



## **NATIONAL HEMOPHILIA FOUNDATION**

*for all bleeding disorders*

October 27, 2015

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

*Re: Docket # FDA-2013-D-1543, Guidance for Industry: Nonproprietary Naming of Biological Products*

*Comments submitted electronically at [www.regulations.gov](http://www.regulations.gov)*

Dear Acting Commissioner Ostroff,

The National Hemophilia Foundation (NHF) appreciates the opportunity to comment on Guidance for Industry: Nonproprietary Naming of Biological Products. NHF is the nation's leading advocacy organization working to ensure that individuals affected by hemophilia and related bleeding disorders have timely access to high quality medical care and services, regardless of financial circumstances or place of residence. People with bleeding disorders depend on biologic products to live healthy, productive lives and the naming policy is critical to ensuring that patients and their physicians understand what treatments they're taking.

Hemophilia is a rare, chronic bleeding disorder affecting approximately 20,000 people in the US, who infuse high-cost clotting factor therapies to replace missing or deficient blood proteins. These biologic therapies are safer and more effective than ever, but are also very expensive. Drug costs for a person with severe hemophilia can be \$250,000 a year or more. Developing an inhibitor (an immune response to treatment), complications such as HIV/AIDS, hepatitis and joint diseases, or bleeding as a result of trauma or surgery can increase those costs to \$1 million. There are also similar bleeding disorders, like von Willebrand Disease (vWD), that affect up to 1 million Americans.

NHF believes that biosimilars have the potential to increase patient access to innovative treatments by reducing the cost of biologic products and supports the development of new treatments. Since biosimilars are, by definition, incapable of exactly replicating biologics, consumers may respond differently to a biosimilar than they do to the innovator product, including experiencing variable levels of effectiveness or having different adverse outcomes. Currently, people with bleeding disorders respond differently to different innovator biologics, and we anticipate that they are likely to respond differently to biosimilars.

For these reasons, NHF commends the Food and Drug Administration (FDA) for its decision to require biologics and biosimilars to have unique names, including a suffix. We agree with FDA that unique names will minimize inadvertent substitution of products not determined to be interchangeable by the FDA, and best facilitate proper and safe use of these treatments. Additionally, NHF agrees with the Agency that a robust pharmacovigilance system increases patient safety and that distinguishable names will enable better tracking of prescriptions and any adverse events. For example, if a person were to

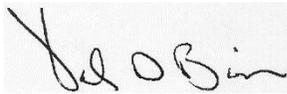
develop an inhibitor, it would be critically important to understand exactly what product he was taking. We are pleased that the Agency intends to apply this policy retrospectively, as well.

NHF believes the choice of treatment should be made only by patients in consultation with their physicians. Patients and their physicians must be informed about all aspects of treatment including the name of the treatment dispensed, and there should be no automatic substitution of biosimilars for biologics unless the prescribing physician explicitly approves it. The use of distinguishable names supports these practices.

However, NHF is concerned that the draft guidance states that biosimilars deemed to be interchangeable may be substituted for a reference product by a pharmacist without the intervention of the prescribing health care provider. NHF advocates for policies that require notification to the prescribing physician and patient prior to any substitution being made. This, too, allows for better tracking in cases of adverse events. We urge FDA to implement a policy where interchangeable biosimilar products also have unique names, in order to give patients and their physicians the information necessary for strong pharmacovigilance and to accurately understand individual responses to biosimilars.

Biosimilars have the potential to improve patients' lives and NHF believes that distinct labeling of biosimilars will support patient education and safety, promote adequate pharmacovigilance, and help facilitate prescribing decisions. If you have any questions, please contact Johanna Gray, NHF's Federal Policy Advisor, at [jgray@dc-crd.com](mailto:jgray@dc-crd.com).

Sincerely yours,

A handwritten signature in black ink, appearing to read "Val Bias", is shown on a light gray rectangular background.

Val Bias  
Chief Executive Officer  
National Hemophilia Foundation