June 30, 2015

Dr. Steven Ostroff
Acting Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Ostroff,

As organizations representing the interests of pharmacists, pharmacies, payers, pharmacy benefit managers, wholesalers, taxpayers, and others, we applaud the FDA's approval of the first biosimilar just this spring, ushering in a new era for cancer patients and the American health care system. This approval ensures that safe, affordable alternatives to life saving biologics are now a reality. We commend the FDA for making it clear that the provision of a placeholder INN for Zarzio® does not represent the Agency's decision on a comprehensive naming policy for these medicines. As the FDA continues implementing the BPCIA, we strongly reiterate that any departure from the currently accepted international nonproprietary name (INN) system could disrupt the ability to smoothly dispense and track these medicines, risking provider confusion and patient safety.

Many of the undersigned groups play a key role in providing safe and cost-effective prescription drug programs, supplying these drugs to pharmacies, managing formularies to ensure that beneficiaries have access to these drugs, and dispensing these drugs to patients. We share the FDA's deep commitment to patient safety, and as such, we believe that biologics and biosimilars should be required to have the same International Nonproprietary Name (INN). Requiring different INNs for biologics and biosimilars could lead to patient and prescriber confusion, increasing the possibility of medication errors, and would also effectively separate the biosimilar from existing safety information about the underlying molecule.

Current Tracking Mechanisms Suffice

We are aware that some groups have expressed concerns regarding this issue and have requested that the FDA assign distinguishable names to reference biologics, biosimilars, and interchangeable biologics. While we agree that it is important to gather data that allows providers to better understand how biologics and biosimilars are performing among various patient groups and to assist in the tracking of adverse events, as we mention above, we believe that the current mechanisms in place (*e.g.*, NDC code, lot number, brand name, manufacturer, etc.) are sufficient. We are concerned that any unnecessary changes may interfere with current pharmacy safety alert systems used by both retail and community pharmacists. In addition, because 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. There is already a precedent for shared names (e.g., erythropoietins, somatropin, interferon), which has not resulted in any known issues. Shared INNs are also safely and effectively utilized in EU, Canada, Australia, and Japan.

Dispensing Complications Likely

It is also critically important that FDA fully considers the technical implications of unique names. The National Council for Prescription Drug Programs (NCPDP) is on record stating that existing software would need to be

updated in order to group Neupogen® (filgrastim) and Zarzio® (filgrastim-sndz) together.[i] Today, this happens automatically for drugs that have the same active ingredient and INN. This could result in biosimilars with the same active ingredient, but different INNs, being in different categories than the reference product in provider databases. According to NCPDP, unique INNs would require some type of mapping to link products that would traditionally share an INN. Each database warehouse would make these decisions independent of each other which would likely result in various mapping scenarios. NCPDP also has examples of where prefixes added to INNs (*e.g.*, tbo-filgrastim) were dropped in some dispensing systems, which resulted in confusion. The same problems could arise with suffixes. This could result in massive confusion among pharmacists, payers, and PBMs and may inhibit patient access to these lifesaving medicines.

Safety and Savings At Risk

Moreover, we are concerned that distinguishable names for every biologic, biosimilar, and interchangeable biologic could confuse providers, patients, and most importantly those of us who dispense many of these drugs, and have the unintended effect of impeding patient access to and slowing the uptake of these cost saving products. A recent study by Express Scripts found that the availability of just two biosimilars – Sandoz' Zarzio® and Celltrion's Remsima® - would save U.S. patients and payers nearly $22.7 billion between now and 2024.[ii]

We believe that the legislative intent of the biosimilar approval pathway included in the Patient Protection and Affordable Care Act was to support the development of less expensive but equally effective alternatives to biologic drugs. However, requiring different INNs would create an unnecessary barrier to the benefits of FDA-determined interchangeability. Patients, prescribers and dispensers of these drugs need to be able to easily identify which drugs bear a relation to one another in order to maximize the potential savings from the biosimilar approval pathway.

With at least four other biosimilars currently awaiting FDA approval, now is indeed an exciting time for biosimilars. Thank you for your careful consideration of this important matter. We welcome the opportunity to work with you to ensure that the new biosimilar market in the United States gives patients access to safe, effective and more affordable alternatives to brand-name biologics.

Yours truly,

Academy of Managed Care Pharmacy (AMCP)
American Pharmacists Association (APhA)
America's Health Insurance Plans (AHIP)
The Biosimilars Council
California Public Employees Retirement System (CalPERS)
Council for Citizens Against Government Waste
CVS Health
Express Scripts
Healthcare Supply Chain Association (HSCA)
National Association of Chain Drug Stores (NACDS)
National Coalition on Health Care (NCHC)
Ohio Public Employees Retirement System (OPERS)
Pharmaceutical Care Management Association (PCMA)

Premier healthcare alliance
Prime Therapeutics
Public Sector Health Care Roundtable
Rite Aid
UAW Retiree Medical Benefits Trust
Walgreens

cc: Sylvia Matthews Burwell
Secretary, U.S. Department of Health and Human Services

[i] [i] Gingery, Derrick. "Biosimilar Naming Is Challenge for Provider Databases." *The Pink Sheet.* 16 March 2015.
[ii] INFOGRAPHIC: Two Biosimilars to Save $22.7 Billion. December 4, 2014. http://lab.express-scripts.com/insights/drug-options/infographic-two-biosimilars-to-save-227-billion?ec_as=28CF8EFFA0D54C0CA651207F82E37862&sthash.UQOIysAN.mjjo