OPERS
Ohio Public Employees Retirement System

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Food and Drug Administration
Division of Dockets Management (HFA-305)
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Rockville, MD 20852

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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 "*Labeling for Biosimilar Products,*" published in the Federal Register on April 4, 2016 (Guidance).

As a basic tenet of biosimilar drug labeling, OPERS believes biosimilar products, like generic drugs, should have the exact same labeling as reference biological products. Requiring distinct labeling for biosimilar products may lead to unwarranted safety concerns among healthcare practitioners and patients, decrease market adoption of biosimilar products and negatively impact access to safe, effective and affordable biosimilar products.

OPERS supports the FDA's position that biosimilar product labeling should not include a description of data from a clinical study that was used to support the licensure of the biosimilar. This data was designed to demonstrate there are no clinically meaningful differences between the proposed biosimilar product and the reference product, and was not designed to demonstrate safety and efficacy of the product for every indication. This data is not needed by healthcare practitioners and could create unnecessary confusion and/or result in an inaccurate understanding of the risk benefit profile of the biosimilar product.

However, we are concerned that the current Guidance creates several barriers to widespread market adoption of biosimilar products by requiring different labels for biosimilar and reference biological products. We believe that these differences will confuse practitioners and patients and/or erode their confidence in biosimilar products that they could see as unsafe or less effective than the reference product.

As the FDA refines its guidance regarding the labeling of biosimilar products, we respectfully request that it consider the impact of its proposals on patient access to biological products and the development of the biosimilar marketplace. In particular, we ask that the FDA avoid impeding the market adoption of biosimilar

products by establishing biosimilar labeling requirements that do not require:

(1) Statements of biosimilarity to be included on biosimilar product labels.
(2) Different approaches to product identification.
(3) Additional information on immunogenicity to be included on biosimilar product labels.
(4) Inconsistency between biological product labels and biosimilar product labels.
(5) Different labels for interchangeable biological products.

Therefore, OPERS recommends that the following concepts should be included when the FDA finalizes its guidance on Labeling for Biosimilar Products:

1. **Biosimilar Drug Labels Should Not Include a Statement of Biosimilarity**
   OPERS does not believe that biosimilar labeling should be required to state that the drug has been approved as a biosimilar to a specific reference biological product for stated indications and routes of administration. We are concerned that this difference will cause practitioners and patients to question the safety and efficacy of the biosimilar product. Further, a statement of biosimilarity currently does not exist on the label of the first FDA-approved biosimilar (Zarxio), and this does not seem to be an issue for healthcare practitioners or patients who prescribe or utilize Zarxio.

2. **Biosimilar Drug Labels Should Not Contain Different Product Identifications**
   OPERS does not believe that different product identifications (biosimilar product name, reference product name, core name and/or combination of these approaches) should be used on biosimilar product labels. The use of several different product identifications within the same label could lead to healthcare practitioner and patient confusion.

   Adding to this confusion would be the potential use of biological and biosimilar proper names with an FDA-approved suffix. Therefore, OPERS recommends utilizing the existing United States Adopted Names (USAN) naming system to name and track biological products.

3. **Biosimilar Labels Should Not Include Additional Information on Immunogenicity**
   OPERS does not believe that biosimilar product labels should be required to include additional information on biosimilar immunogenicity or adverse reactions. We believe that this information is unnecessary and may create unwarranted safety concerns for healthcare practitioners and providers. Biosimilar experience outside of the United States has not resulted in immunogenicity issues compared to reference biological products.

4. **Labeling Requirements for Biological Products and Biosimilar Products Should Be Consistent**
   OPERS believes that labeling requirements for biosimilar products and biological products should be consistent. It is important that biosimilar products and biological products both follow the same requirements, such as the physician labeling rule (21 CFR 201.56(d) and 201.57) and the pregnancy and lactation labeling rule (21 CFR (c)(9)(i-iii)). The presence of multiple versions of labels may create uncertainty and/or confusion for healthcare practitioners and patients which could lead to unnecessary

reductions in the utilization of biosimilar products and/or biological drugs due to efficacy and/or safety concerns by healthcare practitioners or patients.

5. **Interchangeable Biological Product Labels Should Be Identical to Reference Biological Product Labels**

   Although labels for interchangeable biological products were not addressed directly in this Guidance, OPERS firmly believes that interchangeable biological products should have the exact same labeling as reference biological products. We anticipate that we will discuss this matter in greater detail when the FDA's upcoming interchangeable biological products guidance is released later this year.

Comment

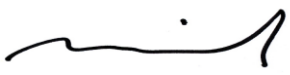
OPERS is the largest public retirement system in Ohio, and has more than 222,000 non-Medicare and Medicare Retiree Health Care Program participants. In 2015, OPERS' total prescription drug cost was $706 million, $174 million of which was spent on specialty drugs. Although only 3.1% of current OPERS Retiree Health Care Program participants utilize specialty drugs, these medications account for 25% of our overall drug cost and represent the fastest growing segment of our annual drug cost. According to current studies, specialty drug costs are projected to increase 17-26% per year over the next three years.[1,2,3]

Biosimilar competition is a necessary part of OPERS' long-term strategy to manage the growth of its health care expenditures and increase patient access to affordable, high quality prescription drugs. Biosimilar products can greatly improve drug access and affordability, but only if they are easily understood and adopted by providers and patients.

We understand and appreciate that the FDA is primarily concerned with ensuring drug safety and efficacy, but we believe the agency is uniquely positioned to ensure that biosimilar products can become a viable and safe alternative for healthcare practitioners and patients through the biosimilar product labeling positions outlined in this letter.

We thank you again for the opportunity to provide comments on this process. 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,



Marianne Steger, MS, CEBS
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[1] Artemetrx Specialty Drug Trend Across the Pharmacy and Medical Benefit, http://www.artemetrx.com/wp-content/uploads/2014/08/artemetrx-specialty-drug-trends.pdf
[2] ESI: The 2014 Drug Trend Report, http://lab.express-scripts.com/drug-trend-report/
[3] Catamaran: 2014 Informed Trends , http://catamaranrx.com/Insights/Trend-Report/