July 1, 2014

Commissioner Margaret A. Hamburg Food and
Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

All of the undersigned groups share the FDA's deep commitment to patient safety. Based on all of the information at our disposal, 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.

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. 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.

Moreover, we are concerned that distinguishable names for every biologic, biosimilar, and interchangeable biologic could confuse both providers and patients, and have the unintended effect of slowing the uptake of these cost saving products. 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.

We know from our members that cost is often a barrier to patient compliance with their drug regimens. Biologic medicines are often the only lifesaving treatments for the most severe diseases, but their high price tag can keep them out of reach for many patients. The average daily cost of a brand name biologic product is approximately 22 times greater than a traditional drug.[i] U.S. average annual spending growth from 2002 to 2007 was 16% for biologics, compared with 3.7% for drugs.[ii] This price trend will be a significant cost driver for public health care programs including Medicare and Medicaid. A recent study[iii] by Express Scripts found that in California alone, patients and payers could save $27.6 billion over the next 10 years from the introduction of biosimilars on 11 biologics whose patents expire in the near future.

[1] http://www.gphaonline.org/issues/biosimilars

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.

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 Federation of Labor and Congress of Industrial Organizations (AFL-CIO)
American Federation of State, County and Municipal Employees (AFSCME)
American Foreign Service Protective Association (AFSPA)
America's Health Insurance Plans (AHIP)
California Public Employees Retirement System (CalPERS)
Communications Workers of America (CWA)
CVS Caremark
Employees Retirement System of Texas
Express Scripts
International Union, United Automobile, Aerospace & Agricultural Implement Workers of America, UAW
J.B. Hunt Transport, Inc.
Kentucky Teachers Retirement System
Know Your Rx Coalition (Kentucky)
MetLife, Inc.
Military Officers Association of America
Missoula County, Montana
National Association of Chain Drug Stores (NACDS)
National Coalition on Health Care (NCHC)
Ohio Public Employees Retirement System (OPERS)
Pharmaceutical Care Management Association (PCMA)
Portico Benefit Services
Premier, Inc.
Prime Therapeutics
Public Sector HealthCare Roundtable
School Employees Retirement System of Ohio (SERS Ohio)
State Health Plan of North Carolina
State Teachers Retirement System of Ohio (STRS Ohio)
UAW Retiree Medical Benefits Trust
U.S. Public Interest Research Group (USPIRG)
Walgreens
West Virginia Public Employees Insurance Agency

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

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[i] Hilary Krame, Why Biologics Remain Expensive, *Forbes* (2009). http://www.forbes.com/2009/12/03/kramer-health-care-intelligent-investing-pharmaceuticals.html

[ii] Murray Aitken, Ernst R. Berndt, and David M. Cutler; Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point. *Health Affairs*, 28, no. 1 (2009)

[iii] Ten-Year Potential Savings from Biosimilars in California (September 26, 2013). http://www.gphaonline.org/media/cms/Biosimilars_CA_white_paper_092613.pdf