Dear Readers,

Common allergens that cause allergic contact dermatitis in adults are also prevalent and relevant in children. Consequently, we are happy to announce what we know will prove to be a significant gift this season to all clinicians involved in patch testing: T.R.U.E. TEST can be used on pediatric patients! T.R.U.E. TEST is now the only diagnostic test for allergic contact dermatitis approved by the Food and Drug Administration for use in children as young as 6 years old. We could not be more excited to share this information with the patch test community and hope that this approval will encourage patch testing of appropriate pediatric patients who, like adults, deserve a diagnosis!

In addition, this issue highlights two articles of interest. One is related to the use of corticosteroids in the treatment of patients with atopic dermatitis. Too often patients with dermatitis are treated with these efficacious but hardly benign drugs. This article offers an international perspective on their use, and we encourage patch testing in appropriate cases to determine whether the cause of a dermatitic condition is an avoidable allergen. The issue closes with a look at moisturizers and, in that context, a return to the potential clinical implications of marketing claims.

We trust your past year devoted to treating patients has been successful and extend our best wishes for a prosperous new year! Remember that SmartPractice is here to help you ensure that it will be.

Kind Regards,
Dr. Curt Hamann
President & CEO, SmartPractice

FDA Approved! T.R.U.E. TEST for Pediatric Patients

H ave you ever wanted to expand your practice to pediatric patients but found the idea of preparing and applying conventional patch test panels to kids to be too daunting? Or, if you already do patch test pediatric patients, have you ever been trying to apply manually prepared allergen panels to the back of a small, squirmy, and possibly cranky kid while you tried to avoid dripping petrolatum or aqueous preparations and wished you could just apply a no-muss, no-fuss T.R.U.E. TEST panel instead? If so, you will be happy to learn that now you can! In September 2017 the United States Food and Drug Administration granted approval for T.R.U.E. TEST to be used on patients as young as 6 years old whose history suggests sensitivity to one or more of the allergens or allergen mixes included on the three panels as an aid in the diagnosis of allergic contact dermatitis.

This long-awaited approval is the culmination of more than a decade of developing and completing 2 large postmarketing clinical trials that included more than 200 pediatric patients between the ages of 6 and 18 years old. The results of the first pediatric study, which evaluated 28 T.R.U.E. TEST allergens, were published in 2011. The results of the second trial, which evaluated 11 T.R.U.E. TEST allergens, are being prepared for publication as of this writing. Together, these two clinical trials demonstrated the safety and efficacy of all allergens on the three T.R.U.E. TEST panels when used in pediatric patients according to the prescribing information.

Allergic contact dermatitis may account for as many as 20% of all cases of dermatitis in children. Furthermore, reported rates of positive patch tests in children suspected of having allergic contact dermatitis range between 27% and almost 96%. In a recent retrospective review of 1,142 pediatric cases in the United States based on data from the Pediatric Contact Dermatitis Registry, 65% of the cases had a positive patch test and the finding was relevant in almost half of the cases.

Continued on next page
Of the 10 most common allergens in those pediatric cases, 8 are included on T.R.U.E. TEST—nickel, fragrance mix, cobalt, balsam of Peru, neomycin, bacitracin, formaldehyde, and gold. So that’s more good news!

As in adults, there is a strong need for patch testing in children. That need is further heightened by the increasing opportunity for children to become sensitized to allergens commonly found in personal hygiene products such as fragrances, balsam of Peru, lanolin, formaldehyde, corticosteroids, and methylchlorothiazalnine (MCI) and methylisothiazalinone—all of which are also found on T.R.U.E. TEST. We are excited about receiving this approval to extend the indications and usage of T.R.U.E. TEST to pediatric patients and hope that your ability to patch test appropriate pediatric candidates will now be enhanced.

Remember, however, that the application of T.R.U.E. TEST to children younger than 6 years old is still considered an off-label use in the United States, even when supported by current medical care guidelines.

For more information about the use of T.R.U.E TEST in pediatric patients or for assistance in extending your patch test practice to the pediatric population, please contact Jeff Anderson at 1-800-878-3837 (ext. 7343). Our goal is to make your job of diagnosing allergic contact dermatitis in those squirmy kids as easy as possible!

References
When is it Appropriate to Use Corticosteroids to Treat Atopic Dermatitis?

In the last issue of this newsletter, we introduced a new series on corticosteroids with a discussion of the common systems used to classify these agents and the associated clinical implications. And we promised to follow up with articles on the major compounds within each group. We still intend to do so! In the meantime, however, a recently published article on the use of corticosteroids to treat atopic dermatitis caught our attention (Drucker AM, Eyerich K, de Bruin-Weller MS, et al. Use of systemic corticosteroids for atopic dermatitis: International Eczema Council consensus statement. Br J Dermatol 2017 Sep 2. Doi:10.1111/bjd.15928 [Epub ahead of print]).

This article represents a consensus statement from the International Eczema Council (IEC), a global nonprofit organization founded in 2014 and composed of 77 atopic dermatitis experts from 21 countries on 5 continents. We wanted to share this information because the overuse of corticosteroids can create long-lasting problems for patients, and more than 30 million individuals in the United States alone suffer from some form of the disease. (For additional information on the diagnosis and management of atopic dermatitis and the role of patch testing, click here.)

The members were surveyed about their use of corticosteroids in the treatment of patients with atopic dermatitis based on age group (i.e., < 12 years, 12-17 years, adults); 79% of the members from 20 countries responded. The criterion for consensus was considered to have been reached if 70% of the respondents were neutral or agreed on a visual analog scale for each statement in the survey. A consensus was reached on 12 key points.

A strong consensus opposed regular use of systemic corticosteroids for patients with severe atopic dermatitis. More than half the respondents agreed that systemic corticosteroids should never be used in children or adolescents, but consensus was not reached. Most (65%) also agreed that nonresponse to topical treatment was an indication for systemic use of corticosteroids. The group, however, agreed that although systemic corticosteroids should be avoided, they could be used rarely in any of the three age-groups. Consensus on the appropriate use of systemic corticosteroids was restricted to only a few scenarios: patients with severe acute flares, the most severe cases, lack of alternative treatment options (e.g., a patient with a contraindication for cyclosporine), a bridge to other systemic therapies (e.g., methotrexate, azathioprine, mycophenolate, which require several weeks to become effective) or to phototherapy, or in anticipation of a major life event. If corticosteroids were used, the consensus (94%) was also that the treatment should be short term. Although no agreement was reached on how that duration should be defined, limiting use to no more than 2 weeks for severe atopic dermatitis almost reached consensus, garnering agreement from 69% of the respondents. No consensus was reached on dosing, which, however, may vary by region as well as by individual prescribing clinician.

When evaluating the consensus results, it is important to remember that the findings are limited by the overall paucity of data and findings from randomized clinical trials to support the statements. Furthermore, the number of consensus statements decreases considerably when more stringent criteria for agreement are applied (e.g., < 20% marking strongly disagree). It is worth remembering, however, that the majority of this diverse group of experts believes that the use of systemic corticosteroids should be short term and limited to specific clinical circumstances. These strictures are especially important to consider in children in whom the use of systemic corticosteroid therapy may promote infections, growth delay, or obesity. Although the IEC consensus statement may not provide definitive answers, it offers guidelines that could curb the overuse of long-term systemic corticosteroids in patients with atopic dermatitis. As such it may be a good basis for comparison to help establish prudent use of this therapy in clinical practice.

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Moisturizers and Allergenicity

Have you found it difficult to identify an allergen-free moisturizer to recommend to your patients? If so, it’s not surprising. In a new study (Xu S, Kwa M, Lohman ME, et al. Consumer preferences, product characteristics, and potentially allergenic ingredients in best-selling moisturizers. J Am Med Assoc Dermatol 2017; 153 (11): 1099-1105), researchers evaluated the ingredients of 174 unique, whole-body moisturizers sold by 3 major online retailers—Amazon, Walmart, and Target. Moisturizers marketed for specific areas of the body such as the face or hands were excluded from the analysis.

The results of the analysis indicated that 88% of 174 best-selling moisturizers contained one or more potentially allergenic chemicals in their ingredients. In other words, only 21 moisturizing products contained no allergens included in the North American Contact Dermatitis Group (NACDG) series. Almost 70% of the products had additional marketing claims beyond the purpose of moisturizing the skin (Table 1), and even the majority of products labeled as “hypoallergenic” (83%) contained at least one allergen. Furthermore, 45% of the products that claimed to be “fragrance-free” contained a fragrance or a botanical ingredient.

The top 5 most common allergens identified in the moisturizers were fragrances, parabens, tocopherol, phenoxyethanol, and formaldehyde releasers.

The clinical implications of using a skin moisturizer that claims to be fragrance-free or hypoallergenic are straightforward—these products have the potential to aggravate skin disorders such as dermatitis, psoriasis, and eczema. As discussed in an earlier issue of this newsletter and as the findings of this investigation underscore, the marketing terms analyzed in this article are not regulated by the U.S. Food and Drug Administration. Consequently, labels such as “fragrance-free” or “hypoallergenic” are no guarantee that sensitized individuals will not have a skin reaction to one or more ingredients in a product or that the product will help improve skin conditions. Caveat emptor—let the buyer beware! Companies are under no obligations to substantiate such marketing claims with regulatory agencies. Likewise, patients should be cautioned that claims such as “organic” and “natural” may be accurate but do not necessarily indicate that a product is hypoallergenic.

The study also assessed the affordability of the moisturizers. Although products labeled as “dermatologist-recommended” cost an average of 20 cents more per ounce than those without the label, those sporting higher prices were no guarantee that users would enjoy increased benefits. It is unfortunately ironic that products marketed to individuals with skin conditions such as eczema and psoriasis tended to cost more, even though the product may include ingredients that could worsen a skin problem.

All moisturizers help patients with skin disorders by retaining moisture in the skin, reducing inflammation, and helping to prevent infection. These products are an important and cost-effective tool for maintaining the viability of the skin barrier, and clinicians have a responsibility to understand the ingredients of skin products that they may recommend. They also must consider a patient’s preferences (and hence likelihood of compliance) and affordability. If you have questions about the moisturizers offered by SmartPractice, please call and let us answer them for you!

Table 1: Marketing Claims on 174 Common Moisturizers

<table>
<thead>
<tr>
<th>Claim</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatologist recommended</td>
<td>40 (23)</td>
</tr>
<tr>
<td>Fragrance free</td>
<td>40 (23)</td>
</tr>
<tr>
<td>Nongreasy</td>
<td>38 (22)</td>
</tr>
<tr>
<td>Organic</td>
<td>38 (22)</td>
</tr>
<tr>
<td>Natural</td>
<td>38 (22)</td>
</tr>
<tr>
<td>Pure</td>
<td>38 (22)</td>
</tr>
<tr>
<td>Noncomedogenic</td>
<td>29 (17)</td>
</tr>
<tr>
<td>Paraben free</td>
<td>29 (17)</td>
</tr>
<tr>
<td>Hypoallergenic</td>
<td>18 (10)</td>
</tr>
<tr>
<td>Clinically proven</td>
<td>16 (9)</td>
</tr>
<tr>
<td>Phthalate free</td>
<td>15 (9)</td>
</tr>
<tr>
<td>National Eczema Foundation approved</td>
<td>9 (5)</td>
</tr>
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</table>

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