

EDITORIAL

Attempting to Define “Hypoallergenic”

Matthew J. Zirwas, MD

The North American Contact Dermatitis Group (NACDG) commends Xu et al¹ for bringing attention to challenges facing dermatologists and consumers. Their original approach of using



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sales data provides a snapshot of what consumers are actually using (lotions!), and their assessment of commonly used marketing terms and their connection to cost and product composition are innovative.

The authors set the bar high for products to be considered “hypoallergenic,” that is, that they could not contain any allergens in the NACDG standard tray. This is probably excessive because the NACDG standard tray includes some uncommon allergens, which when contained in products should not disqualify them from being considered hypoallergenic. In addition, updates to the NACDG standard tray are only published after we have made the changes, collected the data, and analyzed it—a delay of 4 to 5 years. This is unlike the American Contact Dermatitis Society tray, updates to which are published as frequently as necessary.² There is no well-accepted threshold of patch test positivity above which an allergen should be excluded from “hypoallergenic” products.

Members of the NACDG spend enormous amounts of time reviewing product ingredients and counseling patients who either have, or are suspected of having, allergic contact dermatitis. One of the most challenging aspects of this counseling is teaching patients that they cannot trust the terms *hypoallergenic* or *fragrance free*. The work by Xu et al¹ nicely reinforces the importance of emphasizing this, as 83% of best-selling products claiming to be hypoallergenic had at least 1 reported allergen and 45% of best-selling products claiming to be fragrance free contained a potential fragrance allergen.

Why is it that consumers and dermatologists cannot believe written claims on personal care product packaging? In fact, the US Food and Drug Administration (FDA) has addressed the term *hypoallergenic* previously. On June 6, 1975, the FDA issued a final rule on the term *hypoallergenic* that required comparative testing. However, the rule was challenged in court by 2 personal care product companies, and, despite testimony from NACDG members at the time, in late 1977 the court struck down the rule.³ This was an unfortunate outcome for consumers and dermatologists.

Thus, for the foreseeable future, dermatologists and patients will need to continue to practice vigilance when it comes to selecting products that are of low allergenic potential. There are many websites that provide information about product ingredients and/or generate lists of “safe” products, but their ac-

curacy and frequency of updating is variable and they cannot be responsibly recommended.

However, the American Contact Dermatitis Society (ACDS) maintains a constantly updated database of personal care products, the Contact Allergen Management Program (CAMP), that generates lists of products that are free of any chosen set of allergens.⁴ Patients are able to access their custom-generated list online or via a CAMP app that is available for both Android and Apple smartphones. Access to the database is available for dermatologists and allergists who are members of the ACDS, and there is fortunately no cost for their patients to access it.

A number of cosmetic ingredients are also found in drug and household products. Two databases from the National Library of Medicine allow searches to identify product ingredients or a list of products containing a specific ingredient: FDA Daily Med⁵ and Household Products Database.⁶

In light of the foregoing issues, we would make the following recommendations regarding considering products hypoallergenic:

1. Use the most recently published ACDS core series as a list of potentially allergenic ingredients
2. To be considered “hypoallergenic” a product must:
 - A. not contain any potentially allergenic ingredients that have a frequency of positive patch test results of 1% or greater in a patch test data set containing at least 1000 patients that has been published in the past 5 years
 - B. not contain any potentially allergenic ingredients for which there are no published data from the past 5 years
3. Emphasize that there is no such thing as a “nonallergenic product” and that the only way to rule out allergic contact dermatitis is through comprehensive patch testing

We are aware that there is no perfect definition of *hypoallergenic* and that choosing a frequency rate of 1% or less is arbitrary. This rate was selected partially because it is recommended that allergens with a 1% or greater positivity rate be included in screening series, which implies applicability to the general population of patients with dermatitis, which is the group to which the term *hypoallergenic* is relevant.⁷

The term *hypoallergenic* is undoubtedly going to continue to be used for marketing purposes by personal care product companies, so a concrete, practical definition, even if less than perfect, provides helpful, needed guidance. The general definition of *hypoallergenic* is “relatively unlikely to cause an allergic reaction,” and on the basis of our collective experience, we believe that products meeting the aforementioned criteria are much less likely to cause an allergic reaction compared with the general universe of personal care products.

ARTICLE INFORMATION

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Delay and Disparity in Time to Surgical Treatment for Melanoma

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The relationship between patient health insurance status, health care use, and outcomes has been explored in great depth and detail over decades for myriad diseases in the United States.^{1,2} Likewise, health services research has become increasingly relevant within the specialty of dermatology,³ especially as the emergence of "big data" and advanced analytics continue to transform overall health care delivery.⁴

Nevertheless, our understanding of the effect of insurance status on patterns of health care use remains incomplete for many cutaneous diseases. These knowledge gaps may impair our ability to establish benchmarks for high-quality care, implement evidence-based metrics for quality improvement, and objectively demonstrate the value of dermatologic expertise to payers, government, and other external stakeholders.

Accordingly, the retrospective cohort study by Adamson et al⁵ in this issue of *JAMA Dermatology* is a welcome addition to our specialty. The authors' primary question—does patient insurance type (commercial, Medicare, or Medicaid)

influence time to surgery for primary incident melanoma?—addresses a fundamental issue regarding the most commonly used therapy for this serious disease. Using

ceived surgery 6 weeks or later from time of diagnosis. By contrast, only 17% of Medicare patients and 14% of commercial patients experienced equivalent surgical delays.

Moreover, differences in risk of surgical delay by payer status persisted following multivariate generalized linear modeling despite appropriate adjustment for numerous potential sources of confounding, including patient age, sex, race/ethnicity, severity of illness, geographic residence, American Joint Committee on Cancer (AJCC) tumor stage, tumor site, and year of diagnosis. The authors also included specialty (dermatologist vs nondermatologist) of the physician who diagnosed the melanoma and the physician performing surgical excision as covariates of interest, given the potential effects of care coordination on timely care delivery.

Estimates of risk-adjusted delay were significantly greater for Medicaid patients compared with those with commercial insurance, although no differences were observed between the latter group and Medicare patients. The authors also found that diagnosis and treatment by a dermatologist was independently associated with a reduction in risk of surgical delay for melanoma, whereas nonwhite race/ethnicity, tumor location (head/neck and lower extremities relative to the trunk) and advanced disease (AJCC stages II, III) were associated with significantly increased risk of surgical delay.

What, then, can we conclude from these results?

First, it is sufficiently clear that Medicaid patients in North Carolina experience unequal temporal patterns of surgical care for primary melanoma compared with patients covered by other payers. As the authors note, whether these results are generalizable to other regions of the United States is unknown, but it is possible (if not probable) that similar surgical delays occur among Medicaid patients elsewhere.



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a statewide (North Carolina) integrated cancer registry-administrative claims database (University of North Carolina Integrated Cancer Information and Surveillance System) to derive a final sample of 7629 patients with primary melanoma (3631 [48%] Medicare insured; 3667 [48%] commercially insured; 331 [4%] Medicaid insured) diagnosed from years 2004 through 2011, they show that 24% of Medicaid patients re-