



Working Together for an Affordable Future

October 27, 2015

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

**Re: FDA-2013-D-1543—Nonproprietary Naming of Biological Products; Draft Guidance for Industry**

Dear Commissioner Ostroff:

As President and CEO of the National Coalition on Health Care, I write to offer our comments on the Draft Guidance and express alarm at the negative impact it could have on market acceptance and uptake of biosimilars and overall health care affordability.

NCHC is a coalition of health care stakeholder organizations committed to promoting an affordable, high-quality health system in the United States. As the nation's oldest and most diverse group working to achieve comprehensive health reform, we represent more than 90 member organizations, including health care providers, purchasers, payers, and consumers. Collectively, our organizations represent, as employees, members, or congregants, more than 100 million Americans.

In letters dated June 4, 2012, July 1, 2014 and June 30, 2015, NCHC has previously joined consumer advocates, unions, employer, health plans, pharmacists, and manufacturers to call for adoption of shared nonproprietary names for biosimilars. Today, to underscore the importance of this issue, the National Coalition on Health Care reiterates that call under our own letterhead.

1825 K STREET, NW, SUITE 411, WASHINGTON, DC 20006 | (202) 638-7151 | NCHC.ORG

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The rejection of shared nonproprietary names will move the United States' prescription drug policy in a novel direction, which poses danger to patients, seriously undermines past gains in acceptance of generics and erects new barriers to prescription drug affordability and access.

**Unique names are novel and unprecedented.** Requiring unique names, even if those unique names consist of the same core name and a suffix, abandons an existing US precedent of assigning shared names (including already approved biologic products erythropoietins, somatropin and interferon). It departs from the practices of other major industrialized nations such as the European Union, Canada and Japan.

**Unique names will undermine the market acceptance and uptake of biosimilars and interchangeable biologics.** Substitution of safe affordable generics for brand name products—by both prescribing clinicians and pharmacists—has been central to the estimated \$1.46 trillion in cost savings attributable to generics between 2004 and 2013. The legal authority, pharmacy practices and billing procedures for substitution have relied on the convention of shared names. But instead of building on this success, the draft guidance proposes to establish a novel naming approach. The uncertainty resulting from this unprecedented new approach would create a barrier to investment in the development of biosimilars and their market entry—ensuring fewer drugs reach patients and that those that do are less affordable.

**Unique names are unnecessary for patient safety and pharmacovigilance.** While we agree with FDA that a need exists for pharmacovigilance and patient safety with respect to all prescription drugs, unique nonproprietary names are unnecessary for pharmacovigilance and can actually undermine patient safety. Existing pharmacovigilance mechanisms (*e.g.*, NDC code, lot number, brand name, manufacturer, etc.) can and do allow effective tracking of drugs. 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. In fact, we are concerned that unnecessary changes could interfere with pharmacy safety alert systems on which pharmacists now rely.

However, **should FDA proceed to implement the draft guidance, we at a minimum recommend the following steps to limit the damage to prescription drug affordability:**

1. **All brand biologic products, biosimilars, and interchangeables should abide by the same naming convention.** The draft guidance proposes utilizing the same core name + suffix approach for both newly licensed products and products previously licensed. Brand-name chemical drugs and their generics abide by the same naming convention. Applying a suffix only to generic biologics would further differentiate them from their originator products and from chemical generics. This in turn would cast doubt on their safety and efficacy and undermine their market acceptance and uptake.

2. **The originator product and its biosimilars should retain identical core names, and any distinguishing feature should follow rather than precede the core name.** Variance in the core name or use of a prefix would discourage market acceptance and uptake of generic biologic products, keep prices high and negatively affect affordability. We are pleased that the Draft Guidance for industry does not rely on such approaches.
3. **Names for interchangeable biologic must be completely identical to those of the reference product.** BPCIA established the category of interchangeable biologics in part to support pharmacy-level as well as prescriber-level substitution. Allowing interchangeable biologics to have a name that differed in any way would reduce uptake and run contrary to Congressional intent.

Although we do have concerns about the direction laid out in the Draft Guidance, NCHC does appreciate FDA's efforts and attention to this important issue and hope to work with you moving forward. Should you have questions regarding these comments, please contact NCHC's Policy Director Larry McNeely at [lmcneely@nchc.org](mailto:lmcneely@nchc.org).

Yours truly,



John Rother  
President and CEO