

October 27, 2015

Stephen Ostroff, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff,

All of the undersigned groups share the FDA's deep commitment to patient safety. As such, we strongly believe that biologics and biosimilars should be required to have the same International Nonproprietary Name (INN). The FDA's most recent proposal to add a suffix to traditional INNs is an unnecessary and unwise modifier.

Risk of Patient Confusion and Lost Savings

As health care stakeholders, we are concerned that adding distinguishable suffixes to every biologic, biosimilar, and interchangeable biologic will confuse both providers and patients, and have the unintended effect of slowing the uptake of these cost saving products. The European biosimilar experience has clearly demonstrated that these products are safe and effective, and they have been adequately monitored without any alterations to the name of the active substance. The FDA proposal is a distinction in search of a difference that changes the INN from a system that has a proven track record, of over 60 years, of ensuring patient safety and reducing the potential for confusion.

Indeed, adverse events and product recalls for small-molecule and biologic drugs already are successfully identified using the national drug code (NDC code) and lot number. There is no compelling evidence that biosimilars should be handled differently, and to do so risks undermining prescriber confidence in these FDA-approved medicines, and creates barriers to patient access.

Estimates from various economic impact studies predict savings between \$42 billion to as high as \$108 billion over the first 10 years of biosimilar market formation.¹ We believe that it is critically important to patients, providers, and both public and private payers that these substantial cost savings are not lost. By changing the established nonproprietary name of these products, these savings are put at significant risk due to the potential for reductions in utilization.

Implementation Issues Additional Costs

Additionally, the FDA's proposed changed to traditional INN naming will create significant burdens on the pharmaceutical supply chain, which will further hinder biosimilar adoption. The National Council for Prescription Drug Programs (NCPDP) has previously stated that changes will need to be made to existing software in order to account for the addition of a suffix to INNs. Currently, products with identical INNs are automatically grouped together based on the name, but the addition of the hyphenated suffix will require alterations to such systems. These changes will add greater costs to the health care system by treating biosimilar and interchangeable biosimilar products differently from their reference products.

Also, the proposal provides no realistic approach for the naming of interchangeable biosimilars. While the

¹ <http://www.gphaonline.org/issues/biosimilars>

agency has publicly considered multiple options, none avoid additional significant barriers on top of the ones already created by the preliminary proposal.

For all of these reasons, the undersigned believe that **FDA should abandon its current proposal, and instead adopt the use of standard INNs for all biosimilar and interchangeable biosimilar products.** We believe that the purpose of the Biologics Price Competition and Innovation Act (BPCIA), which created the approval pathway for these new products, was to ensure patient access to biosimilars and provide savings to the health care system, while also ensuring patient safety. The use of an additional suffix to distinguish various biosimilar and biosimilar interchangeable products would significantly undermine that original goal, and should be avoided.

Yours truly,

Academy of Managed Care Pharmacy (AMCP)
Blue Cross and Blue Shield Association (BCBSA)
Council for Citizens Against Government Waste (CAGW)
CVS Health
Employees Retirement System of Texas
Express Scripts
Illinois Public Pension Fund Association
Kaiser Permanente
Kentucky Teachers Retirement System
Missoula County, Montana
National Coalition on Health Care (NCHC)
Ohio Public Employees Retirement System (OPERS)
Pharmaceutical Care Management Association (PCMA)
Premier health alliance
Prime Therapeutics
Public Sector HealthCare Roundtable
Rite Aid
School Employees Retirement System of Ohio (SERS Ohio)
State Health Plan of North Carolina
UAW Retiree Medical Benefits Trust
West Virginia Public Employees Insurance Agency

cc: Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research