America's Health Insurance Plans
601 Pennsylvania Avenue, NW
South Building, Suite Five Hundred
Washington, DC 20004

Matthew Eyles
President & Chief Executive Officer

April 9, 2020

Dr. Stephen Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Joseph J. Simons
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Submitted via the Federal Regulations Web Portal https://www.regulations.gov

RE: Docket No. FDA-2019-N-6050 for "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars."

Dear Commissioner Hahn and Chairman Simons:

Drug prices are out of control, and America's Health Insurance Plans (AHIP) joins you in your commitment to improving affordability, choice and innovation in prescription drugs for all Americans. We appreciate the opportunity to offer comments in response to the FDA/FTC Workshop on a Competitive Marketplace for Biosimilars, a public workshop held at FDA headquarters on March 9, 2020.

We applaud the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) for your collaborative efforts to support appropriate adoption of biosimilars, discourage false or misleading communications about biosimilars, and deter anti-competitive behaviors in the biologic product marketplace. We share the agencies' goals of promoting a robust and competitive marketplace for biosimilars—which we believe holds great promise in improving patient access to needed therapies, enhancing prescription drug affordability, and reducing health care costs for hardworking American families.

Health insurance providers are committed to supporting a competitive biosimilars market and our industry continues to engage in collaborative efforts to advance the shared goal of more affordable access to prescription drugs and biologics—including advancing best-practices to increase patient adoption of biosimilars.

Non-partisan studies have found that improved access to biosimilars could result in up to $150 billion in savings[1] over the next decade – and up to 1.2 million more patients gaining access to biologic and biosimilar drugs and treatments by 2025.[2]

[1] RAND Corporation—Biosimilar Cost Savings in the United States. 2017. https://www.rand.org/pubs/perspectives/PE264.html
[2] The Biosimilars Council—Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines. September 2017. http://biosimilarscouncil.org/wp-content/uploads/2019/03/Biosimilars-Council-Patient-Access-Study.pdf

As part of the public workshop, FDA and FTC officials examined a number of policy issues that directly relate to achieving a competitive market for biological products—including increasing availability of biosimilars and interchangeable products.

FDA has made significant progress in supporting the biosimilars marketplace. As a result, there are now 15 FDA-approved biosimilars on the market and available for patients[3]. By working with manufacturers to streamline the approval process, by finalizing regulations and guidance, and by educating providers and patients on the safety and effectiveness of biosimilars, FDA has made strides in supporting competition and increasing patient access to these treatments and therapies.

Yet, as documented by public officials, stakeholders and policy experts at last month's public workshop, significant barriers to the availability of biosimilars remain. If these barriers to competition are not meaningfully addressed, the biosimilar marketplace could fail deliver on its promise of lower costs and greater patient access to vital biologic treatments.

AHIP recommends that the FDA and FTC collaborate to advance the following policies—

- **Continue and accelerate efforts to streamline the FDA approval process, and issue guidance necessary to promote regulatory clarity in the biosimilars marketplace;**

- **Address false and misleading information disseminated by brand-name, reference-product drug makers that sows doubt and confusion about the safety and efficacy of biosimilars;**

- **Develop effective communication tools and strategies to educate physicians, hospitals, patients and other stakeholders to raise awareness about the safety and efficacy of biosimilars;**

- **Use existing enforcement tools and authorities to thwart anti-competitive behaviors and close loopholes that delay or prevent biosimilar competition; and**

- **Pursue additional public policies—at the federal and state level—to promote greater availability of and access to biosimilars and interchangeable products.**

Streamline Approval Processes and Promote Regulatory Clarity

Improving the efficiency of biosimilar product development and approval processes will greatly increase access for patients. FDA's efforts to streamline the review process—including the development of application review templates and other initiatives—can reduce development costs for biosimilar manufacturers and speed regulatory approvals of high-quality and clinically effective biosimilars. In addition, streamlining the approval process and increasing transparency on regulatory standards can help enhance public information about the FDA's process for the evaluation of biosimilar and interchangeable products.

[3] Association of Accessible Medicines/Biosimilars Council Presentation to FDA/FTC Workshop on a Competitive Market for Biosimilars, March 9, 2020.

AHIP also supports the FDA's continued efforts to finalize guidance necessary to complete the regulatory approval pathway for biosimilars and interchangeable products as well as address new challenges and issues that arise.

AHIP strongly supported FDA's standards for determining when a biosimilar product is interchangeable with its reference product.[4] By finalizing this guidance, FDA has opened the door to increased investment in the development of interchangeable products which, in turn, could increase the availability of both biosimilars and interchangeable products.

We also support recent FDA guidance to spur the availability of biosimilar and interchangeable insulin products[5]—which can help alleviate cost pressures for diabetes patients and improve patient access and treatment adherence. AHIP was pleased to join a coalition of 20 organizations in supporting this critical guidance[6] and we encourage FDA to finalize as expeditiously as possible.

We also support many of the FDA's proposals to maximize regulatory clarity, including making available timely and easy-to-understand information about biosimilars. We support the FDA's ongoing efforts to expand the accessibility of, and information available in, the Purple Book so that it can serve as a more useful tool for developers and manufacturers and help speed availability of biosimilars. Future improvements should be aimed at making the Purple Book available in a searchable and interactive format and having it include more complete information (such as any patents for the brand name biologic).

AHIP also supports complementary legislative efforts in Congress to enhance the Purple Book and help biosimilar developers in bringing their products to market.[7]

Addressing False and Misleading Information About the Safety and Effectiveness of Biosimilars

The FDA and FTC can play a crucial role in combatting false and misleading information about the safety and efficacy of biosimilars. As the FDA has observed, brand name biologic manufacturers have published materials that create uncertainty about biosimilars and discourage patients and health care providers from using them.[8] We are pleased that the FDA has issued draft guidance—*Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products Questions and Answers for Industry*[9]—which can help ensure that promotional

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[4] FDA—Considerations in Demonstrating Interchangeability with a Reference Product. Guidance for Industry. May 2019.https://www.fda.gov/media/124907/download

[5] FDA—Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products. Guidance for Industry. November 2019.

[6] Biosimilars Council letter to FDA. January 28, 2020. https://biosimilarscouncil.org/wp-content/uploads/2020/01/Group-Letter_Biosimilar-Interchangeable-Insulin-Guidance_1.28.20.pdf

[7] H.R. 1520, the Purple Book Continuity Act. https://www.congress.gov/bill/116th-congress/house-bill/1520

[8] Dr. Hahn's remarks to the FDA/FTC Workshop on a Competitive Marketplace for Biosimilars. March 9, 2020. https://www.fda.gov/news-events/speeches-fda-officials/dr-hahns-remarks-fdaftc-workshop-competitive-marketplace-biosimilars-03092020

[9] https://www.fda.gov/media/134862/download

and marketing information is truthful and does not mislead the public about the clinical effectiveness of biosimilars.

Moreover, the dissemination of such misleading information is contrary to the FDA/FTC goals of ensuring a level playing field and promoting a fair and competitive market for both biologics and biosimilars. We recommend that the FDA finalize this guidance as soon as possible and take other such actions that are necessary—utilizing FDA and FTC existing tools and authorities to counter misleading information contained in promotional or marketing materials by brand name biologic manufacturers.

Developing Effective Communication Tools to Educate Patients and Providers

AHIP appreciates FDA's efforts to educate the public with unbiased and scientifically sound information about biosimilars—including a public education campaign to make sure that patients and providers know that biosimilars are as safe and effective as their respective reference products. By providing fact- and science-based information about the safety and effectiveness of biosimilars, FDA can help promote physician and patient confidence that is necessary for encouraging market acceptance and widespread adoption of biosimilars. These FDA resources—which include fact sheets, explainers and graphics and are accessible on a new FDA webpage dedicated to biosimilars—can play an important role in increasing public awareness.

Going forward, we encourage FDA to build on this work to develop additional materials. We are especially encouraged to learn about FDA's planned development of resources such as on-line videos and infographics for patients. As part of these outreach efforts, we encourage FDA to partner with physician specialty societies and patient and public health organizations to ensure these resources are widely disseminated. In addition, health insurance providers can play an important role by partnering with the FDA and other stakeholders to educate physicians and patients about the safety and effectiveness of biosimilar drugs and collaborating to incentivize prescribing and use.

Address anti-competitive behavior and close loopholes that delay or prevent biosimilar competition

We appreciate the FDA's and FTC's collaborative efforts to address anti-competitive behavior. The FTC plays a critically important role in both investigating and challenging anti-competitive behavior, which can lead to higher prices and costs for patients and the health care system overall. Moreover, both the FDA and FTC can play an important role in supporting federal and state public policies that facilitate private market competition. Moreover, as trusted and credible resources, FDA and FTC should continue to advise Congress and other public officials as they consider legislation to support the goals of a competitive biosimilars market. Potential areas where the FDA and FTC can focus include:

- Addressing "pay-for-delay" settlements that prevent generics and biosimilars from entering the market in a timely manner;

- Abuses of the regulatory process, such as FDA citizen petitions, to prolong drug monopolies;

- Product hopping, where manufacturers withdraw a certain drug from a market and introduce a newer version with minor changes to prevent the entry of a generic substitute or biosimilar[10]; and

- Product evergreening, where manufacturers make minor updates to an existing product and extend patent protections.

Bipartisan legislation has been introduced[11] that would prohibit anti-competitive "pay-for-delay" settlements between drug makers. Halting such patent settlements and ensuring adequate resources for FTC enforcement are important ways to speed availability of generics and biosimilars and promote more affordable access to prescription drugs.

In addition, there is significant bipartisan support in Congress to advance policies that address product hopping and the creation of patent thickets[12]. Patent litigation through the creation of patent thickets creates disincentives for companies to engage in biosimilar development. Similarly, the ability to "game" the patent system allows opportunities for brand manufacturers to inappropriately extend patent terms, either directly or by creating enough uncertainty, and litigation risk, to chill efforts by potential generic competitors.[13] We encourage the FDA and FTC to engage with Congress and the bill sponsors to identify additional barriers to biosimilar competition and seek ways to strengthen the legislation.

Additional Policies to Support the Biosimilars Market

AHIP also encourages the FDA and FTC to consider additional public policies to support a competitive marketplace for biologics and biosimilars, including:

- **Shortening the market exclusivity period for brand name biologics to promote greater price competition and earlier access to biosimilars.** Many experts believe that the current 12-year exclusivity period—which is the highest in the world—is unnecessary to promote innovation by pioneer biologic drug manufacturers and may discourage manufacturers from developing biosimilars. A shorter exclusivity period—similar to market exclusivity for traditional brand name drugs[14]—can promote greater competition and help alleviate cost

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[10] See Brief of AHIP and ACHP as Amicus Curiae, New York v. Actavis (2d Cir. 2015) (noting that "it is often relatively simple for a brand name drug manufacturer to redesign a groundbreaking drug in a way that allows a new version to be patentable even though it does not fundamentally change the drug's therapeutic effect. Those minor changes present an opportunity for the brand-name manufacturer to extend its monopoly potentially decades into the future.")

[11] H.R. 1499, Protecting Consumer Access to Generic Drugs Act. https://www.congress.gov/bill/116th-congress/house-bill/1499/actions?KWICView=false

[12] S. 1416, Affordable Prescriptions for Patients Act. https://www.congress.gov/bill/116th-congress/senate-bill/1416

[13] See Brief of AHIP as Amicus Curiae, Dr. Reddy's Laboratories v. Eli Lilly (2020)(discussing the need to prevent situations in which branded manufacturers can engage in a "bait and switch" process in which areas of a patent are knowingly ceded when seeking a patent and then are reclaimed when a generic company seeks to compete).

[14] H.R. 3379, introduced by Rep. Schakowsky, would reduce exclusivity period for brand name biologics from 12 years to 5 years. https://schakowsky.house.gov/media/press-releases/bill-introduced-reduce-prescription-drug-companies-exclusivity-period

pressures for all Americans. An alternative approach—adopting a "one-and-done" regulatory framework[15] that would apply to both reference product drug patents and market exclusivity—can also work to tackle the problems of patent thickets and related barriers to generic and biosimilar competition. As part of the agencies' combined efforts, we encourage the agencies to support and work with Congress on public policies that can facilitate earlier access to biosimilar treatments and promote more effective price competition.

- **Address other barriers to biosimilars—such as state anti-substitution laws.** Some states have adopted legislation that may restrict the availability of interchangeable products before they even get to market. These state-level requirements could limit patient access to drugs that are not clinically different yet cost less than their brand name counterparts. Given the FDA's final guidance for interchangeable products, state laws and regulations that place barriers on biosimilar adoption and uptake need to be revisited and revised. The FDA and FTC can work with Congress on legislation that preempts state anti-substitution laws—as such laws are generally prohibited for generic drug substitution.

AHIP appreciates the FDA and FTC for their collaborative efforts to support a competitive biosimilars market. We look forward to further collaborating with the agencies to advance policy solutions that can increase patient access to biosimilar products and deliver meaningful cost-savings for all Americans.

Sincerely,

Matthew Eyles

Matthew Eyles
President & Chief Executive Officer

[15] One-and-done for new drugs could cut patent thickets and boost generic competition. Robin Feldman. Stat News. February 11, 2019. https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/