April 13, 2012

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

Attention: Docket No. FDA–2011–D–0605, FDA–2011–D–0602, and FDA–2011–D–0611

By electronic submission: www.regulations.gov

Re: Draft Guidance Documents on Biosimilar Product Development [Docket No. FDA–2011–D–0605, FDA–2011–D–0602, and FDA–2011–D–0611]

To Whom It May Concern:

Thank you for the opportunity to comment on the Draft Guidance Documents on Biosimilar Product Development and, more specifically, on the implementation of the Biologics Price Competition and Innovation Act (BPCI) which passed as part of the Affordable Care Act. AARP strongly supports the creation of a workable biosimilar approval pathway that will provide consumers with much-needed access to safe, effective biosimilar products.

Background

AARP has long understood the importance of generic versions of biologic drugs, or biosimilars, to our members. Biologic drugs are used to treat many diseases – such as multiple sclerosis, arthritis, and cancer – that often affect older populations. However, the cost of these drugs can put these treatments out of reach for many consumers, even those with comprehensive health insurance. The average costs for biologic products are estimated around $16,000 per year; some biologic treatments can cost as much as $10,000 a month.[1]

The high costs associated with biologic drugs not only have adverse effects on consumers, but also on other health care payers, including employers, private health care plans, and public programs like Medicare and Medicaid. With spending on biologics increasing more than ten times faster than spending on traditionally-developed small-molecule drugs,[2] neither consumers nor health care providers can afford to continue paying the high prices associated with biologics indefinitely.

For these reasons, AARP has long supported the development of an approval pathway for biosimilars, and welcomes this opportunity to address the implementation of the BPCI.

Overall, AARP asks the FDA to consider the implications of BPCI for our members and the sustainability of the programs they rely on for their health care.

In particular, AARP would like the FDA to help ensure that unnecessary barriers do not preclude the monetary savings intended to be achieved through the creation of an approval pathway for biosimilars.

Interchangeability

AARP believes it is extremely important that FDA have the flexibility to determine – based on scientific evidence – instances where biosimilar products can be designated as interchangeable with reference products. Current techniques allow robust characterization of even complex biologics[3], and leading biosimilar manufacturers have been able to demonstrate that their products are virtually indistinguishable from the original products.[4] AARP understands that not all biosimilars will be able to demonstrate interchangeability right away, but FDA should grant such a designation to those who can meet that benchmark.

AARP also firmly believes that, in keeping with the intent of BPCI, FDA should not elevate interchangeability to a degree that makes it unattainable. Products that are designated as interchangeable will allow pharmacists to substitute a biosimilar for the reference product without the involvement of the prescriber. This will encourage adoption of biosimilars and enhance savings and access, much like what happens with traditional generic drugs.[5] In addition, without an interchangeable designation, biosimilar companies would have to expend resources to market and promote their products, driving up the cost to the consumer.[6]

Evergreening

While there continues to be some disagreement over whether evergreening, or the practice of extending exclusivity through minor changes to an already-approved product, is possible under BPCI[7], AARP believes that FDA should err on the side of caution and implement regulations that strongly curtail manufacturers' ability to obtain exclusivity extensions. Manufacturers should have to demonstrate a clear, significant clinical advantage over the reference product in order to receive an additional 12 years of exclusivity. Otherwise, minor structural changes could conceivably result in an additional 12 years of exclusivity, making the monopoly protection for some products effectively indefinite.

Naming

Unless FDA has compelling evidence that it will negatively impact consumer safety, AARP believes biologics and biosimilars should have the same International Nonproprietary Name (INN). Biosimilar market penetration is expected to be slowed by uncertainty about differences between reference and biosimilar products, which could be heightened if the biosimilar product does not have the same name as the reference product.[8] Different INNs could also lead to patient and prescriber confusion and negatively impact interchangeability, thereby reducing patient access. AARP is also concerned that requiring different INNs would separate existing information about a biologic product – including safety information – from its biosimilar counterparts, which would be disadvantageous to prescribers.

Adverse events and product recalls for traditional, small-molecule drugs are successfully tracked at the national drug code and lot number level: it is unclear why that system would not be equally effective for biologic drugs. Further there is already a precedent for shared names (e.g., erythropoietins, somatropin, interferon), which has not resulted in any known issues).[9]

Conclusion

The aforementioned positions reflect AARP's overriding concern that BPCI be implemented in a manner that ensures safety and efficacy without creating barriers that defeat the purpose of the legislation. The pathway will only be utilized if the requirements for biosimilar approval are reduced relative to a traditional biologic license application (BLA). If not, as evidenced by Teva's recent decision to submit a BLA for its biosimilar Neutroval, companies will forgo the biosimilar pathway entirely.[10] Another possibility is that manufacturers will focus on "biobetters," or drugs that are improvements on original biologic products.[11] These, too, would be approved under the traditional BLA process. Either outcome would be disadvantageous from AARP's perspective, as it is unlikely that the prices for these products would be substantially lower than the prices of biologic drugs.

In addition, AARP has repeatedly stressed that the 12-year exclusivity period granted by BPCI is too long. An unnecessarily lengthy market exclusivity period will impede access to biosimilars and increase costs for consumers, employers, and publicly-funded programs like Medicare and Medicaid. AARP strongly suggests that the FDA monitor the development of the biosimilars market and, if necessary, consider promoting and supporting efforts to reduce or eliminate the exclusivity period for biologic drugs in the future.

If you have any questions regarding these comments, please do not hesitate to contact KJ Hertz on our Government Affairs staff at (202) 434-3732 or khertz@aarp.org.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs

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[1] A.F. Bourgoin, "White Paper: What You Need to Know About the Follow-on Biologic Market in the U.S.: Implications, Strategies, and Impact,"Thomson Reuters, January 2011.
[2] IMS Institute for Healthcare Informatics, "The Use of Medicines in the United States: Review of 2010," April 2011.
[3] M. McCamish, "Testimony on behalf of the Novartis Group of Companies," FDA Public Hearing, Approval Pathway for Biosimilar and Interchangeable Biological Products, November 2-3, 2010; J. Windisch, "Comments by the European Generic medicines Association," FDA Public Hearing, Approval Pathway for Biosimilar and Interchangeable Biological Products, November 2-3, 2010.
[4] C. Klein, "Biosimilars – A sophisticated market with attractive growth potential," Sandoz Biopharmaceuticals, Presentation at 3rd DVFA Life Science Conference, June 8, 2010.
[5] M. McCamish and G. Wollett, "Worldwide Experience with Biosimilar Development," *mAbs*, Vol 3(2): 212-220.
[6] U.S. Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, June 2009.
[7] C.A. Landmon and E.P. Retersdorf, "Advocating for Biosimilar Approval Standards Under BPCI," *Pharmaceutical Technology*, Vol 35(6): 81-82.
[8] U.S. Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, June 2009.
[9] S. Miller, "Testimony on Behalf of Express Scripts, Inc.," FDA Public Hearing, Approval Pathway for Biosimilar and Interchangeable Biological Products, November 2-3, 2010.
[10] GaBI Online, "Questions Over US Biosimilars Pathway in Light of Teva's BLA," *Pro Pharma Communications International*, May 20, 2011.
[11] N. Dinwoodie, "Biobetters and the Future Biologics Market," *BioPharm International*, Vol 24 (11): 31-35.