OPERS
Ohio Public Employees Retirement System

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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to submit comments to the Food and Drug Administration ("FDA") on *Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability,*" published in the Federal Register on August 28, 2015 ("Guidance").

OPERS is the largest public retirement system in Ohio, and the eleventh-largest public retirement system in the United States. We provide comprehensive medical and prescription drug coverage to 227,000 non-Medicare and Medicare Retiree Health Care Program participants. Like many health care plan sponsors, OPERS must continually review and revise its plan design in order to effectively balance costs and care.

In recent years, OPERS has experienced an alarming trend within its annual prescription drug spend – in the area of specialty drugs, a significant and increasing percentage of our total cost is being driven by a relatively small percentage of our member population. For example, in 2014, OPERS' total prescription drug costs exceeded $680 million. Of that figure, approximately $137 million – almost one-fifth of the total cost – was spent on specialty drugs, despite the fact that only 3.2 percent of our members utilized specialty drugs in 2014.

Specialty drugs now represent one of the fastest growing segments of our annual drug spend, and without regulatory intervention supporting the development and adoption of biosimilar and interchangeable product alternatives, we expect this trend to continue. According to current studies, specialty drug spend is projected to increase 17-26% per year over the next three years.[1,2,3] The availability of safe, effective and affordable biosimilar medications is an integral part of OPERS' long-term strategy to manage future prescription drugs costs for our retiree health care program and our members.

[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/

OPERS has generally supported the FDA's efforts to implement the Biologics Price Competition and Innovation Act ("BPCIA"). However, we are concerned that the naming convention discussed in the current Guidance will create confusion among health care providers and patients, impact patient safety and negatively impact the success of the biosimilar and interchangeable products now coming to market.

Many observers, including health care payers and purchasers, like OPERS, have suggested repeatedly that the existing International Nonproprietary Naming ("INN") system could and should be used to name and track biological products. However, with this current Guidance, it is clear that the FDA has different thoughts on the matter. Though we are disappointed, we felt it was important to respond to the reasons offered in support of requiring biological products' proper names to include FDA-designated suffixes.

The current Guidance seems to suggest that the FDA believes biological products are inherently less safe when compared with small molecule drugs, and as such, are deserving of some additional level of scrutiny to effectively monitor their usage and proliferation. However, the evidence available to us from countries that have already approved the use of biological products – including biosimilar and interchangeable products – and rely on the INN system to name and track those products shows little evidence (if any) of the immunogenicity and safety concerns contemplated by the FDA. On the contrary, the same INN system that works for small molecule products, which comprise the vast majority of all prescriptions filled, has also worked for biological products and worked well.

It is important to keep in perspective the small number of patients who currently use biological products and the limited number of health care providers who actually are involved in prescribing, administering and dispensing these medications. In OPERS' case, biological products accounted for just 0.33 percent of prescriptions filled in 2014. Additionally, biological products are generally administered in structured settings, overseen by health care providers who are normally specialists in their fields. With these market safeguards already in place, it is less likely that patients will be prescribed a biological product in error or that there will be difficulty in determining whether a specific biological product was dispensed to a patient.

While the current Guidance is meant to convey only the FDA's "current thinking" on the topic of biological product naming, we urge the FDA to consider allowing the current INN system to work before requiring an additional level of complexity that could increase patient and health care provider confusion and decrease market acceptance of biosimilar and interchangeable products.

With that said, OPERS' comments and answers to the questions posed in the current Guidance are provided below.

1. What are the potential benefits and challenges of designating a suffix in the proper name of a biological product that is:

(a) Devoid of meaning versus meaningful (e.g., a suffix derived from the name of the license holder)

(b) Unique to each biological product versus unique to each license holder and shared by each biological product manufactured by that license holder.

As noted above, OPERS believes that designating a suffix in the proper name of a biological product is

unnecessary and will create confusion for patients and health care providers. We are concerned that physicians, providers and pharmacists will have difficulty remembering the various suffixes applied to different biological products and will, as a result, default to well known name-brand products, at the expense of more affordable and equally safe biosimilar and interchangeable products. Requiring biological products to carry proper names with FDA-designated suffixes places an additional burden on health care providers, and as a result, makes its less likely that physicians, providers and pharmacists will familiarize themselves with alternatives to reference brand biological products, much less prescribe, administer or dispense a competing biosimilar or interchangeable product. This limits the chances that competing biosimilar and interchangeable products will succeed in the marketplace, thereby artificially maintaining prohibitively high prices for reference products.

Regarding the issue of whether the suffix should be unique to the product or the license holder, we are concerned that tying the suffix to the license holder, effectively making manufacturer names a part of the product's proper name, may provide a commercial advantage for certain manufacturers and possibly reduce market acceptance for competing biosimilar and interchangeable products.

2. What would be the potential benefits and challenges for an interchangeable product to share the same suffix as designated in the proper name of the reference product?

If an interchangeable product does share the same suffix as the reference product, how would this impact your responses to question 1, including pharmacovigilance?

If a suffix is required, OPERS believes the suffix designated in the proper name of an interchangeable product should be exactly the same as the suffix assigned to the reference product. The benefit of designating identical suffixes for interchangeable products is increased efficiency and decreased confusion among health care professionals and consumers. Patients, physicians, providers, and pharmacists would know immediately, based on the shared suffix, that a biosimilar product had been deemed 'interchangeable', which could decrease confusion among patients who have been prescribed an interchangeable product and increase market acceptance and substitution of interchangeable products. Unfortunately, this raises a question of how to handle biosimilar products that were approved and named before they were deemed 'interchangeable'. While this issue is discussed in greater detail below, the idea of changing suffixes "mid-stream" is inherently confusing.

If interchangeable products share the same suffix as reference products, OPERS maintains that pharmacovigilance can be accomplished through the continued use of existing mechanisms, including utilizing identifying factors such as proprietary name, manufacturer name, national drug code, and lot numbers.

3. Would there be additional benefits or challenges if the suffix designated in the proper name of a biosimilar product that is subsequently determined to be interchangeable were changed to that of the reference product upon a determination of interchangeability?

Would there be benefits or challenges to allowing the manufacturer of the biosimilar product that is subsequently determined to be interchangeable to have the option of retaining its original suffix or adopting the same suffix as the reference product?

As noted in our response to Question 2, OPERS believes that, if a suffix is required, then the suffix designated in the proper name of an interchangeable product should be exactly the same as the reference product. The challenge of allowing interchangeable products to share a suffix with reference products is how to handle biosimilar products that were first approved and named before they were deemed interchangeable. Making changes to the name of an existing biosimilar product, even if the changes are made for positive reasons (e.g., to reflect a new 'interchangeable status), likely will create confusion among health care providers, increased anxiety and confusion for patients and ultimately, will reduce market acceptance and adoption of interchangeable products.

In this situation, it is clear that the use of a suffix in the proper name of a biological product may have a significant impact on the adoption of interchangeable products. If the interchangeable product has a different name than the reference product, it is less likely to succeed in the marketplace; however, if the name is modified to reflect a change in status, confusion will result and again, market acceptance may decrease. This is a no-win situation for manufacturers who wish to bring biosimilar and interchangeable products to market.

In the event that a biosimilar product is deemed to be 'interchangeable' with a reference product, OPERS does not support giving manufacturers the discretion to choose whether they wish to retain their existing suffix or adopt the same suffix as the reference product. We believe consistency and stability are necessary if the market for biosimilar and interchangeable products is to flourish. Providing manufacturers with discretion regarding the naming and re-naming of their products will increase patient and health care provider confusion.

4. (Part 2) How can FDA and/or other Federal partners help ensure that a distinguishable identifier for each biological product would be captured at the point of dispensing or administration to the patient and be routinely accessible in systems used for pharmacovigilance?

OPERS agrees that diligent pharmacovigilance for biological products post-marketing is vital. However, OPERS believes this can be accomplished through the continued use of existing mechanisms, including identifying factors such as proprietary name, manufacturer name, national drug code, and lot numbers.

Outside of the United States, biological products, including biosimilar and interchangeable products have been available to patients for years. For example, biosimilar products have been approved for use in the European Union for more than a decade. Several of these countries, including the member states of the European Union, use an INN without a suffix and have developed effective monitoring and regulatory schemes for biological products using the proprietary name alone to perform diligent pharmacovigilance. This level of monitoring has been tremendously successful as there has been little evidence of the immunogenicity concerns contemplated by the FDA in the current Guidance.

Additionally, the Academy of Managed Care Pharmacy will soon launch a significant nationwide initiative to proactively monitor both biological products (including biosimilar and interchangeable products) using data from millions of de-identified patients, which further supports the use of existing mechanisms to perform pharmacovigilance

8. What strategies could FDA use to enhance stakeholders' understanding of and education about this naming convention?

OPERS believes the FDA should provide focused and tailored education regarding its thoughts on naming and biosimilar products (including interchangeable products) to patients and health care providers (e.g. physicians, pharmacists) who utilize, prescribe, dispense or track biosimilar drugs. The education could occur on a rolling basis as new biosimilar and interchangeable products are introduced to the market. For example, patients and health care providers who have experience with Sandoz's Zarxio would be among the first to receive education, followed by the patients and health care providers who utilize, prescribe or dispense the next biosimilar product to be released to market and so on.

Additionally, easy to understand education materials for patients and health care providers should be made available on the FDA website and in print. Continuing education programs on the FDA's naming convention and biosimilar products in general should be offered to health care providers on an on-going basis.

9. If WHO adopts a Biological Qualifier proposal, how should the biological qualifiers generated by WHO be considered in the determination of FDA-designated proper names for the biological products within the scope of this guidance?

OPERS believes that if WHO adopts a Biological Qualifier ("BQ") proposal, which currently is a random alphabetic code, then the FDA should align with this proposal to assure that the INN with a BQ is consistent around the world in countries whose regulatory agencies have also decided that a BQ is necessary.

The WHO supports biological products, including allowing reference, biosimilar and interchangeable products, to use the same INN. The assignment of an INN is a naming process based on scientific characterization of an active pharmaceutical substance. Due to concerns raised by some regulatory authorities regarding proliferation of separate and distinct national qualifier systems, WHO is developing a complementary nomenclature system of assignment of Biological Qualifiers. The BQ code is not a constituent part of the INN, but an additional and independent element used in conjunction with the INN. The assignment of a BQ is regulatory in nature and countries such as Japan and Australia have decided to utilize this BQ while many other countries have decided that a BQ is unnecessary.

Conclusion

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 biological drugs. These innovative biological medicines have the potential to revolutionize medical care in the future, but only if plan sponsors and consumers can afford to cover and purchase them. Marketplace competition is one of the most effective tools we have for managing prescription drug cost inflation moving forward. We understand the FDA is not concerned primarily with encouraging marketplace competition; however we believe the agency is uniquely positioned to ensure that biosimilar and interchangeable products can become a viable alternative in the marketplace.

OPERS urges the FDA to reassess its "current thinking" regarding the naming of biological products, and work with market participants to ensure that no new barriers to market adoption of biosimilar and

interchangeable products are created. We believe that biosimilar products and interchangeable products should share the same INN as the reference product.

We thank you again for the opportunity to provide comments on the current 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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