AIMED ALLIANCE

April 9, 2020

Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars; Request for Comments (Docket No. FDA-2019-N6050)

Dear Commissioner Hahn:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. On March 9, 2020, the U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) held a workshop entitled "FDA/FTC Workshop on Competitive Marketplace for Biosimilars." Thank you for the opportunity to comment on that workshop.

I. Biosimilars Increase Patients' Options and Provide Cost Savings Through Competition

Biologics and biosimilars play a critical role in treating several serious illnesses, including cancer, autoimmune diseases, and rare genetic disorders.[1] Aimed Alliance supports the development of and improved access to biosimilars because they provide patients with additional treatment options and increase competition. Patients with complex conditions often need multiple options to treat their conditions, and biosimilars add to the range of treatment options available to such patients. The availability of multiple biosimilar products enables health care practitioners to customize care plans to achieve an optimal balance of clinical effectiveness and minimal side effects. According to an Avalere Health study, 1.2 million U.S. patient could gain access to treatment by 2025 as the result of biosimilar availability.[2]

Biosimilars also have the potential to create significant cost savings, which is vital in the current environment. According to a recent Gallop poll, more than one in five Americans reported an inability to pay for a medically necessary medication, and 34 million Americans knew of someone who died because that person could not afford his or her medication.[3] As more products become available, competition increases between product manufacturers, driving down drug prices for patients and resulting in cost-savings for the health care system.[4] Over time, price competition could result in lower insurance premiums, lower out-of-pocket costs, and increased access to

[1] https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdaftcbiologicsstatement.pdf
[2] http://biosimilarscouncil.org/wp-content/uploads/2019/03/Biosimilars-Council-Patient-Access-Study.pdf
[3] https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx
[4] https://www.ncbi.nlm.nih.gov/pubmed/27579939

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medications—all of which are benefits to patients.[5] One RAND study estimates that biosimilars could reduce direct spending on biologic drugs by $54 billion over a ten-year period.[6]

II. Efforts to Improve Adoption of Biosimilars

Given the potential benefits of biologics and biosimilars, Aimed Alliance supports efforts to increase the adoption of biosimilars, including encouraging health plans to cover a wide range of both types of products.

A. Sham Citizen Petitions

One method to speed the adoption of biosimilars would be to prohibit manufacturers from filing frivolous citizen petitions to improperly delay biosimilars from coming to market. A party may submit a citizen petition to the FDA to request the agency to take or refrain from taking a particular administrative action.[7] This includes petitions that ask the agency to take action against a pending biosimilar application.[8] Oftentimes, these petitions are based on claims that the drug pending approval does not meet required pharmacokinetic and bioequivalence standards.[9]

If a reference product manufacturer submits a citizen petition early, such as when the FDA is making decisions about the bioequivalence requirements for a generic drug product, the petition may be a meaningful contribution towards the FDA's evaluation of an application.[10] However, when petitions are submitted late in the review process and do not raise valid scientific or legal issues, they may improperly delay the approval of an application.[11] As a result, Congress enacted Section 505(q) of the Food, Drug, and Cosmetic Act "to ensure that petitions are not used to improperly delay approval of" biosimilars.[12] This statute requires petitioners to certify the date they first discovered the information relied upon in the petition; specifies that the FDA cannot delay approval of a biosimilar due to a request to take an action related to the biosimilar, unless the request is in writing and the agency finds the delay is necessary to protect the public health; and requires the FDA to take final action within 150 days after a petition is submitted.[13]

Yet, in some instances, manufacturers may still use these petitions to delay biosimilar market entry.[14] In these instances, the FDA should engage the FTC to determine if the petition was submitted with the primary purpose of delaying an approval, including when the petitioner has:

- Taken an unreasonable length of time to submit the petition;
- Submitted multiple or serial petitions raising issues that reasonably could have been

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[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6075809/
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6075809/
[7] 21 C.F.R. Sec. 10.30.
[8] *Id.*
[9] *Id.*
[10] https://www.federalregister.gov/documents/2016/11/08/2016-26912/amendments-to-regulations-on-citizen-petitions-petitions-for-stay-of-action-and-submission-of
[11] https://www.federalregister.gov/documents/2016/11/08/2016-26912/amendments-to-regulations-on-citizen-petitions-petitions-for-stay-of-action-and-submission-of
[12] *Id.*
[13] *Id.*
[14] http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulr.

known to the petitioner when it submitted earlier petitions;
- Submitted a petition close to a biosimilar's approval date (e.g., close to the expiration of a blocking patent or exclusivity); or
- Submitted a petition raising the same or substantially similar issues as a prior petition.

B. Nonmedical Switching

While Aimed Alliance supports efforts to increase marketplace adoption of biosimilars, we do not support doing so through nonmedical switching. Nonmedical switching occurs when a health plan requires a stable patient to switch from his or her current, effective medication to a less costly, alternative drug by removing the medication from the formulary list, moving a drug to a higher cost tier, or increasing the out-of-pocket costs owed. Once a patient achieves stability on a prescribed medication, whether it is a biologic or a biosimilar, only the prescribing practitioner in consultation with the patient—not an insurer—should determine when it is appropriate to change the patient's medication.

Health care providers often work with patients for years to find a therapy that helps manage their disease and prevent re-emerging symptoms or the development of new side effects. Often, people living with epilepsy, diabetes, AIDS, cancer, and autoimmune diseases must try multiple medications before finding one that is well tolerated and effective. Forcing stable patients to switch medications simply to save on cost can disrupt that carefully achieved equilibrium. Studies have shown that some stable patients who are forced to switch from one product to another for nonmedical reasons may experience adverse events, increased health care utilization and medical expenses, and missed work.[15] While this is not the case for all patients, the decision to switch medications for a stable patient must remain with the prescriber and be individualized to the patient to minimize a chance of adverse events. As such, efforts to improve access to biosimilars should not include nonmedical switching by health plans.

III. Efforts to Discourage False or Misleading Communications About Biosimilars and to Deter Anti-Competitive Behaviors in the Biologic Product Marketplace

Practitioners must have access to truthful and non-misleading information so they can determine whether biosimilars are medically appropriate for their patients. The public must be educated so they understand that biologics and biosimilars are equally safe and effective and that biosimilars have gone through rigorous scientific requirements to show that they work just as well as their reference products.

Conversely, the FDA and FTC should take enforcement action against any party that disseminates misleading information about biosimilars. It is misleading to state that 1) a biosimilar is less safe or effective or of a lower quality than an interchangeable product; or 2) a biosimilar that has not received interchangeable designation is less safe or effective than a biologic reference product.

However, it is also important to ensure that manufacturers are not prohibited from making truthful statements. During the workshop, some commenters stated that it is misleading to claim

[15] E.g., https://www.ncbi.nlm.nih.gov/pubmed/28870101; https://www.ncbi.nlm.nih.gov/pubmed/31081414.

that biosimilars are only "similar or highly similar," but not exact copies of their reference products. They also stated that it was misleading to state that interchangeability is a higher regulatory standard to meet. Yet, these statements are consistent with legal definitions of "biosimilar" and "interchangeability." The Public Health Safety Act defines a biosimilar as a biological product that "***is highly similar*** to the reference product notwithstanding minor differences in clinically inactive components;" and for which there are no clinically meaningful differences with the reference product.[16] Therefore, given the nature of large molecule drugs and the legal definition of a biosimilar, it would be inaccurate to state that they are identical or exact copies even if there are no clinically meaningful differences.

Likewise, the Public Health Safety Act defines "interchangeability" as a biosimilar that is shown to meet additional standards so that it may be substituted for the reference product without intervention of the health care provider who prescribed the reference product.[17] By statute, to obtain interchangeability designation, the product 1) must be a biosimilar; 2) "can be expected to produce the same clinical results as the reference product in any given patient;" and 3) "for biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."[18] Therefore, given that interchangeability designation requires additional scientific evidence regarding switches above and beyond proving that a product is a biosimilar, it is a higher standard to the extent that it creates an additional burden of scientific data. Therefore, such statements should not be considered misleading or untruthful.

Commenters also stated that it could be misleading to state that while biosimilars may be highly similar, there is a chance that a patient may react differently to the biosimilar than the biologic. This is not a misleading statement. Studies have shown that some patients do react differently to certain products.[19] While it may not be the norm for most patients to have a different reaction, it still occurs. In sum, it is important to ensure that parties do not use language to directly state or imply that one product is not as safe or effective as other; however, it is also important not to restrict speech so much so that patients are unable to receive accurate information.

IV. Conclusion

Aimed Alliance supports the marketplace adoption of biosimilars to improve access to treatment for patients and drive down the cost of medications. To ensure more widespread adoption, the FDA and FTC should take action against bad actors for filing frivolous citizen petitions and making untruthful or misleading statements. However, efforts to promote biosimilars should not include encouraging nonmedical switching or prohibiting truthful statements. Thank you for your consideration.

Sincerely,
Stacey Worthy
Counsel

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[16] 42 U.S.C. 262(i)
[17] 42 U.S.C. 262(i)
[18] 42 U.S.C. 262(k)
[19] E.g., https://www.ncbi.nlm.nih.gov/pubmed/28870101; https://www.ncbi.nlm.nih.gov/pubmed/31081414.