



Mission: To find a cure for psoriasis and psoriatic arthritis  
and to eliminate their devastating effects through research, advocacy and education.

February 28, 2014

The Honorable Edith Ramirez  
Chairwoman  
U.S. Federal Trade Commission  
600 Pennsylvania Avenue, N.W.  
Washington, DC 20580

Re: *Workshop on Follow-On Biologics: Project No. P131208*

Dear Commissioner Ramirez:

On behalf of the estimated 7.5 million Americans living with psoriasis and psoriatic arthritis, the National Psoriasis Foundation (NPF) appreciates the opportunity to provide comment on the FTC's recent *Workshop on Follow-On Biologics (Project No. P131208)*. The issues addressed in this workshop were both complex in their nature, and significant to the chronic disease community. We applaud the Federal Trade Commission for providing thoughtful consideration to this issue.

The National Psoriasis Foundation is the largest psoriasis patient advocacy organization and charitable funder of psoriatic disease research worldwide, and assists approximately 2.1 million people annually through educational programs and services. We are relentless in our mission to find a cure for psoriasis and psoriatic arthritis and to eliminate their devastating effects through research, advocacy and education.

Psoriasis is a chronic, painful, inflammatory disease, and the most prevalent autoimmune disease in the United States. An estimated 7.5 million Americans are affected by psoriasis, and up to 30 percent may also have psoriatic arthritis, which is often disabling and causes progressive joint damage. There is also an increased risk for psoriasis patients developing other serious conditions such as heart disease, stroke, hypertension and diabetes. Access to treatment is important to prevent much of the disability and psychosocial impacts of the disease.

The introduction of biologic products for the treatment of psoriasis and psoriatic arthritis has been the most significant advancement in care for the psoriasis community in recent decades. Biologics have provided some patients with an effective therapy—many for the first time in their lives. Biologics have also opened up a new world of combination therapies, being used alongside systemic treatments, phototherapy and/or topical treatments. However, patients with psoriasis and psoriatic arthritis are keenly aware of the risks associated with biologics, including suppression of the immune system and the lack of long-term safety data in new treatments.

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The psoriasis and psoriatic arthritis community is cautiously optimistic regarding the potential of biosimilars: eager for expanded access to effective and affordable therapies, provided a robust safety and monitoring process is in place. As your agency considers the issue of biosimilar naming, we invite you to look to the deliberations of the National Psoriasis Foundation Medical Board which provides guidance and leadership to the organization on all medical issues relative to the psoriasis and psoriatic arthritis patient community. On July 31, 2013, the NPF Medical Board considered and approved the enclosed Biosimilar Substitution Position Statement.

The National Psoriasis Foundation recommends that the patient-provider relationship remain at the center of all treatment planning and supports unique nonproprietary names for biosimilars to eliminate confusion, to allow providers to accurately track the therapeutic agent in a patient's permanent record, and to allow for the collection of adverse event information. The relationship between patient and provider involves a high level of communication and trust, and unique nonproprietary names for biosimilars will help eliminate confusion and promote transparency between the patient and their health care provider. In addition, unique names are essential to the tracking, reporting, and surveillance system for adverse events for both biologics and biosimilars.

Once again, on behalf of all Americans with psoriasis and psoriatic arthritis, we thank you for your consideration of our comments and recommendations. We recognize that these are complicated issues and appreciate all your efforts to ensure that patients have access to affordable, safe and effective treatment options. We stand ready to work with you and your colleagues on this important effort. If you have any questions about these comments, please contact me at [lhoawrd@psoriasis.org](mailto:lhoawrd@psoriasis.org) or at (503) 546-5553. Thank you in advance for your consideration. We look forward to working with you.

Sincerely,

Leah Howard, J.D.

Director, Government Relations and Advocacy

LH:NH

Enclosure

cc: Commissioner Margaret Hamburg, U.S. Food & Drug Administration



### ***Biosimilar Substitution***

(Considered by the National Psoriasis Foundation Medical Board on February 28, 2013; Revised and Approved on July 31, 2013).

The introduction of biologic products for the treatment of psoriasis and psoriatic arthritis has been the most significant advancement in care for the psoriasis and psoriatic arthritis community in recent decades. Biologics have provided some patients with an effective therapy—many for the first time in their lives. Biologics have also opened up a new world of combination therapies being used alongside systemic treatments, phototherapy and/or topical treatments. With the passage of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), the National Psoriasis Foundation (NPF) welcomed the creation of a regulatory pathway for new, safe and effective biosimilars, adding choice and additional treatment options for the psoriasis and psoriatic arthritis community. While the community welcomes new and affordable treatments, patients with psoriasis and psoriatic arthritis are keenly aware of the risks associated with biologics, including suppression of the immune system and the lack of long-term safety data for new treatments.

In contrast to the case with generic drugs, which are chemically identical to their branded counterparts, biosimilars are not chemically identical to their branded biologics counterparts because, as large, complex molecules derived from living cells using recombinant DNA technology, biologics can never be exactly replicated due to their inherent variability. Due to these significant differences, the NPF has developed the following policy to ensure patient safety.

***The National Psoriasis Foundation recommends that the patient-provider relationship remain at the center of all treatment planning and supports a prohibition on biosimilar substitution unless all of the following minimal thresholds are met:***

- (1) the biosimilar has been designated by the Food and Drug Administration as interchangeable with the prescribed biologic for the specified indicated use;
- (2) the biosimilar has a unique nonproprietary name to eliminate confusion, to allow providers to accurately track the therapeutic agent in a patient's permanent record, and to allow for the collection of adverse event information;
- (3) the biosimilar product follows the same route of administration and dosage form as the reference product;
- (4) the pharmacist notifies the prescriber in writing or electronic communication of the intention to substitute at least 24 hours prior to the substitution;
- (5) if explicit permission from prescribing physician and patient is not obtained within 24 hours, then the original prescription must be filled;
- (6) the patient (or patient's authorized representative) must be informed and educated about a biosimilar substitution at the point of sale; and
- (7) upon notification of a substitution, the pharmacy and the prescribing physician are to retain a permanent record in the patient's medical record of the biosimilar substitution.

The above position statement is to serve as protection for the physicians, pharmacists, insurers and above all, patients from any harm that may result from biosimilar substitution.