



a ray of
hope through
patient
awareness
and education

ISDI Information

Newsletter of the Inflammatory Skin Disease Institute

Volume 5 Number 2

Dermatology Community Speaks Out in Support of Elidel (pimecrolimus) Cream 1% and Protopic (tacrolimus) Ointment

When topical calcineurin inhibitors, sold under the brand names Elidel (pimecrolimus) Cream 1% and Protopic (tacrolimus) ointment, were approved by the Food and Drug Administration (FDA), they were a much needed and welcomed addition to a limited group of eczema treatments. These treatments still remain an important alternative to topical steroid creams for many eczema patients. Because of the FDA's recent actions, many doctors are concerned that patients and caregivers may be unnecessarily scared away from these treatments, which have shown a strong safety profile since their approval.

The FDA's recommendation for a black box warning is based, in part, on a theoretical risk of cancer and not a proven risk substantiated by clinical data or use in humans. This theoretical concern stems from lymphomas that developed in a few

animals that were given very high doses of an experimental oral form (not the topical cream form) of Elidel given over a long period of time in clinical trials designed to show toxicity.

Many in the dermatology community, including ISDI and the American Academy of Dermatology (AAD), feel that the FDA's recommendation is not warranted or supported by existing data. ISDI issued a statement reminding patients that when properly used, according to product labeling, Elidel and Protopic are valuable medications for millions of patients, helping them lead normal itch-free lives. These medications represent a medical breakthrough for patients with eczema. (To read the complete ISDI statement, visit our website at www.isdionline.org. Moreover, in its response, the AAD wrote "these medications are applied to the skin, virtually none of

it gets inside the body. It's not the same as taking a pill."

In a recent interview with ABC News Now, Mark Lebwohl, MD, professor and chairman of the Department of Dermatology, Mount Sinai School of Medicine, commented on the safety profiles of Elidel and Protopic, pointing out that the number of cases of cancer in patients treated with these medications is less frequent than the number of expected cases in the general populations. Dr. Lebwohl also indicated that "the makers of Elidel looked at 19,000 patients, whom they followed very closely, and what they showed was the risk of malignancy was actually 10-times lower in patients using Elidel group than the control group, where patients received placebo or fake pills. So far all of the evidence indicates that the drugs are, in fact, very safe."

If physicians are reluctant to prescribe Elidel

and Protopic due to the black box warning this could have an impact on the quality of care for eczema patients. "I have seen first hand how these new treatments have improved the quality of life for my own 2 children. Elidel and Protopic are the first alternative to topical steroids," states LaDonna Williams, Executive Director of ISDI.

While all medications and medical treatments carry some degree of risk for side effects, it is important for patients to speak with their physicians to discuss any questions or concerns regarding their medication before discontinuing a treatment that has been effective in managing their condition. By talking with their physician, patients and caregivers can make informed healthcare decisions and together can find a safe and effective treatment option for controlling eczema. ☀



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If you would like to be added to our mailing list please contact the ISDI office at the address above.

Mission

The goal of the Inflammatory Skin Disease Institute (ISDI) is to promote public awareness and enhanced treatment of inflammatory skin diseases through education, research, and patient advocacy.

ISDInformation is supported by an unrestricted educational grant from Novartis Pharmaceutical.

Director's Message



Getting involved and staying involved is what ISDI is all about. Dedicated to improving the lives of people with Skin Disease, ISDI continues to meet our mission providing education and awareness on inflammatory skin disease. It was an honor to present at the Dermanities Conference, a program held in conjunction with the American Academy of Dermatology, to further provide a patient's perspective of living with inflammatory skin disease. ISDI continues working with the American Academy of

Dermatology, the American Academy of Asthma, Allergy and Immunology, the Society of Investigative Dermatology and providing education and awareness to physicians, patients and caregivers on a local, state and national level.

ISDI is proud to be a part of the "December is Skin Disease Awareness Month." It was an honor to work with the Governor's office of the Commonwealth of Virginia and the Mayor's office of Newport News, Virginia.

LaDonna
 LaDonna Williams
 Executive Director
 ISDI

ISDI Hits the Hill

The Inflammatory Skin Disease Institute joined the American Academy of Dermatology, the Society of Investigative Dermatology and the Coalition of Skin Diseases in recognition of the 2nd Annual Skin Disease Awareness Day. ISDI provided a voice in



Washington speaking to the Senators and the Congressmen to educate and enhance awareness of incurable and debilitating skin diseases. Our focus was to encourage congress to approve the 6% increase for the National Institutes of Health (NIH) budget. We were power in numbers and our voices were heard loud and clear.

Meeting with our Virginia elected officials to request increased funding for skin disease research.

ISDI attends AAAAI (American Academy of Asthma, Allergy and Immunology) annual meeting. LaDonna, Ruthann and Kathryn Pavlovsky (board member) working exhibits and providing educational information and Awareness on skin disease.

BELOW: Dr. Hugh Sampson, ISDI Scientific Advisory Board Member, Sally Noone, ISDI Executive Board member and LaDonna meet and discuss upcoming issues.



Letters to the Editor:

Unlike the usual trend of “outgrowing” eczema, it was not until early adulthood that mine was in “full bloom”. With the hereditary predisposition towards the triad of asthma, hay fever, and eczema, I had a few bouts of pesky rashes as a pre-adolescent, but nothing major.

With the dissolution of my marriage, I moved to the tropics and remained there to be with my family for two decades. For the most part, the heat and the humidity made the flare-ups and the itching quite unbearable. In addition to topical steroids and antihistamines, I was introduced to cortical steroid injections for full-body eczema. I was referred to an internist and researcher who was having good results with a special cream containing heparin, a liver substance. After the untimely passing of this dear doctor, I was back to traditional treatment modalities, including soaking in the tub with oils, colloidal oatmeal, smelly tar substances and loads of petroleum jelly, making me feel like a greased pig!

Even though the skin is the largest organ of the body, it is generally not thought of as such, except by those who have experienced the worst case scenario ranging in severity from mild itching to serious medical health

complications that could lead to hospitalization.

My eczema took a new twist in my thirties; I was diagnosed with avascular necrosis in one hip and both knees (a degenerative bone disease, which can be a rare side effect of the steroid injections). From that point there was a slow decent into depression with anxiety as my constant companion. I had bone graft surgery on one hip with my young daughter having to wait on me and do more than her share.

With severe and persistent skin disease there are often emotional and psychological components. “Strong emotional overlay” was the phrase I recall – long-term effects of physical, emotional and childhood sexual abuse. Reclaiming my life involved moving back to my college town, reuniting with my adult daughter, redefining myself and rebuilding my life.

Over the years my treatments have varied from steroid creams and antihistamines, ultraviolet light treatments and the newer topical immunomodulators and low dosage immunosuppressant therapy. Now I am considerably more “in step” with my life. Tapping into my creativity and getting in touch with my artistic legacy has perhaps been the most therapeutic. This allows for self-expression via painting watercolors and exhibiting them on

a local, state and national level.

It is refreshing to see inflammatory skin disorders “come out of the closet” with media ads, television advertisements and publications like “ISDInformation” providing support, education and awareness on programs and new treatments, including topical immunomodulators. Despite painful, limited mobility, I face the future with a philosophical bent, one of my favorite adages being that we are all essentially “souls” having a “human” experience.

–Alexandra Austin
Chapel Hill, NC

Thank you so much for organizing the Second Annual ISDI conference. It was the first time I have attended a meeting sponsored by ISDI and I just wanted to thank you for the opportunities it afforded me. The experts who presented gave fantastic and useful information to me and the patients who attended. I think that the balance between research, clinical, and practical information that was presented was just right. I look forward to our continuing relationship with ISDI. Thank you!

–Rebecca Smith

Congratulations to our Inflammatory Skin Disease Institute Scholarship Recipients



KATE ELKE Milwaukee, Wisconsin:

Academic:
~4.0 National Honor Roll
Extra Curricular:
~Art, Music, Photography
Community Involvement: ~
~Founder of Acne Support
Group; Volunteer with the
Homeless
College:
~Concordia University of
Wisconsin

KARI GONTHIER Alabaster, Alabama

Academic: 3.67
Extra Curricular:
~Community outreach
programs for charities; Phi Eta
Sigma
~National Honors Fraternity
Community Involvement:
~Dance Marathon for
Children’s Miracle Network
College:
~Florida State University





ANNOUNCING
3rd Annual Patient/Physician Conference
“Inflammatory Skin Diseases and the Quality of Life”
presented by the Inflammatory Skin Disease Institute (ISDI)
and Eastern Virginia Medical School (EVMS).

For more information or to register call ISDI at (757)223-0795.



Thank You for your Donations

Operating a non-profit organization would not be possible without financial contributions from private and corporate donors. Because of you we can continue to meet our mission. We do not charge

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Donations made to ISDI and fundraisers are the only source of income that we have to produce and distribute our newsletter.





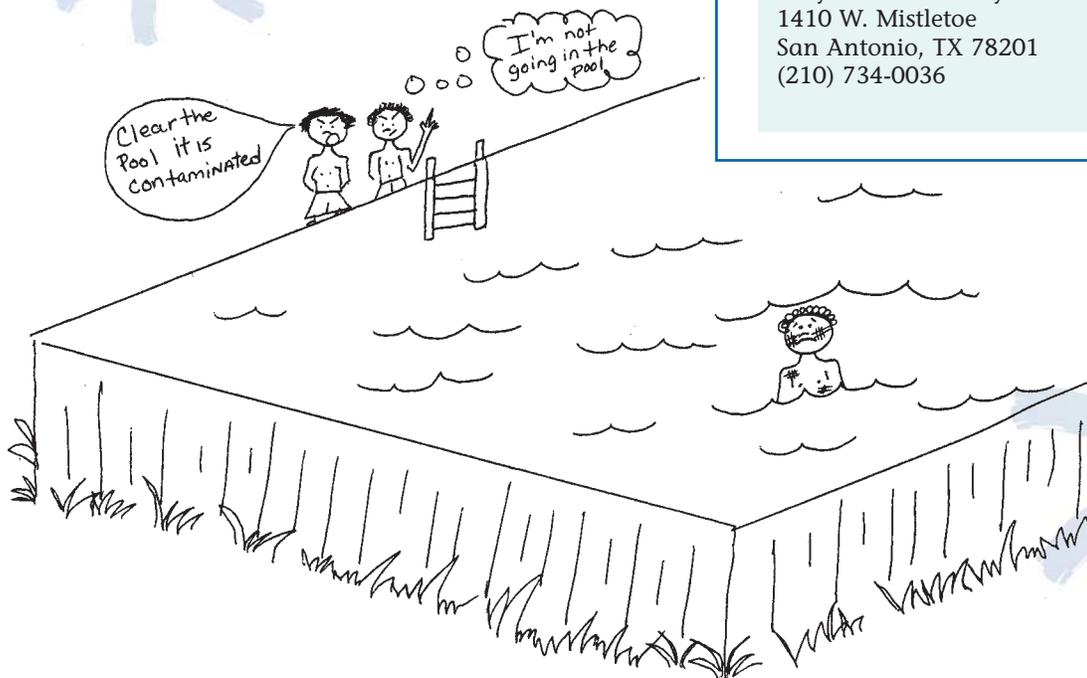
Tasteless Comments

If you are a person with a skin disease, or the parent of a child with a skin disease, you have undoubtedly been faced with those rude, crude, and even well meaning people asking “those questions.”

Do you have any snappy comebacks that you want so much to say, or actually have said? Send us your responses and you might see yours in print.

Editor’s Note: The purpose of this section is three-fold: 1) it is an opportunity to educate and make the public aware of the disorder, 2) it lets society know it is not appropriate to stare and ask hurtful questions, and 3) it is an opportunity to let off steam with a touch of humor, allowing us to laugh.

My family and I were at a pool party recently. My son, who suffers from skin disease, jumped into the pool. One child that was already in the pool started yelling, “He’s contaminated.” My son, not knowing what the word meant, yelled back, “I am not! I’m Catholic!” But it did give me the opportunity to let the children know about my son’s condition and that it is not contagious or that people with skin disorders will not contaminate the water. RN



PENPALS

Reach out to others and share challenges and triumphs in dealing with your disease. Patients often look to others in similar situations to discuss treatments, feelings, etc. The following readers have asked for their names to be presented as possible pen pals. If you are looking for support from someone who has the same disease as you, contact any of the readers listed below. Also, to be added to the list, send your name, address, phone, and/or e-mail to ISDI, P.O. Box 1074, Newport News, VA 23601 or ExDirISDI@aol.com.

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how can I **HELP?**

Yes! I would like to help support the Inflammatory Skin Disease Institute (ISDI).

Name _____
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By donating to **ISDI** you will help us provide a ray of hope to people with inflammatory skin disease. An ISDI information subscription is given to all donors.

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Completed form and payment may be sent to: **Inflammatory Skin Disease Institute (ISDI)** P.O. Box 1074, Newport News, VA 23601

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thank YOU!

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