



**Dermatologic and Ophthalmic Drugs Advisory Committee  
and  
Drugs Safety and Risk Management Advisory Committee**

**July 12, 2004**

**Statement of Dale White**  
**Vice Chairman, Board of Trustees, National Psoriasis Foundation**

[SLIDE 1]

Thank you very much for the introduction. Ladies and gentlemen, I am delighted to be here.

My name is Dale White and I am Vice Chairman of the Board of Trustees of the National Psoriasis Foundation.

I am volunteering to be here today on behalf of the Foundation and the community it represents, to testify in support of the drug oral tazarotene, for the treatment of moderate to severe psoriasis.

As a parent of a teenager with psoriasis, I am excited about testifying today about the urgent need psoriasis patients have for additional treatment options.

[SLIDE 2]

The National Psoriasis Foundation is the leading nonprofit organization fighting to improve the quality of life of the more than 5 million Americans diagnosed with psoriasis and/or psoriatic arthritis and their families.

The Foundation was established in 1968 by a grassroots network of patients and physicians.

Through education and advocacy, the Foundation promotes awareness and understanding, ensures access to treatment, and supports research that will lead to effective management and, ultimately, a cure.

Each year the Foundation receives financial support from tens of thousands of people and from 15 to 20 pharmaceutical companies.

This includes unrestricted support from Allergan and from its competitors.

[SLIDE 3]

You all know psoriasis, but today I want to emphasize a few points.

First, of the more than five million Americans who have psoriasis, an estimated 1.5 million have moderate to severe disease.

The Foundation's national survey research has shown that:

(over)

For 75 percent of these people, the disease has a moderate to large impact on their everyday lives.

For 26 percent, it alters normal daily activities and for 21 percent it stops them.

For 36 percent, it causes trouble with sleep.

For 40 percent, it affects clothing choices.

For every one, moderate to severe psoriasis can profoundly affect one's work, family, and personal relationships.

[SLIDE 4] then [SLIDE 5]

Here are a few photographs that show how physically disabling and emotionally devastating psoriasis can be.

[SLIDE 6]

The Psoriasis Foundation believes there is a need for more treatment options for people with moderate to severe psoriasis.

One, in addition to being a very serious disease, psoriasis is a chronic disease. It typically first strikes people between the ages of 15 and 35, but it can affect anyone at any age, including children.

Two, our research shows that 78% of people with moderate to severe psoriasis are not using aggressive therapies because of concerns about side effects and effectiveness.

Three, in a recent national survey more than one-third of patients said they were "very unsatisfied" with the treatment they were receiving for psoriasis.

Four, while there are several treatments available for moderate to severe psoriasis, none of these treatments works for everyone, or can be used by everyone, or necessarily works the same over time.

Five, an individual patient's psoriasis can change in severity and even in type over years, months, or even weeks.

Six, patients need and deserve choices that meet their individual concerns about safety, effectiveness, cost, and access.

[SLIDE 7]

The Psoriasis Foundation believes psoriasis patients should have access to oral tazarotene.

It may offer many patients a reduction in psoriasis symptoms and thus an improved quality of life. It offers a treatment option for patients that is easy to use and seems to offer a reasonable safety profile.

And its approval for the treatment of moderate to severe psoriasis would give an option to people who cannot use currently approved therapies.

Because retinoids can cause serious birth defects if they are present in a woman's body while she is pregnant, the Foundation supports a risk management program focused on women of child-bearing potential, to minimize to the greatest extent feasible the likelihood that a woman will become pregnant while taking this drug.

We hope Allergan and the Food and Drug Administration adopt a risk management program that addresses this risk without imposing constraints that would effectively limit access to oral tazarotene for the many psoriasis patients whose lives might be greatly enhanced by it.

Finally, as with any new medication, the long-term side effects of oral tazarotene are unknown and need further study.

[SLIDE 8]

In summary: one, moderate to severe psoriasis can dramatically and negatively affect a person's quality of life; two, people with psoriasis need and deserve more treatment options; and three, the Foundation believes access to the new treatment oral tazarotene is important and desirable.

By expanding the array of choices available to treat this serious chronic disease, we empower patients to choose the treatment that works best for them.

I know that my son, and thousands upon thousands of people like him, will really appreciate that.

Thank you.