

AFFORDABLE PRESCRIPTIONS FOR PATIENTS THROUGH
PROMOTING COMPETITION ACT OF 2019

DECEMBER 24, 2020.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

Mr. NADLER, from the Committee on the Judiciary,
submitted the following

R E P O R T

[To accompany H.R. 5133]

The Committee on the Judiciary, to whom was referred the bill (H.R. 5133) to amend the Federal Trade Commission Act to prohibit anticompetitive behaviors by drug product manufacturers, and for other purposes, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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Purpose and Summary

H.R. 5133, the “Affordable Prescriptions for Patients Through Promoting Competition Act,” prohibits “product hopping,” a particularly abusive form of anti-competitive conduct used by drug manufacturers to protect and extend their monopolies on prescription drugs. Product hopping occurs when a branded drug manufacturer seeks to extend its market exclusivity on a drug for which its

patent is about to expire by switching doctors and patients from the old version to a new version, which may not offer any improvements in effectiveness or safety. This practice allows a pharmaceutical company to continue to reap monopoly profits by preventing generic substitution for its new, but not necessarily improved, version of the drug. The result can be years of additional market exclusivity for the pharmaceutical company without substantial improvements for patients in terms of effectiveness or safety.

H.R. 5133 will end this abusive delay tactic by expressly prohibiting product hopping as an unfair method of competition under the Federal Trade Commission Act. Public-interest organizations—including Public Citizen, Consumer Reports, Patients for Affordable Drugs Now, the Coalition for Affordable Prescription Drugs, and the Coalition Against Patent Abuse—support this bipartisan legislation.

Background and Need for the Legislation

BACKGROUND

Americans spend more on prescription drugs—about \$1,200 per person—than residents of any other developed country.¹ Total spending on prescription drugs in the United States is also growing,² rising to \$333.4 billion in 2017.³ Americans also pay more out-of-pocket for prescription drugs than for hospital care or health insurance.⁴

The role of biological products in rising drug costs is particularly striking. A biological product, or biologic—a pharmaceutical derived from living organisms⁵—is significantly larger and has a more complex structure than a conventional chemically derived, small-molecule drug, and it is inherently more costly to develop, more difficult to manufacture, and more expensive per dose.⁶ These dynamics are reflected in high costs and spending totals. In 2018, net spending on biologics totaled \$125.5 billion in the United States,⁷ and annual costs for some biologics can exceed \$250,000 per patient.⁸

¹OECD, *Pharmaceutical Spending* (last accessed on Mar. 1, 2019), <https://data.oecd.org/healthres/pharmaceutical-spending.htm>.

²*A Look at Drug Spending in the U.S.: Estimates and Projections from Various Stakeholders*, PEW CHARITABLE TRUSTS (Feb. 27, 2018), <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/02/a-look-at-drug-spending-in-the-us>.

³*National Health Expenditure Data: NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 20, 2019), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html>.

⁴Yusra Murad, *As Drug Prices Soar, Policymakers Eye Dose of Government Intervention*, MORNING CONSULT (Dec. 20, 2018), <https://morningconsult.com/2018/12/20/drug-prices-soar-policymakers-eye-dose-government-intervention/>.

⁵Kristina M. Lybecker, *The Biologics Revolution in the Production of Drugs* 3 (2016), <https://www.fraserinstitute.org/sites/default/files/biologics-revolution-in-the-production-of-drugs.pdf>; see 42 U.S.C. § 262(i)(1).

⁶Kristina M. Lybecker, *The Biologics Revolution in the Production of Drugs* 3, 7 (2016), <https://www.fraserinstitute.org/sites/default/files/biologics-revolution-in-the-production-of-drugs.pdf>; Andrew W. Mulcahy et al., *The Cost Savings of Potential Biosimilar Drugs in the United States* 1 (2014), https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

⁷MURRAY AITKEN & MICHAEL KLEINROCK, *MEDICINE USE AND SPENDING IN THE U.S.: A REVIEW OF 2018 AND OUTLOOK TO 2023* 26 (2019), <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>.

⁸Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. AM. MED. ASS'N 858, 860 (2016).

Anti-competitive conduct in the pharmaceutical industry harms American consumers through higher drug prices and worse healthcare outcomes. Delaying entry of generic and biosimilar competitors deprives consumers of the lower prices that competition brings to the market. For some consumers, these delays could mean the difference between life and death. As a result of rising prices, many patients skip doses, take less than the prescribed amount of medicine, or do not fill their prescriptions.⁹ According to a study by Kaiser Health News, “[h]undreds of thousands of cancer patients are delaying care, cutting their pills in half or skipping drug treatment entirely.”¹⁰

While decreased competition from generics and biosimilars harms patients, delayed generic entry for a blockbuster drug—even by just a few months—can be worth hundreds of millions of dollars in additional revenue to the branded drug company. For example, the Hepatitis C drug, Sovaldi, reached \$7.9 billion in sales in the United States in 2014.¹¹ At that rate, three additional months would constitute \$1.98 billion in sales.¹² Because branded drug manufacturers have so much to lose from the entry of a generic competitor, they are highly incentivized to block or delay generic entry. Product hopping is one way, among others, that they achieve this—to the detriment of consumers who end up paying higher prescription drug prices.

Product hopping occurs when a branded drug manufacturer seeks to extend its market exclusivity on a drug for which its patent is about to expire by switching doctors and patients from the old version to a new version, which may not offer any improvements in effectiveness or safety. Branded drug manufacturers can accomplish a product hop through what is often referred to as either a hard switch or a soft switch. In the case of a hard switch, the branded drug manufacturer may remove the original drug from the market entirely and replace it with a new product covered by a later-expiring patent, also referred to as a follow-on product.¹³ The manufacturer may even buy back and destroy any of the original drug product that remains in the supply chain. In the case of a soft switch, the branded drug manufacturer may impede the original product’s ability to compete with the follow-on product through more subtle means.¹⁴ In either case, leading experts have noted that the branded drug manufacturer’s conduct threatens to undermine the generic-promoting goals of the Hatch-Waxman Act through a switch to a reformulation for which a generic cannot be automatically substituted.¹⁵ As Professor Michael Carrier and

⁹Liz Szabo, *Sticker Shock Forces Thousands of Cancer Patients To Skip Drugs, Skimp On Treatment*, KAISER HEALTH NEWS (Mar. 15, 2017), <https://khn.org/news/sticker-shock-forces-thousands-of-cancer-patients-to-skip-drugs-skimp-on-treatment/>.

¹⁰*Id.*

¹¹Lacie Glover, *Here Are the Top-Selling Drugs in the US*, TIME (June 26, 2015), <http://time.com/money/3938166/top-selling-drugs-sovaldi-abilify-humira/>.

¹²Although competition would not reduce the sales to zero, a price drop of even a modest 10% would be worth \$198 million for three months.

¹³*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), <https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf> (written testimony of Dr. Aaron S. Kesselheim, Associate Professor of Medicine, Harvard Medical School, at 7).

¹⁴*See, e.g.*, In re Suboxone Antitrust Litigation, 64 F. Supp. 3d 665 (E.D. Pa. 2014).

¹⁵*See, e.g.*, Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171 n.3 (2016); *see id.* at 217–18 (providing examples of generic

Steve Shadowen explain, such conduct “lacks innovation-based justifications because the brand does not build up the prescription base by competing with other brands or expanding the market, but merely leverages already-gained power solely by blocking generic entry.”¹⁶

An example of a hard switch involves Forest Laboratories, which sold memantine, also known as Namenda.¹⁷ Namenda is an immediate-release treatment for Alzheimer’s that must be taken twice daily.¹⁸ Before its patent expired, allowing a generic version of Namenda to come on the market, Forest obtained FDA approval for a new, patented version of the drug (memantine XR). This version of Namenda was extended-release instead of instant and only had to be taken once daily instead of twice.¹⁹ Forest announced that it intended to remove the original version of Namenda (memantine) from the market.²⁰ Forest’s removal of the original product from the market would have forced doctors to switch patients from the original (memantine) to the follow-on product (memantine XR), eliminating the possibility of automatic substitution of a lower-priced generic.²¹

An example of a soft switch can be seen in the case of *In re Suboxone Antitrust Litigation*.²² In that case, the plaintiffs alleged that Reckitt switched the market from a tablet form of Suboxone, a drug that treats opioid dependence, to a sublingual film.²³ The plaintiffs alleged that Reckitt promoted the Suboxone film to doctors, disparaged the tablet version of Suboxone, issued false warnings about safety concerns related to the tablets, announced plans to remove the tablets because of these false safety concerns, and raised the price of the tablets relative to the film even though the film was more expensive to make.²⁴ In this case, Reckitt attempted to shift the market without going so far as to withdraw the tablet version from the market.

APPLICABLE LAWS

The federal antitrust laws preserve competition by preventing cartelization, monopolization, and mergers or acquisitions that may substantially lessen competition or tend to create a monopoly. The first major federal antitrust statute was the Sherman Antitrust Act of 1890.²⁵ Section 1 of the Sherman Act prohibits competitors from colluding or conspiring with each other to restrain trade by reducing their overall output or raising prices.²⁶ Section 2 of the Sherman Act prohibits any individual competitor from unilaterally and

making 2% of sales after hard switch, 25% after soft switch, but 85% in absence of product hopping).

¹⁶*Id.*
¹⁷*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), <https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf> (testimony of Dr. Aaron S. Kesselheim, Associate Professor of Medicine, Harvard Medical School, at 7).

¹⁸*Id.*

¹⁹*Id.*

²⁰*Id.*

²¹*Id.*

²²64 F. Supp. 3d 665 (E.D. Pa. 2014).

²³Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 195 (2016).

²⁴*Id.*

²⁵15 U.S.C. §§ 1–7 (2019).

²⁶15 U.S.C. § 1 (2019).

willfully obtaining or maintaining control of an industry through the use of exclusionary conduct.²⁷

In 1914, Congress established the Federal Trade Commission (FTC) to promote, develop, and protect antitrust law and competition policy.²⁸ Section 5 of the FTC Act empowers the Commission to prevent all “[u]nfair methods of competition in or affecting commerce”²⁹ Although the FTC has no authority to enforce the Sherman Act, the Supreme Court has held that any conduct that violates the Sherman Act also violates section 5 of the FTC Act.³⁰ Section 5 may also reach conduct that does not violate the Sherman or Clayton Acts.³¹ The FTC Act empowers the FTC to: (a) prevent unfair methods of competition, and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; (c) prescribe trade regulation rules defining with specificity acts or practices that are unfair or deceptive, and establishing requirements designed to prevent such acts or practices; (d) conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce; and (e) make reports and legislative recommendations to Congress.³²

NEED FOR THE LEGISLATION

H.R. 5133 is needed to strengthen the FTC’s ability to bring and win cases against prescription drug companies that engage in product hopping. Although some courts have held branded drug manufacturers accountable for engaging in product hopping under existing antitrust law, other courts have let companies off the hook. For example, in *Mylan Pharmaceuticals v. Warner Chilcott (Doryx)*,³³ the Third Circuit Court of Appeals affirmed a district court decision that Warner Chilcott’s product hopping strategy was not anti-competitive. The court of appeals reached this outcome despite a district court finding that “viewing the facts in the light most favorable to Mylan, [] Defendants had indeed made the Doryx ‘hops’ primarily to ‘delay generic market entry.’”³⁴ The law on what constitutes illegal product hopping activity, particularly for soft switches, is conflicting and unsettled. H.R. 5133 is needed to clarify that it is illegal for drug manufacturers to engage in this conduct to the detriment of patients.

Furthermore, H.R. 5133 is needed to improve the agency’s ability to bring and win cases against companies that use product hopping

²⁷ 15 U.S.C. § 2 (2019).

²⁸ *Humphrey’s Ex’r v. United States*, 295 U.S. 602, 625–26 (1935) (“[T]he language of the act, the legislative reports, and the general purposes of the legislation as reflected by the debates, all combine to demonstrate the congressional intent to create a body of experts who shall gain experience by length of service; a body which shall be independent of executive authority, except in its selection, and free to exercise its judgment without the leave or hindrance of any other official or any department of the government.”).

²⁹ 15 U.S.C. § 45(a)(1) (2019).

³⁰ *Fed. Trade Comm’n v. California Dental Ass’n*, 526 U.S. 756, 763 n.3 (1999) (“The FTC Act’s prohibition of unfair competition and deceptive acts or practices . . . overlaps the scope of § 1 of the Sherman Act.”).

³¹ *See Fed. Trade Comm’n v. Sperry & Hutchinson Co.*, 405 U.S. 233, 239 (1972) (holding that section 5 empowers the FTC “to define and proscribe an unfair competitive practice, even though the practice does not infringe either the letter or the spirit of the antitrust laws”).

³² 15 U.S.C. § 45 (2019).

³³ *Mylan Pharmaceuticals v. Warner Chilcott*, 838 F.3d 421 3d Cir. 2016).

³⁴ *Id.* at 431. For criticism of the decision, see Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 SANTA CLARA L. REV. 613, 620–21 (2020) (noting that court “focused exclusively on the effect of [the brand firm’s] conduct on . . . the generic competitor, never even mentioning the effect on consumers”) (emphases omitted).

to block generic or biosimilar competitors from entering the market. Litigation under existing law is extremely resource-intensive in terms of time and money. Even when the FTC is ultimately successful, as it was in the Supreme Court’s decision in *Actavis* on pay-for-delay agreements,³⁵ litigation can take too long to provide timely relief. The *Actavis* case was not fully resolved until a decade after the FTC filed its original complaint.³⁶ As Markus Meier, then-acting director of the FTC’s Bureau of Competition testified before Congress, “litigation . . . can be slow, it’s expensive, and it’s uncertain.”³⁷ By more clearly defining the conduct that constitutes illegal product hopping and establishing a framework for evaluating possible justifications, H.R. 5133 will help deter companies from engaging in this behavior in the first place. In addition, by providing clearer guidance to the courts, when the FTC must go to court and litigate a product hop case, this bill should help expedite those proceedings.

Hearings

In the 116th Congress, the Subcommittee on Antitrust, Commercial, and Administrative Law held a hearing on “Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets.”³⁸ At this hearing, several witnesses testified about competition issues in health care markets, including Dr. Fiona Scott Morton, Professor of Economics at Yale School of Management; Dr. Martin Gaynor, Professor of Economics and Health Policy at Carnegie Mellon University; Michael Kades, Director of Markets and Competition Policy at Washington Center for Equitable Growth; and Dr. Craig Garthwaite, Herman R. Smith Research Professor at Northwestern University’s Kellogg School of Management. This hearing satisfies the requirement of H. Res. 6, sec. 103(i).

In the 115th Congress, the Subcommittee on Regulatory Reform, Commercial, and Antitrust Law held a two-paneled hearing on “Antitrust Concerns and the FDA Approval Process.”³⁹ On the first panel, the Subcommittee heard testimony from Dr. Scott Gottlieb, M.D., then-Commissioner of the U.S. Food and Drug Administration (FDA), and Markus Meier, then-Acting Director, Bureau of Competition at the FTC. On the second panel, the Subcommittee heard testimony from Professor David Olson, Boston College Law School; Professor Erika Lietzan, University of Missouri School of Law; Alden Abbott, Deputy Director and Senior Legal Fellow, the Heritage Foundation; and Professor Aaron Kesselheim, M.D., M.P.H., Harvard Medical School. Dr. Kesselheim described various examples of product hopping and testified that “[p]roduct hopping

³⁵ *Fed. Trade Comm’n v. Actavis, Inc.*, 570 U.S. 136, 158 (2013).

³⁶ *Complaint, Fed. Trade Comm’n v. Watson Pharm., Inc.*, CV 09–00598 (C.D. Cal. Jan. 29, 2009), https://www.ftc.gov/sites/default/files/documents/cases/2009/02/090202androgelcmpt_0.pdf.

³⁷ *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), <https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Transcript-20170727.pdf> (testimony of Markus Meier, Acting Director, Bureau of Competition and Assistant Director, Health Care Division, FTC).

³⁸ *Id.*

³⁹ *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), <https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Transcript-20170727.pdf>.

is especially problematic when the manufacturer removes the original drug from the market shortly before its patent term expires to channel physicians, consumers, and payors towards its new product.”⁴⁰ Dr. Kesselheim continued, “The manufacturer’s conduct in these cases typically makes sense only by harming the generic.”⁴¹

Committee Consideration

On November 20, 2019, the Committee met in open session and ordered the bill, H.R. 5133, favorably reported by unanimous voice vote, a quorum being present.

Committee Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that no rollcall votes occurred during the Committee’s consideration of H.R. 5133.

Committee Oversight Findings

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

New Budget Authority and Tax Expenditures and Congressional Budget Office Cost Estimate

With respect to the requirements of clause 3(c)(2) of rule XIII of the Rules of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 and with respect to requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has requested but not received a cost estimate for this bill from the Director of Congressional Budget Office. The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

Duplication of Federal Programs

No provision of H.R. 5133 establishes or reauthorizes a program of the Federal government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

Performance Goals and Objectives

The Committee states that pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 5133 would

⁴⁰*Id.* (written testimony of Dr. Aaron S. Kesselheim, Associate Professor of Medicine, Harvard Medical School, at 6–7).

⁴¹*Id.* at 7.

make prescription drugs more affordable for patients and increase competition in the prescription drug market by strengthening the FTC’s ability to bring and win cases against drug companies that engage in product hopping.

Advisory on Earmarks

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 5133 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

Section 1. Short Title. Section 1 sets forth the title of the legislation as the “Affordable Prescriptions for Patients Through Promoting Competition Act of 2019.”

Section 2. Product Hopping. Section 2 amends the Federal Trade Commission (FTC) Act by adding a new Section 27 to the FTC Act after Section 26 (15 U.S.C. § 57(c-2)).

New subsection 27(a) sets forth various definitions.

New subsection 27(a)(4) defines “follow-on product” broadly to cover a drug or biological product which shares an indication, in whole or in part, with the listed drug or reference product.

New subsections 27(a)(4)(B)–(D) identify the types of applications or supplements to an application for the new version of the drug or biological product that are excluded from the definition of a “follow-on product.” Subsection 27(a)(4)(B) establishes a narrow exclusion for the specified application or supplement to an application that is requested by the Secretary or necessary to comply with law.

New subsection 27(a)(4)(C) establishes a narrow exclusion when the FDA has granted New Chemical Entity (NCE) exclusivity for the individual application or supplement to an application for the new version of the drug or biological product. This exclusion applies to follow-on products that have been granted NCE exclusivity independent of the listed drug or reference product (original drug) application to which it is a supplement. Whether or not the original drug or biological product was granted NCE exclusivity would not affect whether a product qualifies for this exclusion.

New subsection 27(a)(4)(D) establishes a narrow exclusion for the specified application or supplement to an application that has been granted exclusivity pursuant to section 351(k)(7) of the Federal Food, Drug, and Cosmetic Act.

New subsection 27(a)(6) defines the term “disadvantage” to encompass actions that impede the original drug’s ability to compete on the merits with the follow-on product by creating an obstacle or hindrance to the marketing, sale, or distribution of the original drug.

New subsections 27(a)(6)(A) and (B) establish narrow exclusions from the definition of “disadvantage,” for actions that consist solely of either (1) truthful, non-misleading advertising; or (2) ceasing promotional marketing for the listed drug or reference product. These subsections do not exclude actions that misrepresent or obscure information about the existence, identity, availability, or effi-

cacy of the listed drug or reference product such as the manufacturer removing the product from the list of available drugs on its website.

New subsection 27(b)(1) establishes that a manufacturer of a reference product or listed drug shall be liable for engaging in an unfair method of competition under section 5(a) of the FTC Act if the Commission demonstrates that the manufacturer engaged in a hard switch, as set forth in subsection 27(b)(1)(A), or a soft switch, as set forth in subsection 27(b)(1)(B) during a specified time period. This time period begins when the manufacturer first receives notice that a new drug applicant has submitted an abbreviated new drug application (ANDA) or a biosimilar biological product license application. The time period ends on the date that is the earlier of 180 days after the generic or biosimilar drug referencing the listed drug or reference product is first marketed or 3 years after the manufacturer's follow-on product is first marketed.

New subsection 27(b)(1)(A) establishes that a manufacturer engaged in a hard switch if the Commission demonstrates that the manufacturer engaged in the actions described in subsections 27(b)(1)(A)(i) or 27(b)(1)(A)(ii).

Under subsection 27(b)(1)(A)(i), the actions that constitute a hard switch are that upon the manufacturer's request, the Commissioner of Food and Drugs withdrew the approval of the listed drug's or reference product's application or placed the drug on the discontinued products list, and the manufacturer marketed or sold a follow-on product. Under subsection 27(b)(1)(A)(ii), the actions that constitute a hard switch are, first, that the manufacturer ceased providing a supply of the listed drug or reference product to the marketplace for commercial distribution or sale by withdrawing, discontinuing the manufacture of, or withdrawing the application for the listed drug or reference product in a way that impedes competition from a generic or biosimilar drug (unless this was done in response to a request from the Commissioner of Food and Drugs) and, second, marketed or sold a follow-on product.

An alternate set of actions that constitute a hard switch, under subsection 27(b)(1)(A)(ii), are that, first, the manufacturer destroyed its inventory of the listed drug or reference product in a way that impedes competition from a generic or biosimilar drug and, second, marketed or sold a follow-on product.

New subsection 27(b)(1)(B) sets forth that a manufacturer engaged in a soft switch if the Commission establishes that, first, the manufacturer took one or more actions with respect to the listed drug or reference product that unfairly disadvantage that drug relative to the manufacturer's follow-on product in a way that impedes competition from either a generic or biosimilar drug and, second, the manufacturer marketed or sold a follow-on product. A manufacturer "unfairly" disadvantages the listed drug or reference product where the manufacturer has not demonstrated a justification under subsection 27(b)(2)(A) or where that justification has been rebutted by the Commission's Response.

New subsection 27(b)(2) sets forth certain justifications that a manufacturer can offer for engaging in either a hard or soft switch. For both, the manufacturer first must prove that it would have taken the actions regardless of whether the corresponding generic or biosimilar drug had already entered the market. For a hard

switch, in addition to the first part, the manufacturer must prove that it took these actions due to safety risks to patients or due to a supply disruption outside of its control. For a soft switch, in addition to the first part, the manufacturer must prove that it had legitimate pro-competitive reasons, apart from the financial benefits of reduced competition, for taking the actions.

New subsection 27(b)(3) establishes that if the manufacturer is able to demonstrate one of the justifications, the Commission will nonetheless prevail in its case if it establishes that the hard or soft switch conduct was not reasonably necessary to achieve the justification or that it could have been achieved through less anti-competitive means. Alternatively, the Commission will prevail if it establishes that the pro-competitive benefits from the hard or soft switch conduct do not outweigh the anti-competitive effects.

New subsection 27(c)(1) provides that, except as stated in subsection 27(c)(2), the Commission shall enforce this section pursuant to the same jurisdiction, powers, duties, and remedies provided for by all applicable terms and provisions of the FTC Act.

New subsection 27(c)(2) provides that any manufacturer that is subject to a final order of the Commission may petition for review in the D.C. Court of Appeals or the court of appeals for the circuit in which the manufacturer is incorporated. This subsection also sets forth that on review, the Commission's factual findings shall be conclusive if supported by the evidence.

New subsection 27(c)(3) provides that nothing in new subsection 27 may be construed as requiring the Commission to bring a suit seeking a temporary injunction under paragraph (1)(B) before bringing a suit seeking a permanent injunction under paragraph (1)(C); or affecting any other authority of the Commission under this Act to seek relief or obtain a remedy with respect to a violation of this Act.

Section 2(b) sets the Act's effective date such that the Act applies to all conduct that occurs on or after the date it is enacted.

Section 2(c) establishes that nothing in this Act shall impair, limit, or supersede the applicability of existing antitrust laws. Further, nothing in this Act shall affect the ability of the FTC to bring a cause of action against companies that engage in product hopping under existing antitrust statutes including current section 5 of the FTC Act.

Section 2(d) establishes that the Commission may issue rules to carry out new section 27 of the FTC Act.

Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

FEDERAL TRADE COMMISSION ACT

* * * * *

SEC. 27. PRODUCT HOPPING.

(a) *DEFINITIONS.*—*In this section:*

(1) **ABBREVIATED NEW DRUG APPLICATION.**—The term “abbreviated new drug application” means an application under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(2) **BIOSIMILAR BIOLOGICAL PRODUCT.**—The term “biosimilar biological product” means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(3) **BIOSIMILAR BIOLOGICAL PRODUCT LICENSE APPLICATION.**—The term “biosimilar biological product license application” means an application submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(4) **FOLLOW-ON PRODUCT.**—The term “follow-on product”—

(A) means a drug approved through an application or supplement to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or a biological product licensed through an application or supplement to an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a change, modification, or reformulation to the same manufacturer’s previously approved drug or biological product that treats the same or a related indication;

(B) excludes such an application or supplement to an application for a change, modification, or reformulation of a drug or biological product that is requested by the Secretary or necessary to comply with law, including sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c);

(C) excludes such an application or supplement to an application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) that has been granted New Chemical Entity exclusivity (21 U.S.C. 355(c)(3)(E)(ii)) by the Food and Drug Administration; and

(D) excludes such an application or supplement submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) that has been granted exclusivity pursuant to section 351(k)(7) of such Act (42 U.S.C. 262(k)(7)).

(5) **COMMISSION.**—The term “Commission” means the Federal Trade Commission

(6) **DISADVANTAGE.**—The term “disadvantage” means to impede the listed drug or reference product’s ability to compete on the merits with the follow-on product. This term excludes actions that consist solely of—

(A) truthful, non-misleading promotional marketing; or

(B) ceasing promotional marketing for the listed drug or reference product.

(7) **GENERIC DRUG.**—The term “generic drug” means a drug approved under an application submitted under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(8) **LISTED DRUG.**—The term “listed drug” means a drug listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)).

(9) *MANUFACTURER.*—The term “manufacturer” means the holder, licensee, or assignee of—

(A) an approved application for a drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)); or

(B) a biological product license under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(10) *REFERENCE PRODUCT.*—The term “reference product” has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(11) *ULTIMATE PARENT ENTITY.*—The term “ultimate parent entity” has the meaning given the term in section 801.1 of title 16, Code of Federal Regulations, or any successor regulation.

(b) *PROHIBITION ON PRODUCT HOPPING.*—

(1) *PRIMA FACIE.*—Except as provided in paragraph (2), a manufacturer of a reference product or listed drug shall be considered to have engaged in an unfair method of competition in or affecting commerce in violation of section 5(a) of the Federal Trade Commission Act if complaint counsel or the Commission demonstrates by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that, during the period beginning on the date on which the manufacturer of the reference product or listed drug first receives notice that an applicant has submitted to the Commissioner of Food and Drugs an abbreviated new drug application or biosimilar biological product license application and ending on the date that is the earlier of 180 days after the date on which that generic drug or biosimilar biological product or another generic drug or biosimilar biological product referencing the listed drug or reference product is first marketed or 3 years after the date on which the follow-on product is first marketed, the manufacturer engaged in either of the following actions:

(A) The manufacturer engaged in a hard switch, which shall be established by demonstrating that the manufacturer engaged in either of the actions described in clause (i) or (ii):

(i) Upon the request of the manufacturer of the listed drug or reference product, the Commissioner of Food and Drugs withdrew the approval of the application for the listed drug or reference product or placed the listed drug or reference product on the discontinued products list; and

(I) the manufacturer marketed or sold a follow-on product.

(ii)(I) The manufacturer of the listed drug or reference product—

(aa) withdrew, discontinued the manufacture of, or withdrew the application with respect to, or announced withdrawal of, discontinuance of the manufacture of, or withdrawal of the application with respect to, the drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, as established by objective circumstances, unless such ac-

tions were taken by the manufacturer pursuant to a request of the Commissioner of Food and Drugs; or

(bb) destroyed the inventory of the listed drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, which may be established by objective circumstances; and

(II) marketed or sold a follow-on product.

(B) The manufacturer engaged in a soft switch, which shall be established by demonstrating that the manufacturer engaged in both of the following actions:

(i) The manufacturer took one or more actions with respect to the listed drug or reference product other than those described in subparagraph (A) that unfairly disadvantage the listed drug or reference product relative to the follow-on product described in clause (ii) in a manner that impedes competition from either a generic drug or a biosimilar biological product, which may be established by objective circumstances.

(ii) The manufacturer marketed or sold a follow-on product.

(2) JUSTIFICATION.—

(A) IN GENERAL.—Subject to paragraph (3), the actions described in paragraph (1) by a manufacturer of a listed drug or reference product shall not be considered to be an unfair method of competition in or affecting commerce if—

(i) the manufacturer demonstrates to the Commission or a district court of the United States, as applicable, by a preponderance of the evidence in a proceeding initiated by the Commission under subsection (c)(1), or in a suit brought under subparagraph (B) or (C) of subsection (c)(1), that—

(I) the manufacturer would have taken the actions regardless of whether a generic drug that references the listed drug or biosimilar biological product that references the reference product had already entered the market; and

(II)(aa) with respect to a hard switch under paragraph (1)(A)(i), the manufacturer took the action for reasons relating to the safety risk to patients of the listed drug or reference product;

(bb) with respect to an action described in item (aa) or (bb) of paragraph (1)(A)(ii)(I), there is a supply disruption that—

(AA) is outside of the control of the manufacturer;

(BB) prevents the production or distribution of the applicable listed drug or reference product; and

(CC) cannot be remedied by reasonable efforts; or

(cc) with respect to a soft switch under paragraph (1)(B), the manufacturer had legitimate pro-

competitive reasons, apart from the financial effects of reduced competition, to take the action.

(B) *RULE OF CONSTRUCTION.*—Nothing in subparagraph (A) may be construed to limit the information that the Commission may otherwise obtain in any proceeding or action instituted with respect to a violation of this section.

(3) *RESPONSE.*—With respect to a justification offered by a manufacturer under paragraph (2), complaint counsel or the Commission, as applicable, will prevail in its case if it establishes by a preponderance of the evidence that—

(A) the conduct described in subsection (b)(1) is not reasonably necessary to address or achieve the justifications claimed under paragraph (2)(A)(II)(aa–cc), or such justifications could be reasonably addressed or achieved through less anticompetitive means; or

(B) the pro-competitive benefits from the conduct described in subparagraph (A) or (B) of paragraph (1), as applicable, do not outweigh any anticompetitive effects of the conduct, even in consideration of the justification so offered.

(c) *ENFORCEMENT.*—

(1) *ENFORCEMENT BY THE FEDERAL TRADE COMMISSION.*—Except as provided in paragraph (2), the Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, duties, and remedies provided for by all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 45 et seq.).

(2) *JUDICIAL REVIEW.*—

(A) *IN GENERAL.*—Notwithstanding any provision of section 5 of the Federal Trade Commission Act, any manufacturer that is subject to a final order of the Commission that is issued in a proceeding initiated under paragraph (1) may, not later than 30 days after the date on which the Commission issues the order, petition for review of the order in—

(i) the United States Court of Appeals for the District of Columbia Circuit; or

(ii) the court of appeals of the United States for the circuit in which the ultimate parent entity of the manufacturer is incorporated.

(B) *TREATMENT OF FINDINGS.*—In a review of an order issued by the Commission conducted by a court of appeals of the United States under subparagraph (A), the factual findings of the Commission shall be conclusive if those facts are supported by the evidence.

(3) *RULES OF CONSTRUCTION.*—Nothing in this subsection may be construed as—

(A) requiring the Commission to bring a suit seeking a temporary injunction under paragraph (1)(B) before bringing a suit seeking a permanent injunction under paragraph (1)(C); or

(B) affecting any other authority of the Commission under this Act to seek relief or obtain a remedy with respect to a violation of this Act.

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