AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

Aimed Alliance Statement on Biosimilars

I. What Are Biologics and Biosimilars?

Biologics are large, complex molecule drugs that are produced from living organisms or contain components of living organisms, such as plant or animal cells.[1] Biosimilars are large, complex molecule drugs that are highly similar to and have no clinically meaningful differences from the brand biologic drug.[2][3] Given their nature, including inherent variability that occurs during the manufacturing process, biologics and biosimilars are difficult to replicate. Therefore, unlike small molecule brand and generic drugs, biosimilars cannot be manufactured as equivalent copies of the biologics they reference.[4]

II. Biosimilars Create Patient Options and Competition

Aimed Alliance supports the development of biosimilar medicines. Medications work differently for each patient; a medication that is effective for one patient may not be effective for another. As such, patients need multiple options to treat their conditions. Biosimilars oftentimes are prescribed to treat conditions that require highly individualized treatment, and therefore, the development of biosimilars provides patients with complex medical conditions a greater range of treatment options. The availability of multiple biosimilar products enables physicians to customize care plans to achieve an optimal balance of clinical effectiveness and minimal side effects. In addition, as more products become available in the market to treat a condition, competition should increase between product manufacturers, driving down drug prices for patients and creating cost-savings.[5]

III. Stable Patients Should Not Be Switched

Given the potential benefits of biologics and biosimilars, Aimed Alliance urges insurers and health plans to cover a wide range of both types of products. At the same time, Aimed Alliance believes that once a patient achieves stability on a prescribed medication, only the prescribing physician in consultation with the patient—not an insurer or health system—should determine when it is appropriate to change the patient's medication. This is especially important for patients prescribed biologics and biosimilars, which are difficult to replicate.

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[1] Omudhome Ogbru, *Biolgics (Biologic Drug Class)*, MEDICINENET (July 27, 2018, https://www.medicinenet.com/biologics_biologic_drug_class/article.htm).
[2] *What is a biosimilar product? Biosimilar and Interchangeable Products*, U.S. FOOD & DRUG ADMINISTRATION (Jun. 20, 2018), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#interchange
[3] *Id.*
[4] Paul Declerck, Romano Danesi, Danielle Petersel, & Ira Jacobs, *The Language of Biosimilars: Clarification, Definitions, and Regulatory Aspects*, 77 Drugs 671, 672 (2017).
[5] Chronis H. Manolis, et al., *Biosimilars: Opportunities to Promote Optimization Through Payer and Provider Collaboration*, 22 J. Manag. Care Spec. Pharm. S3, S3 (2016).

However, nonmedical switching is becoming increasingly common. Nonmedical switching occurs when an insurer or health system requires a stable patient to switch from his or her current, effective medication to an alternative drug by excluding the medication from coverage, imposing barriers to access, elevating the medication to a higher cost tier, or otherwise increasing out-of-pocket costs to the patient.

A stable patient who is forced to switch off a biologic or a biosimilar product for nonmedical reasons may experience adverse events, increased health care utilization and medical expenses, and missed work.[6] These third party-driven changes may also violate consumer protection laws governing unfair and deceptive trade practices,[7] especially if such changes are made after the plan year has begun or without proper notice and time for the plan enrollee to appeal or request an exception.[8] Therefore, insurers and health systems should allow stable patients to remain on their current biologic or biosimilar.

IV. Interchangeability Should Be Determined by the FDA

"Interchangeable" is a term of art defined in the Biologics Price Competition and Innovation Act.[9] To obtain an "interchangeable" designation, a biosimilar product must meet a high standard of legal requirements for evaluation and testing.[10] Based on these requirements, the U.S. Food and Drug Administration ("FDA") will deem two products to be interchangeable if they are "expected to produce the same clinical results as the reference product in any given patient."[11] The FDA will also consider the risk of reduced safety or efficacy when switching between two products in making such a determination. An FDA determination of interchangeability provides prescribers with confidence that one product may be substituted for the other without safety and effectiveness concerns.[12] Aimed Alliance believes that only the FDA should determine whether two products are interchangeable, and not pharmacy and therapeutics committees.

V. Biosimilar Substitution Requires Prescriber and Patient Approval

Pharmacists have the authority to substitute small molecule, conventional drugs for generics.[13] Depending on state law, pharmacists may also have the authority to substitute a

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[6] Allan Gibofsky, et al., *Effects of Non-Medical Switching on Outcomes Among Patients Prescribed Tumor Necrosis Factor Inhibitors*, 33 Current Med. Res. Opinion 1945, 1949-50 (2017).
[7] GREGORY L. DEMERS & HARVEY J. WOLKOFF, BUS. TORTS MA. (Ma. Continuing Legal Educ., 2d ed. 2016)
[8] Stacey L. Worthy, Daniel C. McClughen, & Shruti Kulkarni, *Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care*, 48 Loy. U. Chi. L.J. 1042, 1062 (2017).
[9] 42 U.S.C § 262(k)(4).
[10] *What is a biosimilar product? Biosimilar and Interchangeable Products*, U.S. FOOD & DRUG ADMINISTRATION (Jun. 20, 2018), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#interchange
[11] *Id.*
[12] *Id.*
[13] William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 Health Aff. 1383, 1384 (2011).

biologic for a biosimilar.[14] Due to the complexity of biologics and biosimilars, Aimed Alliance believes that pharmacists should only substitute one for the other if they obtain approval from both the practitioner and the patient. If a biologic and biosimilar are deemed interchangeable, however, it may be appropriate to switch the patient from their prescribed product. In those cases, pharmacists should still obtain approval from the patient and provide notice to the practitioner. Aimed Alliance advises practitioners who do not want their patients to be switched at the pharmacy level to write "do not substitute" on the prescription order.

[14] *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, NATIONAL CONFERENCE OF STATE LEGISLATURES (2018), http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx.