Legislative update: Regulating ingredients in personal care products

Kelly E. Flanagan, MS, James T. Pathoulas, BA, Chloe J. Walker, MD, MHS, Isabel Pupo Wiss, BS, and Maryanne M. Senna, MD
Boston, Massachusetts

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The prevalence of personal care product (PCP)-related dermatoses has increased over the last 20 years. The frequency of PCP-related allergen positive patch tests more than doubled between 1996 and 2016.[1] Notably, many dermatologist-recommended shampoos, including prescription-strength and over-the-counter antidandruff shampoos and tar shampoos, contain formaldehyde releasers and other known allergens. PCP allergy has also been associated with lichen planopilaris and frontal fibrosing alopecia. In a study of 42 patients with lichen planopilaris/fibrosing alopecia, 76.2% had positive reactions to allergens in their PCPs used on the face and scalp, and allergen avoidance resulted in decreased scalp inflammation.[2]

Since 1994, consumers have instigated 3 class action lawsuits against hair product companies due to the development of inflammatory alopecia.[3-5] In 2014, consumers were awarded $4.5 million in a class action settlement against the manufacturer of Brazilian Blowout due to failure to warn consumers that the product emitted toxic formaldehyde.[3] In 2016, more than $26 million was awarded to consumers of WEN Hair Care products after 21,000 complaints, and 1386 adverse events (AEs) were reported to the U.S. Food and Drug Administration (FDA), including hair loss, pruritus, and rash.[4] More recently, a suit was brought up against DevaCurl following complaints of hair loss and scalp inflammation secondary to product ingredients.[5]

Abbreviations used:

AE: adverse event
FDA: U.S. Food and Drug Administration
PCP: personal care product

Although consumers assume that their PCPs are safe, PCP ingredients undergo almost no scrutiny due to current FDA regulatory limitations. FDA approval is not required for cosmetic products and ingredients, other than color additives. PCP manufacturers are not required to perform specific safety tests, report safety data or AEs to the FDA, or recall potentially harmful products. The FDA regulates PCPs under the Federal Food, Drug, and Cosmetic Act of 1938 and the Fair Packaging and Labeling Act of 1967, both of which allow manufactures to use any ingredients that do not result in misbranded or adulterated products. The FDA.gov website defines an adulterated product in part as "any filthy, putrid, or decomposed substance," highlighting the need to update these half-century old laws and improve consumer protection.

Dermatologists can advocate for patient protection by supporting the recently introduced Safe Cosmetics and Personal Care Products Act of 2019, which will immediately ban toxic, allergenic, and unnecessary ingredients from PCPs, including formaldehyde, formaldehyde releasers, and paraphenylenediamine. This list will be updated annually as ingredients with harmful chronic health effects are

From the Department of Dermatology, Massachusetts General Hospital.
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Correspondence to: Maryanne M. Senna, MD, Department of Dermatology, Massachusetts General Hospital, 50 Staniford Street, 2nd Floor, Boston, MA 02114-2517. E-mail: msenna@partners.org.
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identified. The bill will also mandate manufacturers to label products with all ingredients and contaminants, including fragrance ingredients deemed allergenic or hazardous to health, and to disclose all ingredients and their function on product websites. Manufacturers will also be required to submit safety information regarding each PCP ingredient and report associated serious AEs within 15 days to the FDA, which will make serious AE reports publicly available. More importantly, the proposed bill will authorize the FDA to recall or cease distribution of products deemed unsafe.

Given the number of dermatologist-recommended PCPs, it is vital that dermatologists become aware of these proposed changes to PCP regulation. The dermatology specialty has an opportunity to be at the forefront of this important step.

Conflicts of interest

None disclosed.

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