



Our mission is to improve the quality of life of people who have psoriasis and psoriatic arthritis. Through education and advocacy, we promote awareness and understanding, ensure access to treatment and support research that will lead to effective management and, ultimately, a cure.

August 24, 2004

Jonathan Wilkin, M.D.
Director, Division of Dermatologic and Dental Drug Products
Food and Drug Administration, HFD-170
9201 Corporate Boulevard, Room N214
Rockville, MD 20850

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Dear Jonathan,

I attended the July 12 advisory committees' meeting on oral tazarotene along with some of my staff, Board of Trustees members and volunteers. I have been reflecting on, and discussing, points made at the hearing and the recommendation of the committees that oral tazarotene not be approved as a psoriasis treatment. I have identified, below, common concerns and observations that we have as an organization.

The National Psoriasis Foundation supports the committees' concern that there be a well-done pregnancy risk management program to provide maximum protection for patients using oral tazarotene and that there be every effort by Allergan and the medical community to protect against the possibility of birth defects resulting from the use of this drug.

However, we feel the committees did not give sufficient weight to the benefits of this drug. In fact, we felt the tone and tenor of the discussion regarding oral tazarotene reflected an incomplete understanding of how psoriasis is treated, how a drug like oral tazarotene would be used in actual practice, and how beneficial this drug would be for some patients suffering with moderate to severe psoriasis.

A majority of clinical trial patients achieved moderate to complete clearing, which in our view represents treatment success. Also, the data show this drug is as effective as the biologic therapies that have been recently approved for psoriasis.

Moreover, the drug offers a therapy option to women of child-bearing potential who have psoriasis because it leaves the body so much more quickly than other retinoids that are on the market.

We heard the concerns expressed by the committees about possible off-label use of this drug for the treatment of acne. We do not understand how it is fair to deny access to oral tazarotene due to theoretical concerns about possible off-label use to treat another disease in a different population. We also feel it is unlikely a physician would do such a thing with a drug that has a potential for teratogenic side effects.

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In summary, the Psoriasis Foundation believes the Food and Drug Administration should approve oral tazarotene for the treatment of moderate to severe psoriasis. We appeal to you to work with Allergan to make that happen.

As a final comment, I have to say on behalf of the Psoriasis Foundation staff, Board members, volunteers and myself, that we felt there was a definite bias against the therapy evident throughout the discussion and a lack of respect displayed for psoriasis as a serious chronic disease for which patients need additional treatment options.

We realize and respect the difficult task you and your FDA colleagues have to do in weighing benefit versus risk. At the same time, we ask that advisory committee members weigh carefully their public comments – keeping in mind that patients are in the audience – and become as informed as they can about the diseases and treatments they discuss.

Sincerely,

A handwritten signature in cursive script that reads "Gail".

Gail M. Zimmerman
President and CEO
gzimmerman@psoriasis.org

cc: National Psoriasis Foundation Board of Trustees
National Psoriasis Foundation Medical Board