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

July 20, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Patient Preference Information – Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling

On behalf of the 7.5 million Americans living with psoriasis, the National Psoriasis Foundation (NPF) appreciates the opportunity to offer input on the *Patient Participation Information – Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling issued by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) on May 18, 2015.* As the agency gathers input from stakeholders, we hope that the Centers and the Food and Drug Administration (FDA) more broadly will continue to encourage developers of all medical products to include more fully the patient perspective on a variety of topics, particular benefit/risk thresholds. The NPF applauds the Centers for proposing a high degree of clarity and definition to the process behind securing and presenting patient preference information to inform regulatory decision-making. We particularly appreciate the Centers' recognition that such patient information can be vital at all steps of the product life cycle from ideation through to post-market surveillance. We also appreciate the recognition of the heterogeneity of patient perspectives on benefit/risk preferences and related topics even when the patients have the same underlying condition. Given the personalized nature of psoriasis and psoriatic arthritis, a treatment that may work well for one patient may be largely ineffective for another patient who presents similarly. Additionally, a treatment that may serve one patient well for years may at some point cease being effective, necessitating a transition to another therapy. All of these issues would influence the development and use of patient-preference studies in the psoriatic disease space.

Background on Psoriasis

The National Psoriasis Foundation exists to drive efforts to cure psoriatic disease and improve the lives of those affected. The most prevalent autoimmune disorder in the nation, psoriasis is a noncontagious, chronic, inflammatory, painful, disfiguring and disabling disease for which there is no cure. Psoriasis appears on the skin, most often as red, scaly patches that itch, can bleed, and requires sophisticated medical intervention. Up to 30 percent of people with psoriasis also develop psoriatic arthritis. Of serious concern is the mounting evidence that psoriasis is not just a disease of the skin and joints, but is in fact a systemic, inflammatory disease associated with an elevated risk for other serious, chronic and life-threatening conditions, - including cardiovascular disease, diabetes, stroke, and malignancies. People with severe psoriasis die four years younger, on average, than people without the disease.[i]

Overview of Phototherapy

There is no known cure for psoriasis and psoriatic arthritis but multiple FDA-approved treatment options are available today and include topics, phototherapy and large and small molecule systemic treatments. Phototherapy is the only FDA-approved medical device used by psoriasis patients.

Phototherapy or light therapy is used to treat and manage a number of skin and related disorders including psoriasis, psoriatic arthritis, eczema, cutaneous lymphoma and vitiligo. In total, tens of millions of Americans suffer from these conditions and could be candidates for phototherapy or laser treatment. They are well-proven, safe and effective therapies administered primarily within a physician's office, though they can also be delivered in hospital outpatient settings. In the case of phototherapy, home-based device is also an option, particularly in the most severe of cases.

As a treatment option, phototherapy and laser therapy can help a patient's condition go into remission when used alone or when coupled with other treatments including topicals (lotions and ointments), pharmaceuticals or biologics. Phototherapy is a particularly necessary treatment option for certain patients such as those whose immune system is suppressed and who thus might not be a candidate for a biologic. It is also a cost-effective treatment option, particularly compared to biologics and other novel therapies, and appropriate use of phototherapy can help delay or lessen use of biologics or other more expensive therapies.

Patient Engagement

NPF strongly supports the FDA's commitment to patient tolerance for risk and perspective on benefit and the ability to capture the heterogeneity of patients' preference. Psoriasis is a relentless and unpredictable disease, individual and diverse, presenting differently from one person to the next. Treatments that work for one person may not for others. Many patients cycle through accepted treatment options unsuccessfully or achieve temporary success but are ultimately left with no alternatives.[ii]

We believe that FDA can capitalize on its patient engagement work by helping foster patient engagement in the research, device and development and labeling process. Although there is great interest in engaging patients, patient advocates are engaged inconsistently and in some cases ineffectively. It is essential that patients with the experience relevant have the opportunity to provide input to product and policy decisions made by the FDA particularly with regard to safety and efficacy and risk tolerance associated with the use of specific products.

FDA can help further patient engagement by:

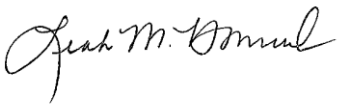
- Encouraging the development of a common definition of meaningful and appropriate patient engagement
- Establish a process to work with patient organizations to gather patient reported data to inform advisory committee decision-making
- Include patient representatives within each advisory committee

We therefore support meaningful and purposeful engagement of patients in all stages of the development and regulation of medical devices, ranging from the early stages of product development to regulatory approval and post-market activities.

Conclusion

The issue of patient engagement across the spectrum of health care, particularly regarding medical devices, is one of great importance to both the patient community and the stakeholders that depend on patient information to inform their work. We are encouraged by the progress we see and look forward to continuing to work with the FDA on this important topic. Thank you for your consideration. We stand ready to work with you and your colleagues on this important effort. If you have any questions about these comments, please contact Mr. Quardricos Driskell, NPF's Health Policy Manager, at qdriskell@psoraisis.org or at (503) 546-5559.

Sincerely,



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LH:QBD
Enclosure

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[i] Gelfand JM, Troxel AB, Lewis JD, Kurd SK, Shin DB, Wang X, Margolis DJ, Strom BL. The risk of mortality in patients with psoriasis: results from a population-based study. Archives of Dermatology. 2007 Dec; 143(12):1493-9.

[ii] 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