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April 9, 2020

Lowell J. Schiller
Principal Associate Commissioner for Policy
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2019-N-6050, Food and Drug Administration/Federal Trade Commission Workshop on a Competitive Marketplace for Biosimilars; Public Workshop

Dear Principal Associate Schiller:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to the FDA/Federal Trade Commission (FTC) Workshop on a Competitive Marketplace for Biosimilars, held on March 9, 2020. We appreciate the opportunity to leverage our members' expertise in offering feedback on this workshop. As an organization representing health care professionals, AMCP believes that a health care system that is based upon a competitive marketplace will provide greater value to patients and to payers and that biosimilar products are playing an increasingly important role in the health care system, both in improving the treatment of disease and in lowering costs. We thank the FDA and the FTC for holding this workshop on this important topic.

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 healthcare 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 a competitive health care delivery marketplace and believes that competition will provide greater value to patients and payers than a one-size-fits-all system that relies on central government controls and regulatory mandates. Managed care organizations operating within a competitive marketplace have designed effective health benefits programs to meet the needs of their patient populations. Through innovative and integrated strategies focused on provider and patient education, quality assurance, and drug utilization management, managed care pharmacy has delivered a clinically sound, accessible, and affordable comprehensive pharmacy benefit. We

agree that "competition brings substantial benefits to consumers through lower prices, greater access to higher quality goods and services, and increased innovation" and that that supporting a competitive marketplace for biosimilars is essential for improving patient access to needed medications and reducing costs.[1] We commend the FDA and the FTC for their collaborative work to promote a competitive marketplace for pharmaceuticals and biologic products.

AMCP is pleased with the recent efforts of the FDA to reduce barriers to interchangeability status for biosimilars such as the approval pathway allowing the use of comparator products not approved in the United States for biosimilar development as well as the FDA's final guidance limiting the cases in which a switching study must be conducted. While we are encouraged by these actions, in order to continue to facilitate a competitive marketplace for biosimilars, AMCP urges the FDA to ensure that additional barriers to therapeutic substitution of lower cost biosimilars are not erected that would prevent or slow an increase in biosimilar utilization. The FDA should provide clear guidance to states that would allow for product substitution without unnecessary barriers such as notification requirements. It is understandable, due to the novelty of these therapies, that patients may be hesitant to switch therapies and that clinicians may be uncertain about substitution. Direct and clear guidance from the FDA, in its capacity as the premier agency on drug safety and efficacy, on the labeling and marketing of approved interchangeable products as truly interchangeable, could alleviate much of the uncertainty and remove impediments to a competitive biosimilar marketplace.

AMCP is committed to ensuring that patients and clinicians have access to up-to-date research and information on biological products and as such, established the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) in 2015. The BBCIC is a non-profit research consortium that monitors the safety and effectiveness of biosimilars and novel biologics and provides the assurance needed to determine which medications deliver the best health outcomes.

In 2017, the BBCIC established a workgroup "consisting of academic researchers, industry scientists, and practicing clinicians to establish best practice recommendations for the conduct of noninterventional studies of biosimilar and reference biologic switching." These post-approval noninterventional studies can help in understanding factors that drive switching from reference biologics to biosimilars as well as evaluating comparative outcomes between patients who switch from a reference biologic to a biosimilar and those that do not for an indication for which the biosimilar was approved but had not been directly studied in premarketing randomized control trials. The workgroup developed and published recommendations on five considerations for these noninterventional studies including selecting appropriate data sources, study designs, outcomes of interest, analytical approaches, and other special considerations. These post-approval studies provide "robust real-world evidence related to the comparative effectiveness and safety of biosimilars relative to reference biologics" and can aid in clinical and policy decision making.[2] The evidence from these studies can protect the safety of patients, provide evidence for cost effective treatments, and address key questions and uncertainties around biosimilars. AMCP and BBCIC are committed to providing education, research, and information on biosimilars to health care providers

[1] Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace February 3, 2020; https://www.fda.gov/media/134864/download
[2] Desai RJ, Kim SC, Curtis JR, et al. Methodologic considerations for noninterventional studies of switching from reference biologic to biosimilars. Pharmacoepidemiol Drug Saf. 2019;1–13. https://doi.org/10.1002/pds.4809

and other stakeholders and believes this work will support a safe and effective market for the increased use of biosimilar products.

Managed care pharmacy tools also play a vital role in ensuring safe and effective access to and use of medications while lowering costs for patients. Utilization management strategies employed by prescription drug benefit program include prior authorization, step therapy, quantity management, drug utilization review, and the formulary development and exception process. Prior authorization, for example, can be used to promote appropriate drug use and prevent misuse by limiting coverage of certain drugs to FDA-approved indications and requiring prior authorization for any intended off-label use. It can also be used to obtain additional clinical patient information to evaluate established coverage guidelines and determine whether coverage is appropriate.

While utilization management tools such as prior authorization have been used successfully in pharmacy benefit programs for decades, there is agreement from stakeholders that there is room for improvement in the prior authorization process. To this end, in 2019, AMCP held a Partnership Forum titled "Optimizing Prior Authorization for Appropriate Medication Selection" that brought together a diverse set of health care experts to recommend ways to improve the prior authorization process. Participants at the Forum, including stakeholders representing managed care, providers, pharmacy, the biopharmaceutical industry, and patients, recommended improvements such as real time benefit checks, common definitions and reporting outputs, greater collaboration and trust among the players, and ensuring that prior authorizations focus on safety and effectiveness, not just cost.[3] Additionally, AMCP's Professional Practice Committee developed nine best practices to support more timely, efficient, and collaborative prior authorization processes including automated decision support, transparency and advanced notice, provider collaboration, and evidence-based review criteria.[4]

In addition to these utilization management tools, the formulary development and exception process play a key role in promoting clinically sound, cost-effective medication therapy and positive therapeutic outcomes. A formulary enhances the quality of care by encouraging the use of those prescription medications that are demonstrated to be the safest, the most effective, and that produce positive patient outcomes. AMCP supports the use of appropriately designed formularies that base coverage decisions primarily on sound clinical evidence and which consider costs only after safety, efficacy, therapeutic need, and patient outcomes have been assessed and which are developed and maintained by a Pharmacy & Therapeutics committee. Effective formularies also include exceptions processes through which individuals can request coverage of a drug that is not on the formulary or continued coverage of a drug that has been removed from a formulary for reasons other than safety or because the drug cannot be supplied, to provide continued patient access.

Recent studies have shown the cost savings that can be achieved using utilization management tools. One study found that the prospective Medicaid Drug Utilization Review program saved states on average $53 million in 2016.[5] Another study found that the implementation of a value-based

[3] https://www.jmcp.org/doi/full/10.18553/jmcp.2020.26.1.55
[4] https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.19069
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6404806/pdf/ahdb-12-7.pdf

formulary resulted in a decrease of 11% from expected costs with no significant decline in medication use or adherence.[6] A predictive analysis of changes to the use of formulary placement and utilization management tools for diabetes drugs in the TRICARE program found that the changes were predicted to increase TRICARE savings by approximately $24 million in the first year and up to $43 million in the third year after the program took effect.[7] One pharmacy benefit manager's biosimilar utilization management program resulted in a shift of 86% of patients to a biosimilar product and savings of 34%.[8]

AMCP supports the continued use of well designed and implemented utilization management programs and formularies that ensure patients receive needed medications at lower costs, including biosimilars. Pharmacy benefit plans are in a unique position to be able to drive competition in this market and an increase in the use of biosimilars through their negotiations with manufacturers and in the design of their benefit management programs. We again commend the FDA and the FTC for their important collaborative work on ensuring a competitive marketplace for biosimilars and encourage the agencies not to take any actions that could hinder the ability of plans to implement clinically sound, cost-effective pharmacy benefit programs.

Conclusion

AMCP appreciates the opportunity to comment on FDA-2019-N-6050, FDA/FTC Workshop on a Competitive Marketplace for Biosimilars; Public Workshop. We are committed to be being a valuable resource to FDA on improving access to prescription drugs at lower costs and on biosimilars. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer

[6] https://www.jmcp.org/doi/abs/10.18553/jmcp.2015.21.4.269
[7] https://www.jmcp.org/doi/full/10.18553/jmcp.2019.25.3.342
[8] https://ir.magellanhealth.com/news-releases/news-release-details/magellan-rx-management-biosimilar-program-shifts-infliximab