OPERS

July 9, 2015

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Rockville, MD 20852

Delivered electronically through http://www.regulations.gov

Reference: Docket No. FDA 2011-D-0611

To the Food and Drug Administration:

The Ohio Public Employees Retirement System (OPERS) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on "*Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovations Act of 2009; Draft Guidance for Industry; Availability*", published in the Federal Register on May 13, 2015.

OPERS provides comprehensive medical and prescription drug coverage to 227,000 non-Medicare and Medicare Retiree Health Care Program participants. In 2014, the total prescription drug cost for OPERS' was $680 million, of which $137 million was spent on specialty drugs. Although only 3.2% of current OPERS Health Care Program participants utilize specialty drugs, these medicines account for 20% of overall drug spend and is the fastest growing segment of our annual drug cost. According to Artemetrx, specialty drug spend is projected to increase at an average of 20% per year over the next last four years.

The availability of biosimilar drugs, which compete against reference brand biological drugs, is an integral part of OPERS' long-term strategy to keep prescription drug costs affordable for our retiree health care plan and our plan participants. Express Scripts, OPERS' Pharmacy Benefits Manager, projects that OPERS could save more than $129 million if just eleven biosimilars enter the market within the next ten years (2015-2024).[1]

OPERS supports the FDA's efforts to implement the Biologics Price Competition and Innovation Act (BPCIA). We are encouraged by the FDA's efforts to ensure that Americans have access to safe and effective biosimilar medications. And although the FDA is not concerned primarily with encouraging marketplace competition, we believe the agency is uniquely positioned to ensure that biosimilar drugs can become a viable prescription drug alternative in the marketplace.

With that in mind, OPERS respectfully requests that the FDA:

1) Post on the FDA website all pertinent information regarding FDA's previous determination that certain biological products are safe, pure and potent.
2) Release guidance on *Considerations in Demonstrating Interchangeability to a Reference Product*.
3) Release and finalize all remaining biosimilar guidance pertaining to BCPIA.

[1] Express Scripts, Inc. financial model, based on 11 existing biologic drugs that are the most likely candidates for biosimilars in the next 10 years. The assumptions were based on conservative estimates of utilization, cost and consumer inflation

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Questions and Answers - Biosimilarity or Interchangeability

Q&A. I.13. Regarding what constitutes "publicly-available information" for purposes of a previous FDA determination that a reference product is safe, pure, and potent to include in a 351(k) application

OPERS supports the FDA, posting on their website pertinent "action package" information regarding the FDA's previous determination that certain biological products are safe, pure and potent.

OPERS desires that 351(k) applicants have access to all pertinent information that will help facilitate quicker biosimilar development programs and submission of 351(k) applications. Getting biosimilars to the market quicker will translate into faster access to safe, effective and lower cost biosimilar medications.

Q&A. I.14. Regarding an applicant obtaining a determination of interchangeability between its proposed product and the reference product of an original 351(k) application

Allowing manufacturers to apply for interchangeability in an original 351(k) application will encourage manufacturers to apply more often for interchangeability. OPERS wants manufacturers to apply more often for interchangeability because interchangeable biosimilars are stronger competition than biosimilars to reference biologicals. Interchangeable biosimilars may be substituted for reference biologicals by pharmacists just as generic drugs are substituted for brand drugs. This ability to substitute drugs, has led to the success of the generic drug market and will significantly contribute to the success of the biosimilar market.

OPERS is looking forward to the FDA releasing proposed guidance on interchangeability as well as remaining biosimilar guidance. The release of remaining biosmilar guidance and finalization of all future guidance will ensure a clearly defined pathway for manufacturers as well as ensure the pathway becomes successfully function for various stakeholders who are depending on its success. OPERS looks forward to participating in the public comment period(s) as additional guidance is released.

Q&A. I.16. Regarding how a proposed biosimilar product applicant can fulfill the requirement for pediatric assessments under the Pediatric Research Equity Act (PREA)

OPERS supports the proposed answer that biosimilar applicants may fulfill PREA requirements by satisfying the statutory requirements for showing biosimilarity and providing adequate scientific justification under BPCIA for extrapolating the pediatric information from the reference product to the proposed biosimilar product. This will prevent manufactures from having to perform duplicate efforts under BPCIA and PREA. It is understood and reasonable that if scientific justification is inadequate under BPCIA that a biosimilar applicant must submit appropriate data to fulfill PREA requirements.

In the proposed answer, the FDA clarifies the difference between "extrapolation" in the context of a proposed biosimilar product under BPCIA and in the context of PREA. With regards to the former, OPERS supports science-based extrapolation of proposed biosimilar product approval under the BPCIA. Extrapolation is vital to the success of biosimilars; it reduces the time and cost of development. Extrapolation allows for safe, effective and high-quality medicines to be accessible more quickly and to a larger number of individuals.

Exclusivity

Q&A. III.1. Regarding whether an applicant can include in its 351(a) BLA submission a request for reference product exclusivity under section 351(k)(7) of the PHS Act

OPERS appreciates the clarification and supports the answer, A.III. 1., that an applicant may include in its Biologics License Application (BLA) submission a request for reference product exclusivity under section 351(k)(7) of the PHS Act for consideration by the FDA.

OPERS supports an efficient drug approval process. Allowing manufacturers to submit only one application is more efficient and reduces manufacturer's drug development costs. OPERS hopes that manufacturers will then pass on reduced drug development costs to governments, plan sponsors and consumers.

OPERS submitted comments to the FDA draft guidance on Reference Product Exclusivity for Biological Products Filed under Section 351(a) of the PHS Act. OPERS' position is that biological product exclusivity should not be extended, except in cases where manufacturers can demonstrate that a structural change has resulted in a clear, significant improvement in product safety, purity or potency. OPERS supports the FDA creating a market exclusivity framework that prevents Manufacturers from executing the practice known as "evergreening", because the impact is far-reaching, resulting in a less competitive marketplace and ultimately, higher costs for payors, taxpayers and consumers.[2]

Conclusion

Biosimilar competition is a necessary part of OPERS' long-term strategy to manage the growth of its health care expenditures. These innovative biological medicines can be an integral part of valuable medical care in the future, but only if payors, taxpayers and consumers can afford them. Marketplace competition is one of the most effective tools we have for managing these costs moving forward.

We thank you again for the opportunity to provide comments on the draft guidance. If you have questions or would like additional information regarding OPERS' comments, please contact Brian Pack, OPERS' Health Care Finance and Policy Officer at 614-225-1858.

Sincerely,

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[2] Evergreening is the practice of prolonging market exclusivity by patenting peripheral features or making marginal improvements to a biological product