AARP
Real Possibilities

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August 2, 2016

Dr. Robert Califf
Commissioner of Food and Drugs
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

*Submitted via www.regulations.gov*

Re: Draft Guidance for Industry on Labeling for Biosimilar Products [Docket No. FDA-2016-D-0643]

Dear Dr. Califf:

Thank you for the opportunity to comment on the Draft Guidance on Labeling for Biosimilar Products and the ongoing implementation of the Biologics Price Competition and Innovation Act (BPCI). AARP strongly supports the creation of a clear, workable biosimilar approval pathway that will provide consumers with access to safe, effective biosimilar products.

AARP has long understood the importance of less expensive generic versions of biologic drugs, known as biosimilars or follow-on biologics. While biologics currently represent a relatively small number of prescriptions, spending on such products is already substantial. For example, biologics represented 62 percent—or more than $11 billion—of total Medicare Part B drug spending in 2014.[1] Beneficiary cost sharing under Medicare Part B is 20 percent with no out-of-pocket limit, leaving some older adults and people with disabilities with out-of-pocket costs that can reach as much as $100,000 per year.[2] In combination with expectations that biologics will comprise an even larger share of drug spending and utilization in the future, [3] it is clear that a robust biosimilar market

[1] S. Sheingold, E. Marchetti-Bowick, N. Nguyen and R.K. Yabroff, *Medicare Part B Drugs: Pricing and Incentives*, ASPE Issue Brief, March 2016.
[2] Government Accountability Office, *Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly to Beneficiaries*, October 2015.
[3] S.C. Sungh and K.M. Bagnato, "The Economic Implications of Biosimilars," *American Journal of Managed Care*, Vol. 21(16): S331-S340.

will be critical to efforts to ensure that patients have affordable access to prescription drugs.

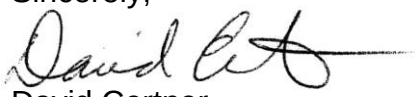
In its draft guidance, FDA proposes that biosimilar product labels should include the clinical data that supports the safety and efficacy of the reference product. AARP supports this approach. The clinical studies used to establish biosimilarity are designed to demonstrate that there are no clinically meaningful differences between the biosimilar and reference product, not to re-establish safety and efficacy. Thus, it would not be appropriate to include biosimilarity data in the label.

FDA also proposes that the label include a statement that the product is biosimilar to a reference biologic. Given that FDA approval of a biosimilar denotes "no clinically meaningful differences in terms of safety and effectiveness from the reference product,"[4] AARP does not believe that such a statement is necessary. Further, we are concerned that requiring a labeling statement that only applies to biosimilars could create confusion and discourage biosimilar adoption. Unnecessary differentiation between biosimilars and reference products also reinforces the false narrative that biosimilar products are somehow inferior, reducing prescriber and patient comfort with these products. We strongly urge FDA to reconsider its approach.

AARP's position on this draft guidance reflects our overriding concern that BPCI be implemented in a manner that ensures safety and efficacy without creating unnecessary barriers that defeat the purpose of the legislation. The development of a robust and competitive biosimilar market is integral to the sustainability of our health care system. More importantly, it will help ensure that consumers have affordable access to safe and effective prescription drugs.

Thank you for the opportunity to comment. If you have any questions, please do not hesitate to contact me or KJ Hertz on our Government Affairs staff at khertz@aarp.org or 202-434-3770.

Sincerely,



David Certner
Legislative Counsel & Legislative Policy Director
Government Affairs

[4] U.S. Food and Drug Administration, "Information on Biosimilars." http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/