AMCP Academy of Managed Care Pharmacy®

September 21, 2018

Food and Drug Administration
Division of Dockets Management Staff (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments

Dear Sir or Madam,

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to "*Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments"* as published in the *Federal Register* on July 25, 2018. AMCP shares the FDA's commitment to developing a robust biological products market that will both ensure that Americans have access to safe, effective, and affordable biologics and biosimilars and allow for cost savings that facilitate the use and adoption of other innovative treatments and medications.

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.

The United States has experienced a slow uptake, with few biosimilars and no interchangeable biologic products currently on the market, in part due to misconceptions that they are less clinically effective than their reference biologics. Additional barriers include the lack of final and workable interchangeability guidance; inadequate health provider information regarding the comparative effectiveness of different categories of biological products; unclear naming and labeling guidance for biosimilar and interchangeable biologic products; incomplete information in the *Purple Book*; and challenges related to billing and coding for biosimilars in different payer systems.

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.

FDA must 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 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 encourages the FDA to withdraw 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.

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. As described below, AMCP has launched the BBCIC to facilitate this data collection process.

FDA should focus on collection of post-marketing real-world evidence and partner with organizations such as BBCIC as resources for unbiased data on biologics and biosimilars.

As noted above, AMCP launched BBCIC in 2015 to support post-marketing surveillance of biologics and biosimilars. BBCIC is a nonprofit, scientific public service initiative that monitors biosimilars and corresponding novel biologics for effectiveness and safety to provide assurances that prescribers, pharmacists, and patients can confidently prescribe, dispense and use biologics

and biosimilars. BBCIC is the only research network dedicated to monitoring biosimilars and biologics and draws on large sets of de-identified medical and pharmacy data to harness cutting-edge distributed research network and surveillance methods. BBCIC's work includes:

- Comparative effectiveness research on biologics to biosimilars.
- Descriptive analysis research in the areas of insulins, G-CSF, anti-inflammatories, and erythropoiesis-stimulating agents.
- A completed evaluation on the impact of switching. The results are being compiled to release consensus recommendations for how to approach medication switching patterns in observational, claims-based studies.
- Mapping the use of ICD-9 to ICD-10 codes and issues related to National Drug Code (NDC) and health care common procedure coding system (HCPCS) use for biologics and biosimilars.

FDA should continue to support efforts like BBCIC in post-market studies to provide evidence-based data for biosimilars. AMCP supports post marketing surveillance and studies to provide valuable evidence for a subsequent review for interchangeability.

FDA should follow conventional naming and labeling mechanisms for biosimilar and interchangeable drugs.

AMCP reiterates its comments previously raised in regard to FDA's draft naming guidance titled *Nonproprietary Naming of Biological Products*,[1] to adopt a four- letter randomized hyphenated suffix affixed to the nonproprietary name, when responding to FDA's request for comment on the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years 2018 through 2022. AMCP continues to support the use of the international nonproprietary name for both biologics and biosimilars with no prefix or suffix. To allow for tracking and post-marketing surveillance, AMCP supports the use of the NDCs on all claims for medications, including biologics and biosimilars.

The use of NDCs, along with lot number and manufacturer name, provides an existing mechanism to individually identify products. AMCP urges FDA to reconsider the ramifications of using a suffix and to provide results from cognition testing on pharmacists, physicians and other providers and patients demonstrating that the proposed naming framework adds value to the public safety, is easily understood and comprehended by the public, and does not result in increased confusion.

The need for biologic products to share common nonproprietary names is particularly critical for interchangeable biologic products. FDA final guidance on interchangeability must include provisions for nonproprietary naming and AMCP recommends that interchangeable biologic products share common names with no prefixes or suffixes.

[1] United States. Food & Drug Administration. Center for Drug Evaluation and Research (CDER). Nonproprietary Naming of Biological Products. January 2017. Accessed September 20, 2018. https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf.

FDA should also consider removing the biosimilarity statement from labels, and adopting conventional labeling standards for these drugs, because the use of alternative labeling standards may lead health care providers and patients to unnecessary conclusions that biosimilars are not safe and effective in comparison to the reference products.

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. FDA should also partner with AMCP and other organizations to increase awareness. AMCP supports the continued use of FDA's website and its social media platforms such as Twitter, LinkedIn, and Facebook to engage with providers and share information on biological products.

FDA should develop and promote educational materials that emphasize 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.[2] 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 Resource Center (BRC)[3] 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.

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[2] http://www.amcp.org/Newsletter.aspx?id=23808

[3] 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/.

FDA should revise the *Purple Book* to create a comprehensive resource for biologic and biosimilar information.

AMCP supports FDA's efforts to enhance the *Purple Book* to include comprehensive information about biologics, including the biologics license application (BLA) number, product name, proprietary name, manufacturer name, dosage, date of licensure, expiration of exclusivity, clear information regarding the process to obtain a positive interchangeable or biosimilar determination, and date of withdrawal or approval. AMCP also supports improved functionality of the *Purple Book* by making the database interactive and searchable. Health care providers must rely on a single, comprehensive, neutral and reliable source of information for biologics and biosimilars. For many years, pharmacists and other health care providers have relied on FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the *Orange Book*) for small molecule agents and, therefore, it logically follows that the FDA should maintain a similar comprehensive resource for biologics and biosimilars.

FDA should support efforts of federal agencies to ensure that billing and coding practices for biosimilar products promote uptake and adoption.

Use of NDCs on Medicare Part B Claims

AMCP recognizes that performing diligent collection of real-world evidence on use biologic products active post-marketing surveillance is vital to ensuring safe use by patients and to provide clinicians and payers with information to use in making product selection determinations. Use of HCPCS codes by Medicare Part B for billing and payment of medications is insufficient for tracking specific products and therefore, AMCP advocates for the use of NDCs on all medication claims. The ability to track the medication administered to the specific NDC number is critical to truly implement post-marketing surveillance activities as documentation of NDCs will allow for specific data analysis and measure assessment. AMCP further believes that electronic medical records will need to have timely updating of their drug libraries to include the new biosimilars and adapt for NDC-level documentation in order to more readily identify specific product utilization and to facilitate appropriate billing and reimbursement.

Utilization Management under Medicare Part B

AMCP further encourages consideration of how the allowance for formularies and utilization management tools under Medicare Part B may decrease costs, improve quality, and increase value as demonstrated in Medicare Part D, and the commercial market. AMCP supports the Centers for Medicare and Medicaid Services (CMS's) recent decision to allow Medicare Advantage plans to use step therapy as a Medicare Part B utilization management policy for newly diagnosed patients. AMCP believes that this provision help reduce costs for patients by providing for increased biosimilar uptake before the use of high-cost reference products. To fully implement these provisions, AMCP understands that efficient prior authorization (PA) and utilization management processes must be in place and are engaging members and other stakeholders to make recommendations in this area. AMCP will communicate recommendations to both FDA and CMS. AMCP also suggests implementation of additional pilot programs to test new payment and coding models for biologics and biosimilars and continuous evaluation of the

impact of any coding and reimbursement strategy adopted under Medicare Part B to determine success and areas for improvement as the biosimilar marketplace grows in the coming years.

Encourage Adoption of Standardized Electronic PA for Pharmacy-Billed Claims

AMCP is concerned that product-specific prior authorization (PA) websites are commonly used by physician offices for ordering biologic drugs, posing a distinct disadvantage for biosimilars. Encouraging the adoption of the National Council for Prescription Drug Program electronic PA standard (part of the e-prescribing standard) could help supplant these product-specific PA websites.

Medicare Part D Changes

AMCP supports recent changes to Medicare Part D, approved in March 2018 under the Bipartisan Budget Act, that will allow Medicare beneficiaries to access biosimilars at lower costs starting in 2019. These changes will make beneficiaries eligible for cost-sharing reductions in the Medicare coverage gap. Under the new rule, beneficiaries will be responsible for 25% of costs and will receive 70% rebates from manufacturers and 5% coverage from health plans, closing the donut hole one year earlier than anticipated. AMCP also supports changes made to the Medicare Part D final rule that allow for reduced cost-sharing of biosimilars for beneficiaries who are eligible for low-income subsidies. These changes will also help to facilitate greater biosimilar adoption by improving their affordability for Medicare beneficiaries.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with the FDA. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2645 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer