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See IQVIA Inst. for Human Data Sci., Medicine Use and Spending in the U.S. 6 (April 2018), https://www.iqvia.com/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf (discussing specialty drug prevalence ang apec9 s.

Amendments created an abbreviated approval process for generic versions of small molecule drugs. Competition from generic drugs has saved Americans hundreds of billions of dollars in drug costs.[5] Similarly, with these benefits of competition in mind, in 2010 Congress enacted the Biologics Price Competition and Innovation Act (BPCI Act) to foster competition for biologics.[6] The BPCI Act created an abbreviated pathway for biological products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference product. A biosimilar is a biological product that is highly similar to its reference product, a biological medication already approved by FDA. Biosimilars have no clinically meaningful differences from the reference product in terms of safety or effectiveness. Generally described, an interchangeable is a biosimilar to the reference product that meets additional requirements outlined in the BPCI Act. Additional information is needed to show that an interchangeable is expected to produce the same clinical result as the reference product in any given patient. Also, for a biological product administered more than once to patients, FDA will have evaluated the risk in terms of safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product. An interchangeable product may be substituted for the reference product without the involvement of the prescriber.[7] The abbreviated pathway enables potentially shorter and less costly drug development programs for biosimilar and interchangeable products while maintaining FDAxhn(en)1 DAxhn(en)1 DAxhn4blecth.3 3C 7.98 -0 0r (eab c (ga1 (l)-e1co)-1 s (gty i)-1s.)(

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

FDA issued a Biosimilars Action Plan (BAP) in July 2018 that outlines four key strategies to accelerate biosimilar competition.[12] One key goal in the BAP is to support market competition by reducing "gaming" and other attempts to unfairly delay competition. Strengthening the partnership and interagency coordination between FDA and FTC will help each agency address and deter anticompetitive behavior in the U.S. market for biological products. Such behavior might include anticompetitive reverse payment agreements, aby 82 (ude)-1xigde smititernt Í1l1 (i) d1 (m)4 (p)1

Joint Goals

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

We jointly identified four goals to help in this effort:

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

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

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

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

- FDA and

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

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

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

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

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

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

Signatures

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

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