information*, https://www.fda.gov/drugs/biosimilars/biosimilar-product-information; *see also* Press Release, FDA, *FDA Updates Guidance on Interchangeability*, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-guidance-interchangeability.

[9] FDA, Notice of *Considerations in Demonstrating Interchangeability with a Reference Product: Update; Guidance for Industry*, 89 Fed. Reg. 52060 (June 21, 2024), https://www.federalregister.gov/documents/2024/06/21/2024-13429/considerations-in-demonstrating-interchangeability-with-a-reference-product-update-draft-guidance.

[10] FDA, *Considerations in Demonstrating Interchangeability with a Reference Product: Update; Guidance for Industry* [hereinafter "Draft Guidance"] at 3, https://www.fda.gov/media/179456/download.

[11] Draft Guidance at 4.

[12] The FTC takes no position on whether the Draft Guidance would affect the FDA's ability to ensure the safety or efficacy of any particular biosimilar product, as that is an area outside our core expertise.

healthcare goods and services.[13] Congress has taken action to foster competition in markets for life-saving treatments that the FDA deems are safe and effective. For instance, to facilitate increased competition in the pharmaceutical industry, the 1984 Hatch-Waxman Amendments created an abbreviated approval process for generic versions of small molecule drugs. This legislation, coupled with widespread adoption of state substitution laws,[14] spurred competition from generic drugs that has saved hundreds of billions of dollars in drug costs.[15]

Yet for competition to deliver these benefits, the Commission must act to prevent anticompetitive conduct that undermines that competition. The FTC has a long history of addressing illegal conduct that interferes with competitive and robust marketplaces for generic and biosimilar products.[16] For example, the FTC has enforced U.S. antitrust laws to prevent anticompetitive reverse-payment agreements between pharmaceutical brand and generic companies, which can arise when parties settle patent disputes with the brand company paying its would-be generic competitor to drop the challenge and stay off the market.[17] The FTC has also taken aim against brand companies that may be engaged in other unfair methods of competition, including sham patent litigation,[18] anticompetitive loyalty programs that impede generic entry,[19] and product hopping schemes that preserve monopoly profits on a patented product by making modest reformulations that offer little or no therapeutic advantages and deprive the public of the benefits of generic competition.[20] More recently, the FTC has been

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[13] FDA & Fed. Trade Comm'n, *Summary Report on the FDA/FTC Workshop on a Competitive Marketplace for Biosimilars* (March 9, 2020), at 2, https://www.ftc.gov/system/files/ftc_gov/pdf/fda-ftc-workshopbiosimilars-summaryreport.pdf.

[14] A 1979 FTC staff report studied the effects of state "anti-substitution" laws, which prevented pharmacists from dispensing a lower-cost generic drug unless the physician specifically prescribed the drug by its non-proprietary name. The FTC published staff's empirical findings, along with a model state law developed with the FDA, to assist states in reforming their regulations to promote competition and facilitate consumer access to lower cost generic drugs. *See* Fed. Trade Comm'n, *Staff Report to the Federal Trade Commission on Drug Product Selection* (1979), https://www.ftc.gov/reports/staff-report-drug-product-selection; *see also* Fed. Trade Comm'n , *Staff Report of the Bureau of Economics, Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (1985), https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economiceffects-state-drug-product-selection-laws/massonsteiner.pdf.

[15] Association for Accessible Medicines, *The U.S. Generic and Biosimilar Medicines Savings Report* (Sept. 2023), at 8, https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf ("Annual savings from generics and biosimilars exceeded $408 billion in 2022.").

[16] Albert, et al., Overview of FTC Actions in Pharm., *supra* note 2.

[17] *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

[18] Complaint, *FTC v. AbbVie Inc.*, No. 2:14-cv-05151 (E.D. Pa. filed Sept. 26, 2014), https://www.ftc.gov/system/-files/documents/cases/140908abbviecmpt1.pdf.

[19] Amended Complaint, *FTC v. Syngenta Corp.*, No. 1:22-cv-00828 (M.D.N.C. filed Dec. 23, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/amended_complaint_public_redacted.pdf; *see also* Federal Trade Comm'n, *Report on Rebate Walls* (May 2021), https://www.ftc.gov/reports/federal-trade-commission-report-rebate-walls (explaining that rebate walls may give payers strong incentive to block patient access to lower-priced products and may violate the antitrust laws).

[20] Joint Motion for Entry of Stipulated Order for Permanent Injunction and Equitable Monetary Relief and Dismissal, *FTC v. Indivior, Inc.*, No. 1:20-cv-00036 (W.D. Va. filed Jul. 24, 2020), ECF No. 3, https://www.ftc.gov/system/files/documents/cases/jt_mtn.pdf; Joint Motion for Entry of Stipulated Order for

scrutinizing brand drug companies' potentially improper listing of patents in the FDA's Orange Book, which can delay and deter entry of lower-cost generic and biosimilar competitors.[21] Further, the FTC has supported rulemaking efforts of the U.S. Patent Office to curtail brand drug firms' patent thicket strategies, which increase patent barriers to generic and biosimilar entry by misusing terminal disclaimers.[22]

In July 2024, the FTC's Interim Staff Report on Pharmacy Benefit Managers ("Interim Staff Report") identified conduct by other market participants that can inhibit robust competition in generic and biologic marketplaces. In response to orders issued by the FTC to study the business practices of Pharmacy Benefit Managers,[23] the largest PBMs provided documents and information concerning their influence on the drugs prescribed to patients, the pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Staff's initial review of agreements between brand drug companies and PBMs show rebate structures that may impede competition and patient access to affordable medicines such as generics and biosimilars.[24] Additionally, the Interim Staff Report discussed how vertical integration of PBMs with pharmaceutical manufacturers may distort PBMs incentives. For example, CVS Caremark made formulary changes for Humira and its biosimilars that resulted in a sharp increase in prescriptions for Hyrimoz, a biosimilar from CVS's own private label, even though Hyrimoz was

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Permanent Injunction and Equitable Monetary Relief and Dismissal, *FTC v. Reckitt Benckiser Group PLC*, No. 1:19-cv-00028 (W.D. Va. filed Jul. 11, 2019), ECF No. 2, https://www.ftc.gov/system/files/documents/cases/-reckitt_joint_motion_for_stipulated_order_7-11-19.pdf.

[21] Press Release, Fed. Trade Comm'n, *FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book* (Nov. 7, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book; Press Release, Fed. Trade Comm'n, *FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs* (Apr. 30, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma; *see also* Press Release, Fed. Trade Comm'n, *FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book'* (Sep. 14, 2023), https://www.ftc.gov/newsevents/news/press-releases/2023/09/ftc-issues-policy-statement-brandpharmaceutical-manufacturers-improper-listing-patents-food-drug ("The FDA appreciates and supports the FTC's efforts to examine whether brand drug companies are impeding generic drug competition by improperly listing patents in the Orange Book,' said FDA Commissioner Robert M. Califf, M.D.").

[22] Fed. Trade Comm'n, *Comment of the U.S. Fed. Trade Comm'n on the United States Patent and Trademark Office's Proposed Rulemaking on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting* (July 9, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-Comment-on-USPTO-Terminal-Disclaimer-NPRM-7-9-2024.pdf.

[23] Press Release, Fed. Trade Comm'n, *FTC Launches Inquiry Into Prescription Drug Middlemen Industry* (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

[24] Fed. Trade Comm'n, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middleman Inflating Drug Costs and Squeezing Main Street Pharmacies* [hereinafter "FTC Interim Staff Report"] (July 2024) at 66, https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; *see also* Fed. Trade Comm'n, *Report on Rebate Walls* (May 2021), https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf.

not the lowest price product.[25] Hyrimoz's share of prescriptions jumped from five percent to 35 to 45 percent of adalumimab products within a month.[26]

In addition to these efforts, the FTC has been working together with the FDA to help advance competition for biologics, including biosimilars and interchangeable biosimilars. On February 3, 2020, the FTC and the FDA issued a joint statement regarding collaborative efforts to advance competition in the biologic marketplace.[27] Among other things, this statement addressed the agencies' shared concerns about false or misleading statements and their impact on competition and public health.[28] As the Joint Statement explained, "false or misleading comparisons of reference products and biosimilars may constitute unfair or deceptive practices that undermine confidence in biosimilars."[29] Following this statement, the FDA and the FTC held a public workshop, entitled "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars,"[30] and later issued a joint report summarizing the workshop.[31] The 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."[32] The joint report concluded that "false or misleading comparisons of reference products and biosimilars may constitute unfair or deceptive practices that undermine confidence in biosimilars."[33]

The FTC is committed to ensuring that health care professionals and patients receive truthful and non-misleading information about biosimilar and interchangeable biosimilar products. The FTC's law-enforcement efforts against deceptive advertising deter the dissemination of misleading information, including claims about healthcare products and services, and enable consumers to make well-informed decisions.[34]

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[25] FTC Interim Staff Report at 27-28.

[26] FTC Interim Staff Report at 28.

[27] Fed. Trade Comm'n, *Joint Statement of the U.S. Food & Drug Admin and Fed. Trade Comm'n Regarding a Collaboration to Advance Competition in the Biologic Marketplace* [hereinafter "Joint Statement"] (Feb. 3, 2020), https://www.ftc.gov/legal-library/browse/joint-fda-ftc-statement-regarding-collaboration-advance-competition-biologic-marketplace.

[28] Joint Statement at 3.

[29] *Id.*

[30] FDA, Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars (March 9, 2020), https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020.

[31] FDA & Fed Trade Comm'n, Summary Report, *supra,* at note 11.

[32] *Id.* at 24.

[33] *Id.*

[34] *See, e.g.*, *In re POM Wonderful, LLC*, 155 F.T.C. 1 (2013), *aff'd in part*, *POM Wonderful LLC v. FTC*, 777 F.3d 478 (D.C. Cir. 2015) (deceptive treatment, prevention, and risk claims for heart disease, prostate cancer, erectile dysfunction, and other diseases); *In re Daniel Chapter One*, 148 F.T.C. 832 (2009) (deceptive cancer prevention, treatment, and cure claims), *aff'd,* 405 Fed. App'x 505 (D.C. Cir. 2010); *FTC v. Nat'l Urological Grp.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff'd*, 356 Fed. App'x 358 (11th Cir. 2009) (deceptive erectile performance and weight-

III. The Draft Guidance Supports Increased Competition in Biologic Marketplaces

In order for a biosimilar to be designated by the FDA as interchangeable, the applicant must show that its product "can be expected to produce the same clinical result as the reference product in any given patient," and that "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of 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 switch."[35] As noted earlier, when the FDA designates a biosimilar product as "interchangeable," pharmacists can substitute that product for a biologic without prescriber intervention, consistent with state law. This system of pharmacy-level drug substitution for generic and biosimilar drugs supports increased access to treatments and price competition.

Under existing guidance, the FDA recommends that biosimilar applicants provide clinical switching studies to demonstrate that the biosimilar can be interchangeable with the reference biologic.[36] In clinical switching studies, patients are treated with an alternating regimen of the reference product and the biosimilar, and then those patients are compared to patients who did not receive alternating treatment regimens.[37] Clinical switching studies can be time-consuming and expensive, and in the Draft Guidance the FDA has concluded that they are no longer recommended for applications seeking an interchangeable designation.[38]

Relying on clinical switching studies to establish interchangeability has likely contributed to marketplace confusion about biosimilars. The FDA itself has recognized that the distinction between biosimilars and interchangeable biosimilars creates confusion for patients and providers

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loss claims); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285 (D. Mass. 2008), 624 F.3d 1 (1st Cir. 2010) (deceptive prevention, treatment, and cure claims for cancer, Parkinson's disease, heart disease, diabetes, and autoimmune diseases such as multiple sclerosis and lupus); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir.) (deceptive pain relief claims); *In re Novartis Corp.*, 127 F.T.C. 580, 1999 WL 33913005 (May 13, 1999), *aff'd*, *Novartis Corp. v. FTC*, 223 F.3d 783 (D.C. Cir. 2000) (deceptive back pain remedy claims).

[35] Public Health Service Act ("PHS Act") §§ 351(k)(4)(A)(ii) and (k)(4)(B).

[36] Draft Guidance at 3, *supra* note 9 ("In the Interchangeability Guidance, the Agency recommended that applications or supplements seeking a determination of interchangeability include data from a switching study or studies to help provide the added assurance with respect to any immunogenicity risk associated with switching or alternating between the reference product and the proposed interchangeable biosimilar."). Switching studies are sometimes referred to as immunogenicity studies.

[37] *See* FDA, *FDA Review and Approval, "Are there additional data requirements for interchangeable biosimilar products?*", https://www.fda.gov/drugs/biosimilars/review-and-approval.

[38] Draft Guidance at 4 (explaining that over the last ten years the agency has gained further experience and confidence using current analytical technologies to evaluate the potential analytical differences between proposed biosimilar products and their reference products and to reliably characterize the structure of the products and predict their functional effect); *see also* Lauren Biscaldi, *Hurdles in Access: Costly Switch Studies Block Wider Biosimilar Use*, Drug Topics (May 2, 2024), https://www.drugtopics.com/view/hurdles-in-access-costly-switch-studies-block-wider-biosimilar-use.

about whether biosimilars are as safe and effective as other biologic products.[39] The FDA has sought to reassure the public that providers "don't have to wait for a biosimilar product to be approved as interchangeable to prescribe that product to patients."[40] As the FDA explained, "because the level of product quality and similarity, and of safety and efficacy is the same, biosimilars and interchangeables both can be used for patients."[41]

Both the FDA and the FTC have expressed serious concerns about false or misleading statements disparaging biosimilars and their safety and efficacy.[42] Disparagement and misinformation can increase provider and patient mistrust of and confusion about biosimilar and interchangeable products. False or misleading comparisons of reference products or biosimilars may constitute unfair or deceptive practices that undermine confidence in biosimilars and deter switching. Other recent FDA draft guidance explained that it would be false or misleading to suggest that a reference product is safer or more effective than a biosimilar product or that the different pathways to FDA approval impact the relative safety and effectiveness of the products.[43] By removing the recommendation of switching studies for interchangeable biosimilars, the Draft Guidance would help combat marketplace confusion about the safety and efficacy of biosimilars.

If implemented, this Draft Guidance would likely have a positive impact on the number of biosimilars designated as interchangeable and the uptake of biosimilar products in general by reducing barriers to entry and increasing competition in biologic marketplaces.[44] This is a step in the right direction to fully realizing the goals of the BPCIA to increase competition and innovation among biologics, which could lead to lower prices and increased choice for consumers who depend on these life-saving medicines.[45]

To the extent that this guidance is implemented, the Commission urges the FDA to provide further guidance on how already-approved non-interchangeable biosimilars may request an interchangeable designation. The Draft Guidance explains that applicants with a pending application for a proposed biosimilar can submit an amendment requesting an interchangeable designation based on the data submitted in the application.[46] But, as noted above, of the 56

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[39] FDA, *Switching Between Biosimilars and Their Reference Counterparts with Dr. Sarah Yim*, *Q&A with FDA*, (podcast transcript) (May 8, 2024), https://www.fda.gov/drugs/news-events-human-drugs/switching-between-biosimilars-and-their-reference-counterparts-dr-sarah-yim.

[40] *Id.*

[41] *Id.*

[42] Joint Statement at 3, *supra* note 25.

[43] FDA, *Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products*, (April 25, 2024), at 6-7, https://www.fda.gov/media/134862/download.

[44] In Europe, biosimilars have a decades-long history of safe switching, supporting increased competition and lower prices. S*ee, e.g.,* E. Allocati, et al, *Switching Among Biosimilars: A Review of Clinical Evidence*, 13 FRONTIERS IN PHARMACOL. 917814 (Aug. 24, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9449694.

[45] *See* FDA, *Biological Product Innovation and Competition* (last updated April 2024) https://www.fda.gov/drugs/biosimilars/biological-product-innovation-and-competition.

[46] Draft Guidance at 4, *supra* note 9.

biosimilar products approved by the FDA as of July 1, 2024, there are 43 that are not designated as interchangeable.[47] There is no guidance for how an already-approved biosimilar may request an interchangeable designation under the simplified process. Applying the draft guidance to all biosimilars, including already-approved products that treat conditions affecting large patient populations, such as insulins and Humira biosimilars, would support increased access to biosimilars and facilitate patient choice among safe and effective treatments.

Further, to ensure Americans receive the benefits of the increased access to interchangeable biosimilars that FDA's revised guidance would support, agencies must continue to be attentive to the risk that anticompetitive practices, if left unchecked, could foreclose or forestall such access. For example, the Commission's Interim Staff Report on Pharmacy Benefit Managers exposed that some brand pharmaceutical companies and PBMs are entering contracts that categorically prohibit insurance from reimbursing pharmacists who fill a prescription with a generic.[48] Contract terms like these can frustrate the intent of state drug substitution laws and undermine the goals of the BPCIA to increase competition and innovation among biologics.

IV. Conclusion

The Commission appreciates the FDA's commitment to help advance competition and a truthful marketplace for biologics, including biosimilars and interchangeable biosimilars. Biosimilars, and in particular interchangeable biosimilars, can improve access to biologic treatment options and potentially reduce costs for patients and the health care system through market competition. However, a competitive and robust marketplace for biologics is not a guarantee and must be supported by policies that facilitate entry and do not create confusion in the marketplace.

The Commission believes the FDA's revised guidance on interchangeability would reduce the burden and associated cost of showing that switching from a reference biologic to a biosimilar is safe and effective. This proposed change would lower barriers to entry, simplify the approval process, help to dispel the false impression of separate safety and efficacy standards for interchangeables and other biosimilars, and foster increased competition in biologic marketplaces. The Commission looks forward to continuing to work with the FDA to advance our agencies' shared goals of supporting the appropriate adoption of biosimilars, addressing false or misleading statements about these products, and stopping anticompetitive conduct in biologic markets.

[47] *See* FDA, *Biosimilar Product Information*, https://www.fda.gov/drugs/biosimilars/biosimilar-product-information; *see also* Press Release, FDA, *FDA Updates Guidance on Interchangeability*, https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-guidance-interchangeability.

[48] FTC Interim Staff Report at 68-70, *supra* note 22.