July 16, 2014

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

On behalf of the millions of members and supporters of our respective organizations, we are writing to ask that the Food and Drug Administration (FDA) use the same International Nonproprietary Name (INN), or generic name, for an originator (reference) biologic product and an equivalent biosimilar.

It has been more than four years since the Biologics Price Competition and Innovation Act (BPCIA) was signed into law as part of the Affordable Care Act (ACA.) Yet, not one biologic product has been approved by the FDA as a biosimilar or interchangeable product. The Congressional Budget Office estimated that competition from biosimilars would reduce drug spending by roughly $25 billion over 10 years, saving the federal government nearly $6 billion. But rather than simply following Europe's decision to allow a biosimilar to share the same INN as its reference product, the FDA is wasting valuable time and resources contemplating whether it should require different nonproprietary names for biosimilars.

In a May 2012 joint comment to FDA's draft biosimilar guidances, the American Pharmacists Association, the National Association of Chain Drug Stores, and the National Community Pharmacists Association expressed their opposition to having a different INN for a biosimilar. They said, "The use of different INNs would increase the burden of being able to distinguish which products are biosimilar and interchangeable with which reference drug and may pose difficulties in recognizing the best alternative drug for therapeutic use in a timely manner. Such confusion may lead to medication errors such as therapeutic duplication. Furthermore, unique

INNs would be contrary to the World Health Organization (WHO) naming system that is accepted globally, causing confusion within the global marketplace." We agree with their assessment.

Furthermore, six senators who served on the Senate Committee on Finance or the Senate Committee on Health, Education, Labor, and Pensions when ACA was being crafted, stated in an October 23, 2013 letter to you that they believe "BPCIA prohibits the FDA from approving a biosimilar with pharmacologically relevant differences from the brand product, thus no unique name should be required for a FDA-approved biosimilar."

As you know, the INN was created by the World Health Organization (WHO) in order to identify pharmaceutical substances and this system has been in use for more than 60 years. The INN currently includes approximately 7,000 unique, globally-recognized names. According to the WHO, "the existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide."

Proponents for separate INNs for the reference biologic and a corresponding biosimilar argue that such a naming system is necessary in order to ensure safety, and will help track and trace adverse events back to the appropriate source. The May 2012 joint letter weighed in on this issue: "We acknowledge that the ability to uniquely identify which biological product a patient is taking is important, especially in cases of adverse events and quality issues. However, the use of INNs is not a warranted solution and may interfere with current pharmacy safety alert systems and complicate the collection of global safety information. Using examples of successful biopharmaceuticals marketed under the same INN, such as human growth hormone and insulin, the FDA can apply the same concept for naming the biosimilar products."

In addition to utilizing the proprietary or trade name, the national drug code (NDC), the manufacturer's name, the batch and lot numbers are also utilized to track and trace products in case of an adverse event. In Europe, where biosimilars have been marketed since 2006 and the reference product and biosimilar share the same INN, there have not been any track and trace problems.

The summary minutes of the October 2013 meeting of the European Commission's Pharmaceutical Committee stated that, the "majority of the Member States strongly supported the current EU thinking that biosimilar medicinal products should be closely aligned with their

reference medicinal products and that an INN qualifier for biosimilar medicinal products would be contrary to such alignment. Several Member States voiced concern that a distinct INN for biosimilar medicinal products could undermine the trust of healthcare professionals and the public in biosimilar medicinal products. The same INN should be used for both the reference medicinal products and the biosimilar medicinal products."

The call for a unique naming system for biosimilars is nothing more than an effort to stifle access to long-overdue competition. We ask that the FDA focus on completing its mandated role to deliver a clear, regulatory pathway for bringing biosimilar products to the marketplace and provide well-defined guidance on when a biosimilar can be substituted for a branded biologic. Taxpayers and patients are waiting. There is not a moment more to lose.

Sincerely,

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Competitive Enterprise Institute

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