



April 27, 2015

The Honorable Sylvia Mathews Burwell
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell,

I am writing in regard to the U.S. Food and Drug Administration's (FDA), implementation of the Biologic Price Competition and Innovation Act (BPCIA). I congratulate the agency on its approval of Zarxio, the first biosimilar in the United States. Biosimilars have the potential to improve patient access to affordable and effective versions of lifesaving biologics and save the U.S. healthcare system billions of dollars. In order to ensure that the potential of the biosimilars pathway is fully realized, I am writing on behalf of the Ohio Public Employees Retirement System (OPERS) to share my views on the issue of naming of biosimilars and the current placeholder naming structure.

With assets of \$91.2 billion, OPERS is the largest public pension fund in Ohio and the eleventh largest public pension fund in the United States. OPERS provides retirement, disability and survivor benefits for more than one million public employees, including more than 190,000 retirees and beneficiaries. OPERS also provides comprehensive health care coverage to 227,000 retiree health care program participants, and in 2014, our gross prescription drug spend was close to \$680 million.

The high price tag for biologic medicines can keep them out of the reach of many patients who could benefit from them to treat the most severe diseases. The intent of the BPCIA was to create a safe and competitive marketplace for biosimilars, analogous to the marketplace for generic drugs. By allowing market competition, prices will come down, giving consumers more affordable access to these important medicines and reducing prescription drug costs for the healthcare system. A recent study conducted by Express Scripts, OPERS' pharmacy benefit manager, projects savings of \$250 billion in ten years if only the eleven likeliest biosimilars enter the market. Express Scripts projects that OPERS itself would save more than \$129 million.

That said, the name that will be given to the active ingredient for biosimilars, the International Nonproprietary Name (INN), has significant implications for both patients and providers beyond affordability. It is our understanding that for the first biosimilar approval, the FDA has designated a placeholder nonproprietary name that does not necessarily reflect the agency's long-term policy. We are concerned that patient access and safety could be jeopardized if the agency's forthcoming guidance reflects this placeholder naming structure and biosimilars are



unable to share the same INN as the reference product. Requiring unique INNs for biosimilars could result in prescriber confusion, inhibit market competition and disrupt the current global naming system. Such a requirement would also severely slow the uptake of biosimilars, resulting in the loss of potentially billions of dollars of cost savings and reduced access to innovative and potentially life-saving medicines.

As the Department considers guidance related to the naming of biosimilars, we urge you to reject a unique INN requirement for biosimilars and instead establish a system of shared INNs for biosimilars and the reference brand product. Thank you for your consideration of this important matter.

If you have questions or concerns regarding OPERS' comments, please do not hesitate to contact OPERS' Health Care Finance and Policy Officer, Brian Pack at 614-225-1858.

Sincerely,

A handwritten signature in black ink, appearing to read "Marianne Steger".

Marianne Steger, MS, CEBS
OPERS Health Care Director

cc: Margaret A. Hamburg
Commissioner, U.S. Food and Drug Administration