



Our Mission: To drive efforts to cure psoriatic disease and improve the lives of those affected.

June 17, 2016

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RE: **June 16 NPF – ICER Scoping Call Regarding NE CEPAC Review of Psoriasis**

Dear Drs. Dreitlein and Linder,

Thanks to you both, Sara Edmond, Dan Ollendorf, and additional colleagues from the Institute for Clinical and Economic Review (ICER) for meeting with myself and leadership of the National Psoriasis Foundation by phone on Jun 16, 2016. We appreciated the opportunity to explore – as a follow up to the call you held on May 19th with Leah Howard, VP of Government Relations and Advocacy – the issues surrounding ICER's planned review of treatment options for psoriatic disease. Beyond thanking you for your time, we wanted to express our thanks as well for the opportunity to exchange information and discuss the challenges and concerns faced by too many of the 7.5 million Americans living with psoriasis and psoriatic arthritis struggling to manage their symptoms.

We welcome the opportunity to continue the dialogue on the questions you raised during our meeting and are glad to hear of your interest in seeing patient perspectives incorporated into the ICER psoriatic disease review. In addition to talking with us, we also encourage you to meaningfully engage individual patients directly in your process. We are constantly humbled by the individuals living with psoriasis and psoriatic arthritis who bravely share their personal experiences and challenges with policymakers and influencers. As we have previously offered, we would be glad to make personal introductions to patients should you desire such direct patient participation. We hope you take us up on this offer!

While we await the release of the draft psoriasis scoping document on June 24, 2016, we wanted to offer a summary of, references for, and additional thoughts on, our meeting yesterday:

What is important to patients when considering the treatment of psoriasis?

As we discussed, psoriasis is a relentless and unpredictable disease, individual and diverse, presenting differently from one person to the next. Answering the simple question of "*what is important to patients*" is, therefore, quite challenging. We do know from talking with patients that they place value on a number of items including: the expected efficacy of the treatment, the ability to access ALL psoriatic disease treatments, the safety of the treatment, the burden of utilizing this particular treatment, the impact that the therapy may (or may not) have on related or concurrent health conditions (including physical, mental and emotional health), and cost – among others. We would again encourage you to view the March 17, 2016 Food and Drug Administration (FDA) Patient Focused Drug Development (PFDD) meeting webcast which is archived here: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm>.

Time and again during this day-long meeting, patient participants, shared their frustrations and the challenges of managing the wily symptoms of psoriasis and the unpredictable nature of the body's response to treatments. The second panel of this meeting, in fact, focused specifically on discussing patient perspectives on treatments. In addition to viewing this discussion, we would also again direct you to review the 84 comments

<https://www.regulations.gov/document?D=FDA-2015-N-4166-0001> submitted by organizations such as the National Psoriasis Foundation, American Academy of Dermatology and individual patients and providers – many of which touch on treatment concerns and outcome expectations and aspirations.

As we noted yesterday, any discussion of treatments should also bear in mind that treatments that work for one person may not for others. Many patients cycle through accepted treatment options unsuccessfully, or temporarily successfully, and are ultimately left at the end of the treatment road with no alternatives.ⁱ As we noted on several occasions during our discussion, adding to the burden of the disease are often insurance policies and practices that erect barriers for patients in urgent need of treatment. These “access to care” issues include:

- Increasing the patient share of the treatment cost (along with the general costs of managing this disease);
- Fail-first or step therapy requirements;
- Narrowing provider networks that limit patient access to specialists; and
- Burdensome pre-authorization and re-authorization processes patients and providers must overcome to achieve access to clinically recommended treatments.

How meaningful are the current outcomes measures in use to patients? Are there more meaningful measures?

Despite dozens of outcomes measures in our space, none were created with patient involvement from the beginning and as we discussed, many fail to properly capture the most bothersome symptoms of the disease. The NPF has been pleased to work with leading experts through the International Dermatology Outcomes Measures (IDEOM) initiative to bring together physicians, researchers, government agencies, pharmaceutical companies, payers and patients from around the globe to develop, validate and standardize measures throughout the field of dermatology with an initial focus on psoriasis. The move to a standardized approach with a trusted validated outcomes measure instrument developed with patient input and designed to capture criteria meaningful to patients - including itch and other symptoms - will be critical to inform provider decision-making in prescribing therapies to best address the needs of every patient.

As we explored during our call, a disconnect currently exists between research outcomes and clinical outcomes. There are not good patient reported outcomes, and those measures that are in use – such as DLQI – were not developed with patient input and have not been validated in a psoriasis population specifically. Additionally, the fact that these tools are not used standardly in clinical practice results in wide variations in treatment design. Given this, it is not surprising that according to a 2014 study, 55% of patients with moderate -to -severe psoriasis, patients and 41 % of patients with psoriatic arthritis, are not being treated to the established standards of care.ⁱⁱ Going hand-in-hand with this data on the community being undertreated is data from the 2015 NPF annual survey in which 40% of individuals living with psoriatic disease report being unsatisfied with their psoriatic disease treatment (score of 1-5 out of 10).

To address these issues, the National Psoriasis Foundation Medical Board – which is made up of more than two dozen experts in Dermatology, Rheumatology, and related fields – undertook a project for more than two years to orient practicing clinicians toward more appropriate standards. As we shared, this approach is consistent with the changes which have occurred in other disease management practices including blood pressure, diabetes, and rheumatology. The results of this two year effort are expected to be published in the coming quarter, and we look forward to sharing the targets with you upon acceptance of this paper.

What do patients think of the current treatment options? Are patients satisfied with the current armamentarium of drugs?

The psoriatic disease patient community is, again, quite diverse. According to the 2015 NPF Survey, moderate-to-severe psoriasis patients are relying on a variety of therapies to manage their disease:

- 28% on biologic drugs;
- 11% on phototherapy,
- 63% on prescription topicals,
- 22% on prescription systemics,
- 35% on OTC topicals,
- 8% on nothing.

As we discussed, it is critical that individuals living with psoriasis and psoriatic arthritis have access to the wide range of treatment options approved today and, hopefully, the many more that will be approved tomorrow. This is in part due to the unpredictable nature of the disease as discussed during our call and in the letter above. As was previously noted, what works for one patient may not work for others. We were glad we had some time to explore these issues with you, and the way in which they impact prescribing practices. Without the ability to administer a test able to detail which agent a patient will respond to best, physicians must work with whichever treatment options are covered. Regrettably, sometimes even when patients are pleased with their treatment option, insurance coverage changes or cost-shifting force the physician and patient to move on to different therapies.

We again encourage you to review the National Psoriasis Foundations comment letter to the FDA on the Psoriasis PFDD meeting. Now available on regulations.gov (<https://www.regulations.gov/document?D=FDA-2015-N-4166-0072>), this letter includes extensive data citations on patient perspectives regarding such issues as: *how well treatment address specific skin symptoms, downsides to treatments, impact of treatments on daily life, ideal treatments, and factors and information patients are interested in when making treatment decisions.*

Other contextual issues that are important to consider

As ICER refines the scope of review and moves ahead with your process, we again urge you to remain mindful, as patient perspectives illustrate, of the how challenging it is to live with these chronic diseases. It is important to note that the 2013 Public Health Agenda for Psoriasis and Psoriatic Arthritis published by the Centers for Disease Control and Prevention states “psoriasis and psoriatic arthritis present a substantial public health burden.”ⁱⁱⁱ Unfortunately, psoriasis often is overlooked or dismissed because it is not typically a direct cause of death. The fact that it is commonly and incorrectly considered by insurers, employers, policymakers and the public as a mere annoyance—a superficial problem, mistakenly thought to be contagious and/or attributable to poor hygiene – is insulting to those living with the disease. We again urge you, as you conduct your review, to consider the implications of the systemic nature of this disease – including concurrent health conditions and the emotional and mental impact of the disease.

Thanks to the number of effective therapies on the market there has not been a better time in human history to be diagnosed with psoriasis than today. Yet too few individuals are reporting their disease to be well-managed. Many patients remain frustrated that the tools for treating the disease fail to address their most burdensome symptoms and greatest concerns, such as itch. This is consistent with the frustration felt by individuals living with psoriasis that the measures being used by their clinician to measure treatment efficacy do not appropriately capture their experience on treatment. For this reason, it is important for patients and physicians to know that there are new therapies in the pipeline and new agents coming to market. You asked about how patients and providers categorize or group these therapies – and as we noted, this sort of categorizing (as topicals, light therapy, conventional/traditional systemics, biologics) is a gross oversimplification that fails to take into account the different advantages of each treatment.

Conclusion

On behalf of National Psoriasis Foundation staff leadership, thank you again for the productive discussion yesterday. We hope that the perspectives offered through this meeting and reiterated in this letter, along with the resources we have directed you toward, have highlighted issues that may not have been well-understood or yet-explored by ICER. We thank

you for your thoughtful consideration of the issues discussed and invite you to call upon the National Psoriasis, our Medical Board, and our patient community as you move forward in your review. If you have any questions about these comments, please contact Leah Howard, JD, Vice President of Government Relations and Advocacy at 503-546-5553. Thank you in advance for your consideration.

Sincerely,



Abby Van Voorhees
Chairwoman, NPF Medical Board

Cc: Randy Beranek, President & CEO, National Psoriasis Foundation
Leah Howard, JD, VP Government Relations and Advocacy, National Psoriasis Foundation
Michael Siegel, PhD., Director Research Programs, National Psoriasis Foundation
Emily Boyd, VP, Clinical Affairs and Strategic Alliances, National Psoriasis Foundation

ⁱ Stern RS, Nijsten T, Feldman SR, Margolis DJ, Rolstad T. Psoriasis is common, carries a substantial burden even when not extensive, and is associated with widespread treatment dissatisfaction. *Journal of Investigative Dermatology Symposium Proceedings*. 2004 Mar; 9(2):136-9

ⁱⁱ 21. Lebwohl MG, Bachelez H, Barker J, et al. Patient perspectives in the management of psoriasis: results from the population-based Multinational Assessment of Psoriasis and Psoriatic Arthritis Survey. *J Am Acad Dermatol*. 2014;70(5):871-881.e30. doi:10.1016/j.jaad.2013.12.018.

ⁱⁱⁱ Helmick CG, Sacks JJ, Gelfand JM, et al. Psoriasis and Psoriatic Arthritis: A Public Health Agenda. *American journal of preventive medicine*. 2013;44(4):424-426. doi:10.1016/j.amepre.2013.01.004.