



Academy of  
Managed Care  
Pharmacy®

February 18, 2019

The Honorable Richard Neal, Chairman  
The Honorable Kevin Brady, Ranking Member  
United State House of Representatives  
Committee on Ways and Means  
Washington, D.C. 20515

Dear Chairman Neal and Ranking Member Brady,

The Academy of Managed Care Pharmacy (AMCP) respectfully submits the following letter for the record to the House of Representatives Committee on Ways and Means regarding the February 12, 2019 hearing on “The Cost of Rising Drug Prices.” AMCP shares the committee’s concerns about the unsustainable burden of high drug pricing on patients and providers and has been working with stakeholders to educate Congress on ways that AMCP pharmacists, physicians, and nurses can improve health outcomes while lowering costs. AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

### **AMCP supports efforts to curb the inappropriate use of shared system REMS**

AMCP agrees with FDA Commissioner Scott Gottlieb that the REMS requirements, while protecting patient safety, can also be leveraged by manufacturers to deter generic entry into the market. One method that such companies have utilized to stop generic and biosimilar competition is to assert that the REMS program allows them to deny samples. In fact, FDA Commissioner Scott Gottlieb wrote, “We see problems accessing testing samples when branded products are subject to limited distribution . . . in some cases, branded sponsors may use these limited distribution arrangements, whether or not they are REMS – related, as a basis or blocking generic firms from accessing the testing samples they need.<sup>1</sup>” Secretary Azar recently stated that

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<sup>1</sup> FDA Voice, FDA Working to Lift Barriers to Generic Competition by Scott Gottlieb, M.D. June 21, 2017. <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm612018.htm>. Accessed February 4, 2019, 2018.

“we know that certain brand-name manufacturers are abusing the system by blocking access to samples and hiding behind FDA’s rules when they do it.”<sup>2</sup>”

To this end, AMCP supports the *Creating and Restoring Equal Access to Equivalent Samples* (CREATES) Act introduced on February 5, 2019.

### **The Committee Should Ensure that Biosimilars are Fully Utilized**

Biological products were identified as high-cost prescription drugs that make up a large share of spending on medications in the United States. While less than 2% of U.S. patients use biologics, they totaled more than \$105 billion in 2016, or about 40% of total prescription drug spending and represented 70% of drug spending growth between 2010 and 2015.<sup>3</sup> The United States has experienced slow adoption of biosimilars, with only a small number of the 16 approved actually marketed and no interchangeable biologic products are currently on the market, in part due to misconceptions that they are less clinically effective than their reference biologics.

AMCP supports a robust biosimilar market that will allow for cost savings that facilitate the use and adoption of other innovative treatments and medications. If all biosimilars approved to date had been marketed, the FDA estimates that Americans would have saved more than \$4.5 billion in 2017.<sup>4</sup>

AMCP has undertaken proactive initiatives to support biosimilar adoption. In 2015, AMCP created the [Biologics and Biosimilars Collective Intelligence Consortium \(BBCIC\)](#) to conduct active post-marketing surveillance of biologics and biosimilars and provide transparent, unbiased data on their safety and effectiveness. AMCP has also launched the [Biosimilars Resource Center \(BRC\)](#) to provide education and information on biosimilars to health care providers and other stakeholders in a policy-neutral and non-promotional manner.

AMCP offers the following comments on facilitating biosimilar adoption and the interchangeability designation.

### **Congress should urge the FDA to withdraw the current interchangeability guidance and release a new, streamlined guidance.**

AMCP supports the implementation of a two-step process for demonstrating biosimilar and interchangeable status with the first step determining the biosimilarity of an applicant product and the second step determining the interchangeability of the biosimilar with the reference product. We also support FDA’s definition of interchangeability and agree that any applications

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<sup>2</sup> Prepared Remarks on Drug Pricing Blueprint by Alex M. Azar II, May 14, 2018.

<https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>. Accessed July 6, 2018

<sup>3</sup> Gottlieb S. Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA’s Biosimilars Action Plan; July 19, 2018; Washington, DC. Available at. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613881.htm>. Accessed January 31, 2019.

<sup>4</sup> Ibid.

demonstrating that a product can be expected to produce the same clinical results as the reference product in any given patient, as required by statute, should be deemed interchangeable.

Health care providers and decision makers require clear guidance on interchangeability to ensure that patients receive appropriate and cost-effective medications, make important formulary decisions, and ensure the electronic health record systems and databases used for purposes of payment, prescribing, distribution, and other health care functions convey and share information in a safe, accurate, and efficient way. AMCP. To this end, AMCP encouraged the FDA to withdraw the existing draft and replace it with provisions that provide a clearer pathway to allow the designation of a biosimilar product as interchangeable with a reference product. We recommend Congress engage with the FDA to determine where the agency is in the process of issuing final regulations on interchangeability.

AMCP disagrees with the direction outlined in the draft guidance *Considerations in Demonstrating Interchangeability with a Reference Product*, to require an applicant seeking an interchangeable designation to rely on switching studies sourced from U.S.-licensed reference products. There is no scientifically valid distinction between reference products acquired in the U. S. and those licensed in other comparable markets. This requirement will create significant burden on biosimilar manufacturers pursuing switching studies who can often acquire equivalent samples of reference products from other highly regulated markets at much lower costs. Requiring switching studies to rely on more expensive U.S.-licensed reference product samples over less costly samples from other markets, without any real clinical difference between the two, will simply create additional, unnecessary barriers to entry for biosimilar developers.

Switching studies are also costly to conduct and therefore, as FDA considers approaches to determine interchangeability, AMCP recommends the use of real-world evidence obtained about biosimilars.

**The FDA should enhance its current education campaign on biosimilar and interchangeable biologic products to ensure that health care providers and consumers receive adequate information to make informed decisions.**

AMCP appreciates FDA's previous education efforts and believes that it should continue to build upon those efforts and use its resources and influence to enhance its current education campaign on biosimilar and interchangeable biologic products. We previously recommended that FDA should also partner with AMCP and other organizations to increase awareness.

Congress could reaffirm that a biological given an 'interchangeability' designation means a biosimilar can automatically be dispensed for a branded reference biologic and does not require physician consultation with a pharmacist prior to dispensing.<sup>5</sup> These two efforts could significantly prompt utilization of biosimilars, which so far have gained little traction in the U.S.

AMCP also supports efforts for training and development of education resources, including the adoption and dissemination of existing education resources, such as AMCP's Biosimilars

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<sup>5</sup> <http://www.amcp.org/Newsletter.aspx?id=23808>

Resource Center (BRC)<sup>6</sup> to provide neutral, unbiased education resources to pharmacists, physicians, nurses, and other health care providers.

The BRC website includes information from FDA's website, including continuing education for health care providers on FDALearn. The BRC can help FDA disseminate educational resources and information.

AMCP appreciates your consideration of the concerns outlined above and looks forward to working with you and your staff on ways to address the drug pricing issue before Congress. If you have any questions regarding AMCP's comments or would like further information, please contact Christ Topoleski, AMCP's Director of Government Affairs at 703-684-2620 or at [ctopoleski@amcp.org](mailto:ctopoleski@amcp.org).

Sincerely,



Susan A. Cantrell, RPh, CAE  
Chief Executive Officer

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<sup>6</sup> The Biosimilars Resource Center (BRC) provides educational resources and information on biosimilars to health care providers and other stakeholders in a policy-neutral and non-promotional manner. Biosimilars have the potential to significantly decrease health care costs in the United States and improve access to treatment for patients. The need for education of health care providers on how to prescribe and dispense cost effective biosimilars is critical to driving adoption and maximizing their use in a safe and effective manner for patients. The BRC provides access to educational tools and training materials for biosimilars, including one-pagers, web-based educational seminars, continuing education and journal articles. The BRC was launched in 2016 by the Academy of Managed Care Pharmacy in partnership with the American Association of Colleges of Pharmacy, America's Health Insurance Plans, the American Pharmacists Association, the American Society of Consultant Pharmacists, the Hematology/Oncology Pharmacists Association, the National Alliance of State Pharmacy Associations, and the National Community Pharmacists Association. For more information on the BRC, please visit <https://www.biosimilarsresourcecenter.org/>.