The American Consumer Institute
Center for Citizen Research

July 10, 2014

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

Dear Commissioner Hamburg:

On behalf of The American Consumer Institute (ACI), a nonprofit educational and research organization, we are writing to raise an issue of critical concern regarding the naming of biosimilar drugs. We respectfully request that the Food and Drug Administration (FDA) reject calls by biologic drug makers to stray from the globally recognized naming system, which would impede biosimilar competition in the United States and limit access to life-saving care for millions of consumers. Instead, we urge the FDA to remain focused on completing the pathway for biosimilars to bring more affordable treatment options to the market as quickly as possible by encouraging market entry and competition.

Some have argued for the creation of a unique system for International Nonproprietary Names (INNs) that would lead to increased transparency and safety in the U.S. The reality is that unique INNs would create confusion for doctors, pharmacists and patients, and it could lead to dangerous medication errors. As leading U.S. pharmacist groups said in a letter sent to your agency, "physicians are already pressed for time, and therefore it is imperative that there are no additional and unnecessary obstacles that hinder them from timely decision-making, especially in cases of urgent care." This is why "Congress ultimately rejected a statutory requirement that biosimilars must be given unique INNs," during the Affordable Care Act debate, according to an October 23, 2013 bipartisan Senate letter.

In addition, similar efforts were rejected by the FDA's European equivalent (the European Medicines Agency) during the biosimilar pathway creation process in the European Union (EU), where the international World Health Organization (WHO) INN system is used, and where the INNs of the original product and the biosimilar version are the same. To date, there has been no evidence of safety and efficacy issues. The fact is that European consumers have been benefitting from biosimilars competition since 2006, the same year that the FDA went on record supporting the WHO INN system.

At a minimum, the FDA should put the naming issue on hold and, instead, accelerate its rulemaking to encourage market entry and heighten industry price competition. The issue is urgent, because speeding market entry will yield savings both in terms of dollars and lives. In

the face of growing demand, biologic drugs are projected to account for up to 75 percent of U.S. health care spending by 2020, according to above-mentioned Senate letter. With biologics costing on average 22 times more than traditional drugs, out-of-pocket expenses for patients will rise significantly. The best medical advances in the world are useless if no one can afford to use them. Consumers deserve better; patients deserve more choice.

The lower price of biosimilar drugs would profoundly impact both consumers and the government, given the increasing burden of biologic drug costs on Medicare and Medicaid. In Europe, Canada and elsewhere, biosimilars have reduced costs to upwards of 40 percent – a significant cost savings for government and private health programs. Besides the direct savings to consumers, lower-priced biosimilars would have the potential to reach more patients, thereby achieving better outcomes over traditional medical options.

We urge the FDA to reject the misleading campaign to introduce a unique INN system. Reinventing and then implementing a new naming system for biosimilars – to the detriment of U.S. consumers – simply cannot be the best use of FDA's limited resources, given the agency's vast responsibility. Instead, the FDA needs to move ahead quickly and promulgate rules that will facilitate market entry, heighten industry price competition, save consumers money, and produce better patient outcomes. The benefits of biosimilars provide a clear direction for action and we look forward to your continued leadership on this vitally important consumer issue.

Sincerely,

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