HISTORICAL PERSPECTIVE

The earliest recorded description of allergic contact dermatitis (ACD) was documented in the first century AD by Pliny the Younger, who described an adult with “a severe itching from cutting pine trees.” While numerous anecdotal accounts of contact dermatitis exist through the literature, our working knowledge of the condition was first enlightened in 1895 by Josef Jadassohn, a dermatologist and syphilologist at the University of Bern, who performed the first delayed-reading patch test on an adult sensitized to a mercurial treatment for pediculosis pubis. While patch testing was furthered throughout the ensuing decades, including its introduction to North America in the 1930s by Sulzberger, it wasn’t until 1939 that Paul Bonnevie published the first standard series of patch test antigens (see Table 1). Of his 21 original allergens, six are still used in today’s patch-testing kits and, remarkably, these were recently reported in the United States to be top sensitizers in children.

Despite several pivotal studies, much controversy has surrounded ACD in children. For quite some time, dermatologists and pediatricians alike have debated whether the rates of sensitization and ACD in children rival those seen in adults. The fact that children were able to mount an appropriate immune response to contact allergens was defined by Strauss in 1931. His experiments demonstrated that poison ivy-naïve infants could develop ACD to the plant after artificial sensitization, while rates of sensitization were determined much later.

Of interest, during World War II, an increasing prevalence of occupational dermatitis led to an appreciation for the importance of proper patch testing. The first clinic devoted entirely to contact dermatitis was founded in 1953 at St. John’s Hospital for Skin Disease in London. Numerous other clinics began to form around Europe and North America, but each was testing with its own set of allergens in varying concentrations and vehicles. It was Scandinavian researchers...
who led the way for standardized patch testing through the directives of the Scandinavian Committee for Standardization of Routine Patch Testing (circa 1962). Soon after, Alexander A. Fisher, Howard I. Maibach, Marion Sulzberger, and others, formed the North American Contact Dermatitis Group (NACDG). This invitation-only group helped to bring together North American contact dermatitis experts, and eventually led to the development of the first standardized allergen kit in the 1980s, the American Academy of Dermatology Patch Test Kit, manufactured by Hermal and Trolab.

Over the last 40 years, Fisher and other NACDG group members have greatly advanced our knowledge of ACD in U.S. adults and children. Their work has helped to identify numerous chemicals responsible for ACD in cosmetics and occupational settings. During the same time, most clinicians considered ACD to be an infrequent occurrence among children based primarily on two beliefs: 1) that patients under 18 had less exposure to allergens, and 2) that the juvenile immune system may be less responsive than the adults to contact allergens. These assumptions, among other reasons, lead to a general lack of epicutaneous patch testing of children among dermatologists and pediatricians in the United States.

That being said, 25 years ago, Weston and Weston put forth that ACD accounted for up to 20% of dermatitis seen in children based on a review of the literature available at the time. Two years later, they demonstrated a contact allergy (a positive patch test in a well person, or irrelevant positive in an affected person) rate of 20% in of 314 healthy volunteer children, who had at least one positive patch test reaction to the 20-allergen American Academy of Dermatology Patch Test Kit. This confirmed that well children could elicit contact allergy (a positive patch test) when provoked by epicutaneous patch testing.

**ADVANCES IN THE LAST DECADE IN PATCH TESTING CHILDREN**

In 2000, Bruckner et al corroborated the findings of the Weston study, when they demonstrated that 24.5% of healthy volunteers under 5 years old had at least one positive patch test reaction (contact allergy) to the newly FDA-indicated (for adults) TRUE test kit. Children as young as 6 months of age were able to mount immune responses (produce a positive patch test) to the common allergens in the TRUE test.

In reviewing the North American-based literature, three articles published between 2000 and 2006 noted that patch testing was being performed in children in the United States. Silverberg et al found that in 30 children with a personal history of umbilical or wrist dermatitis or a family history of nickel ACD, 100% of patients had a positive reaction to a nickel sulfate 5% patch test (Trolab), and 50% had an idiopathic reaction to nickel. In addition, the NACDG 2001 to 2002 data recorded the testing of patients aged 2 to 97, and the Mayo group 1998 to 2005 data tested patients aged 3 to 94 (mean age 54.7); however, no further mention was made about these groups’ findings in the children tested.

Meanwhile, numerous studies from abroad during this time period continued to report the significance of ACD and contact allergy in their patch-tested populations, some reporting positive patch test rates in affected children as high as 56%. In 2006, the first U.S. series of affected children being patch tested and having clinically relevant results and improvement after allergen avoidance was presented at the American Contact Dermatitis Society (ACDS) Annual Meeting. Soon thereafter, the Canadian group published the first retrospective data from 100 affected children patch tested.

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**Table 1. BONNEVIE’S 1939 ORIGINAL STANDARD SERIES**

| Turpentine | Colophony |
| Balsam of Peru (Myroxylon pereirae) | Salicylic acid |
| Formaldehyde | Mercuric chloride |
| Potassium dichromate | Silver nitrate |
| Nickel sulfate | Resorcinol |
| Primula obconica | Sodium perborate |
| Brown soap | Coal tar |
| Wood tar | Quinine chlorhydrate |
| Iodine | Pyrogallol |
| p-Phenylenediamine | Aminophenol |
| Adhesive plaster |

Bolded allergens have been top allergen offenders for more than 70 years and are on the top 10 for children.
tested at the Ottawa center over the prior 10 years. This first published North American data paper was pivotal in demonstrating both similar (but not equal) allergen profiles in children to that of adults, and the efficacy of patch testing children in North America. These authors concluded that proper identification of contact allergens early in life can lead to the prevention of ACD for a lifetime.

Subsequently, data has been published from three multi-center patch-test tertiary clinics in the United States. These three studies, ranging from 65 to 391 patients per study, have reported the most relevant allergens among affected children comprehensively patch tested in the United States (with one also reporting from Canada). Of note, comprehensive patch testing refers to standard and custom allergens prepared for the individual based on exposure history, as opposed to the commercially available limited allergen kits mentioned previously, which were used in the Weston and Bruckner studies. Taking these three North American studies together and combining the data summates a total of 592 affected children being tested by a total of 19 patch testers over an average of 5.3 years (an average of six patients per year). Even though the data is limited, it is important, because 1) it demonstrated that patch testing was efficacious and safe in U.S. children; 2) that North American children are suffering from dermatitis elicited by many of the same allergens as North American adults (see Table 2); and 3) when patch testing is used appropriately, and a culprit allergen is identified and further avoided, children, like adults, get well.

As the data reflects, the number of children who are able to access comprehensive patch test care is staggeringly low, leading to many of these children being misdiagnosed with ‘eczema’, and some being treated with potentially avoidable immunosuppressants (corticosteroids, cyclosporine A, etc.).

### Table 2. TOP 21 ALLERGENS IN U.S. CHILDREN TODAY

<table>
<thead>
<tr>
<th>Allergen</th>
<th>Common Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nickel sulfate</td>
<td>Jewelry, piercings, clothing, kitchen items, keys, cell phones, musical instruments, taps</td>
</tr>
<tr>
<td>2. Cobalt chloride</td>
<td>Paints and dyes, metal-plated objects, vitamins</td>
</tr>
<tr>
<td>3. Thimerosal</td>
<td>Some cosmetics, ophthalmic medicaments, vaccines</td>
</tr>
<tr>
<td>4. Gold</td>
<td>Jewelry, dentistry, Groshlager</td>
</tr>
<tr>
<td>5. Fragrance Mix</td>
<td>Cosmetics, lotions, perfumes</td>
</tr>
<tr>
<td>6. Neomycin</td>
<td>Antibiotic ointments</td>
</tr>
<tr>
<td>7. Myroxylon pereirae (balsam of Peru)</td>
<td>Cosmetics, lotions, perfumes, baby diaper balms, fragrances, flavorants</td>
</tr>
<tr>
<td>8. Colophony</td>
<td>Adhesives, cosmetics, diapers</td>
</tr>
<tr>
<td>9. Formaldehyde</td>
<td>Personal hygiene products, clothing, building materials</td>
</tr>
<tr>
<td>10. Lanolin</td>
<td>Personal hygiene products, medicaments, industrial products</td>
</tr>
<tr>
<td>11. Quaternium 15</td>
<td>[Formaldehyde releaser] Cosmetics, shampoos, shaving creams, sunscreen</td>
</tr>
<tr>
<td>12. Benzalkonium chloride</td>
<td>Nasal spray, eye drops, hand sanitizers/wipes</td>
</tr>
<tr>
<td>13. Potassium dichromate</td>
<td>Paints, leather goods, cements, vitamins (chromium)</td>
</tr>
<tr>
<td>14. p-Phenylenediamine</td>
<td>Hair dye, clothing, black henna tattoos</td>
</tr>
<tr>
<td>15. Bacitracin</td>
<td>Antibiotic ointments</td>
</tr>
<tr>
<td>16. Cocamidopropyl betaine</td>
<td>Shampoos, soaps, toothpastes, cosmetics</td>
</tr>
<tr>
<td>17. Carbamates</td>
<td>Rubber products</td>
</tr>
<tr>
<td>18. Disperse blue dye</td>
<td>Clothing, diapers</td>
</tr>
<tr>
<td>19. Propylene glycol</td>
<td>Topical steroid creams, cosmetics, deodorants, antifreeze, food preservation</td>
</tr>
<tr>
<td>20. Imidazolidinyl urea</td>
<td>Personal hygiene products, medications</td>
</tr>
<tr>
<td>21. Cinnamic aldehyde</td>
<td>Food, beverages, hygiene products, fragrances</td>
</tr>
</tbody>
</table>

This composite list was compiled based on data from Jacob 2008, Zug 2008, Hogeling 2008, and Hammonds 2009.
ACD, this translates to approximately half a million patients per tester, or an average access rate (based on 192/year) of 0.04%.

Addressing the reasons behind the shortage of comprehensive patch testing is a difficult endeavor. Currently, economics in dermatology have influenced a trend toward cosmetic and surgical procedures. But with ACD costing the United States an estimated $1.9 billion a year, the economic burden of not patch testing is great. The number of children affected and the exact economic costs to these families is not exactly known, but, again, these costs are certainly high. Given the current shortage of patch-testing practitioners, it is imperative that, at a minimum, action be taken to reduce children’s contact with chemicals known to be high-level sensitizers. These chemicals can be identified from the aforementioned pivotal studies in children and from our knowledge of adult studies, especially since many of the top sensitizers are one and the same, and six have been on the top list since 1939! (See Table 1.)

**PROTECTIVE DIRECTIVES OVERSEAS AND THE ISSUES FACING AMERICA**

Unlike for food and drug additives, the FDA does not require that cosmetics be tested for safety before hitting the shelves. A review of more than 23,000 products by the Environmental Working Group, found that more than 750 products sold in the United States violate safety standards set in other industrialized countries. In fact, the European Union has banned more than 1,100 chemicals from cosmetics, while the FDA, in stark contrast, has banned only 10. Table 3 lists the 10 chemicals banned in the United States.

In fact, three of the top sensitizers in U.S. children have been banned, regulated or both in other countries. These chemicals fall under the umbrella of environmental risk factors for disease. The World Health Organization Task Force on Protection of Children’s Environmental Health has declared that one-third of the global burden of disease can be attributed to these potentially preventable environmental risk factors.

And what do the regulating agencies do to protect us from the barrage of environmental chemicals we are exposed to every day? Current estimates are that only 25% of the 82,000 chemicals in use in the United States today have ever been subject to a basic testing. Compare this to the 65,000 chemicals that have been identified as causal agents of irritant contact dermatitis and the 3,700 agents of allergic contact dermatitis.

**Table 3. FDA PROHIBITED OR REGULATED COSMETIC INGREDIENTS**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bithionol</td>
<td>may cause photocontact sensitization</td>
</tr>
<tr>
<td>Chlorofluorocarbon propellants</td>
<td>environmental damage?</td>
</tr>
<tr>
<td>Chloroform</td>
<td>carcinogenic</td>
</tr>
<tr>
<td>Halogenated salicylanilides</td>
<td>photocontact sensitization</td>
</tr>
<tr>
<td>Methylene chloride</td>
<td>carcinogenic</td>
</tr>
<tr>
<td>Vinyl chloride</td>
<td>carcinogenic</td>
</tr>
<tr>
<td>Zirconium</td>
<td>pulmonary toxicity</td>
</tr>
<tr>
<td>Certain cattle materials</td>
<td>Mad Cow Disease Warning</td>
</tr>
<tr>
<td>Hexachlorophene</td>
<td>may not exceed 0.1% - toxic</td>
</tr>
<tr>
<td>Mercury</td>
<td>limited to 1 ppm — allergic reactions and neurotoxic</td>
</tr>
</tbody>
</table>

Attempts to curb nickel allergies were enacted in Europe 15 years ago. “The Nickel Directive,” passed by the European Union (EU) in 1994, limited allowable release of nickel in objects that come into direct and prolonged contact with the skin to 0.5 mg/cm² per week. They addressed the growing problem with piercings in 2004 by reducing the permitted release of nickel from posts placed in wounds after piercing to just 0.02 mg/cm² per week. This legislation triggered a noticeable decrease in nickel allergy. In Germany, for example, sensitization in women under 30 decreased from 36.7% to 25.8% over an 8-year period. Having enacted their own nickel legislation 2 years before the rest of Europe, Denmark has seen even more dramatic changes. Rates of nickel sensitization among Danish children went from 24.8% in 1985 to only 9.2% in 1998.

The American Academy of Dermatology (AAD) and AAD Association Advisory Board passed a resolution this spring put forth by the ACD to encourage a similar nickel directive in the United States similar to the ones in Europe. The Academy’s Board of Directors subsequently voted to refer the proposal to the Environment and Drugs Committee, which recently approved moving forward with the recommendations. One priority for the AAD is to educate its members on this issue. Along with the AAD, the Nickel Institute, a nonprofit organization representing the 24 companies that produce more than 90% of the world’s nickel, has been encouraging the implementation of a nickel directive in the United States. The Institute issued the following statement regarding nickel regulation: “The Nickel Institute believes that appropriate regulation — based on nickel release, not nickel content — can provide protection against nickel allergy without placing unnecessary restrictions on legitimate applications of nickel. In the absence of regulation, voluntary industry initiatives — such as those by clothing suppliers Levi Strauss and H&M — can also serve to protect against nickel allergy. We would love to see a major American retailer such as
Wal-Mart initiate a similar policy for skin contact items such as jewelry, belt buckles and clothing fasteners.14

**para-Phenylenediamine (PPD)**

In the last decade, U.S. children have been increasingly exposed to one of the other notorious contact allergens first designated on Bonneville’s original standard allergen panel in 1939. Notably, PPD is an oxidative chemical used widely in hair dyes. Its recent notoriety grew because of its addition to henna to make “black henna tattoos.” It is added to natural henna to darken the dye and decrease drying time and has become a common sensitizer to ACD in children.39 Prior to 1990, the only reports of ACD from henna tattoos were coming from South Asia.36 But since 2000, a flood of case reports from the United States has been seen in the literature.38 We now know of hundreds of reports of ACD to PPD in henna ranging from mild eczema to severe bullous reactions with permanent pigmentary changes,36 with some patients as young as 3 years old.37

It is important to note that PPD has been banned in the United States from skin application practices since the Food, Drug, and Cosmetic Act of 1938.35 This act, a revision of the previous Food and Drug Act of 1906, was put into place following a flood of ACD caused by PPD in a popular cosmetic of the time, Lash Lure. Interestingly, use of PPDs in hair dyes remained exempt from the legislation. And, of note in hair dye, the concentration is restricted to 6% in Europe; most commercially available black dyes contain between 2.0% and 4.0%.38 In the “black henna tattoos,” however and unfortunately, concentrations of PPD have been reported as high as 15.7%.39 In a study by Kligman in 1966, it was noted that a concentration of 10% was enough to sensitize 100% of the persons tested.40

Health Canada, a federal program responsible for helping citizens stay healthy, has warned Canadians to avoid PPD and prohibited the sale and application of PPD-containing cosmetics, including black henna tattoos.35 Last year, a resolution for FDA action was put forth by the ACDS and endorsed by the Society of Pediatric Dermatology and the Advisory Board of the AAD to address current lack of regulation on black henna tattoo practices in the United States. The AAD has officially endorsed a ban on the practice of applying temporary black henna tattoos containing PPD.41 Furthermore, the AAD initiated a public education campaign, issuing a consumer alert to print and broadcast media across the country. Because of this outreach, national and local newspapers and TV news stations nationwide ran features to educate the public about the serious skin reactions associated with black henna tattoos. Advocacy and public education is paramount to prevent children from being exposed to this potentially serious allergen.

**Formaldehyde**

Formaldehyde, a preservative found in numerous everyday items, including cosmetics and baby products, has demonstrated in several studies to be a potent sensitizing agent.6,7,8 In fact, formaldehyde has been shown to be present in numerous personal care products when it is released over time from formaldehyde-releasing preservatives (FRPs). Formaldehyde has long been known to be a skin sensitizer, as noted again by Bonneville in 1939. Furthermore, levels as low as 250 ppm have been reported to trigger reactions in some people.12

In personal hygiene products, manufacturers often produce formulations that have FRPs, rather than using formaldehyde itself. The FRPs are small compounds that slowly release formaldehyde over time. The most sensitizing of the FRPs, Quaternium-15 (Q15), was found to cause clinically relevant reactions in 9.3% of 4,910 patients patch tested by the NACDG from 2001 to 2002,18 and 4% of children from the Hoggeling and Pratt study.8 In fact, Zug et al placed Q15 among the top six allergens in children when they found that 3.6% of patients under the age of 18 had clinically relevant reactions.7

Currently, there are no restrictions in place in the United States limiting the amount formaldehyde permitted in personal care products. This is in stark contrast to its being banned entirely in personal care products in Japan and Sweden, and levels being tightly regulated in the European Union and Canada.43

In the March 2009 “Toxic Tub” report from the Campaign for Safe Cosmetics (CFSC), a significant proportion of the tested popular baby products reportedly contained both formaldehyde and 1,4-dioxane, both of which are byproducts of the manufacturing process and considered to be probable human carcinogens.44 Because formaldehyde and 1,4-dioxane are byproducts and not added ingredients, neither of these chemicals was listed on the ingredients. As it currently stands, companies in the United States are not required to list potential byproduct names in the ingredients or on the labels.45 In fact, the study found lotions with enough formaldehyde to require a warning label by EU standards.44

Lundov et al recently reviewed the literature regarding preservatives in personal hygiene products and found that many contain concentrations of preservatives, namely parabens, methylchloroisothiazoline/methylisothiazolinone, and FRPs, that may be in excess of what is required for antimicrobial activity.46 Because sensitization is dose-dependent, these excessive concentrations may be contributing to the finding that approximately 6% of the general population has a ‘cosmetic-related contact allergy.’46 Additionally, three separate studies have found that 28%, 17%, and 23% of skin creams labeled the ingredients incorrectly according to specific regulations.46 Furthermore, in the United States, there is no requirement on cosmetic manufacturers to report to the FDA what preservatives are used or in what concentration.46

The responsibility for regulating ‘toxic chemicals in personal products’ has fallen to the state level.44 For example, California passed the Safe Cosmetics Act in 2005, requiring companies to disclose the use of carcinogenic or teratogenic chemicals to the state.47 Likewise, 3 years later, Washington banned phthalates from children’s products with the passage of the Children’s Safe Product Act.48 Despite these efforts, comprehensive federal legislation is still lacking, leaving consumers nationwide at risk of exposure.

According to the FDA, “cosmetics and their ingredients are not required to undergo approval before they are sold to the
public. Generally, FDA regulates these products after they have been released to the marketplace. This means that manufacturers may use any ingredient or raw material, except for color additives and a few [10] prohibited substances, to market a product without a government review or approval.” The FDA essentially passes the responsibility of determining the safety of the products and ingredients onto the cosmetic companies and manufacturers.44

MADE IN CHINA – WHAT DOES THIS REALLY MEAN?

In the not so distant past, we have seen major conglomerate retail stores changing their mottos to reflect the American state of mind. What began as a “Life. Well spent.” (Sears) and “The stuff of life” (Kmart) transitioned as the nation saw a rise in major chains encouraging Americans to live well by buying more at lower prices “Save money. Live better” (Wal-mart) and “Expect More. Pay Less” (Target). This getting more for less was achieved as part of a larger business model, which included foreign outsourcing of manufacturing. For one example, as of 2004, 70% of goods sold by Wal-Mart were made in China.50 Per-hour costs for [outsourced] factory workers are often less than $1 an hour.51 And, thus by lowering costs during production, companies can then pass the savings on to the consumer. But are they also passing on an unseen cost? An even bigger question is whether consumers — that is, children — are paying for these savings with an increased exposure to potentially harmful chemicals, as are the workers, many of whom are under 18.52 For example, who would have anticipated Mattel’s recalling nearly 9 million Chinese-made toys due to lead-containing paint found in the toys?53

With the rise of global free trade comes an increased influx of unregulated or unscreened internationally produced wares into U.S. households.54 An estimated $3.5 million worth of imported goods enters the country every minute.55 A case in point: In 2006, hundreds of cases of contact dermatitis to newly acquired sofas and chairs were reported in Great Britain56 and Finland.57 Patients were demonstrating severe dermatitis of buttocks, back and posterolateral thighs. In some cases, the dermatitis was resistant to even the most potent topical steroids and required courses of oral corticosteroids to resolve.58 Eventually, a connection was made to recliners and sofas manufactured in China and with press coverage of a few cases, hundreds more came to attention. The source of the allergen was traced to furniture imported from China containing dimethylfumarate (DMF), a novel potent sensitizer. Patch testing confirmed the chemical as the allergen. Notably, this chemical had been added to the furniture to inhibit mold growth while in storage or transport.58 As of May 1, 2009, DMF is banned from the EU for use in consumer products including sofas, shoes and soft toys.59

Imported cosmetics, jewelry, and clothing accessories have also been reported in the literature to cause reactions that range from contact dermatitis, to lead poisoning54 to death.60 In 2008, Thyssen and Maibach purchased earrings from a variety of stores and local artists around San Francisco. Out of 277 different earrings purchased, 30.7% tested positive for nickel using a dimethylglyoximine spot test.61 This is a very high rate for a possible exposure source for the most common contact allergen in North America.

Over the past year, reports have come out regarding children developing contact dermatitis from a number of sportsgear and apparel wares designed for them. For example, a case of a young boy with contact dermatitis traced to his Crocs™ sandals has been reported.62 The child’s dermatitis, which had been present for more than 2 years, subsided after he discontinued wearing his made-in-China sandals. Contact with the company to obtain information regarding the chemicals used in these sandals was unsuccessful after the company cited “propriety status” to prevent specific disclosure.62 A more extensive outbreak of contact dermatitis involved Chinese-made beach sandals sold at Wal-Mart in 2007. After numerous reports of ACD to the straps of the sandals, Wal-Mart was forced to recall the items from their shelves.63 The offending chemical has not yet been identified.

Furthermore, a recent study by Ventura et al has suggested that the close contact between skin and sports equipment and the changes that occur in the skin with increased physical activity contribute to the increased incidence of dermatitis associated with sports equipment.64 A search of the literature reveals the evidence of this in children, with confirmed cases of ACD to swimming goggles,65 hockey gloves,66 basketballs,67 soccer guards68 and gymnastic grips69 all being reported. The one link in all of this was that all the products were made in China and the manufacturers failed to disclose the chemicals in their products, stating proprietary protection laws or by admitting they “didn’t know” due to outsourcing.

Furthermore, the persons working for $1/hour off shores may also be paying a personal health cost for these lower priced items. For example, a 2005 study out of India found that nearly 8% of workers at a rural tie-dye factory, including working children under the age of 10, had clinically relevant ACD and positive patch tests to the dyes used.70 And, in 2007, 268 workers from a Chinese toy factory were diagnosed with Paederus dermatitis, an irritant contact dermatitis...
to the secretions of insects in the genus *Paisedorus*.71 Crowded and insanitary working conditions in which the factory workers lived and worked around the clock in shifts helped to create an environment ideal for the offending arthropods.71 Unfortunately, many of these factory workers cases go unreported.

### THE COST TO CONSUMERS

Thus, while we are living “easier” with more “buying power,” we may not be realizing that there may be other real costs behind the discounts. It appears that our consumers (our children) are being exposed to and subsequently having contact dermatitis to many chemicals that we should be protecting them against.

Andrew Breithaupt, BS

Dr. Jacek is Assistant Professor of Pediatrics and Medicine (Dermatology), University of California, San Diego – Rady Children’s Hospital, San Diego, CA.

Mr. Breithaupt is a third-year medical student, University of California, San Diego, School of Medicine, San Diego, CA.

Disclosures: The authors have no conflicts of interest to disclose.

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**Dr. Jacob Memorial Foundation**

Dr. Jacob is Assistant Professor of Pediatrics and Medicine (Dermatology), University of California, San Diego – Rady Children’s Hospital, San Diego, CA.

**Mr. Breithaupt is a third-year medical student, University of California, San Diego, School of Medicine, San Diego, CA.**

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