

Paraphenylenediamine in black henna temporary tattoos: 12-year Food and Drug Administration data on incidence, symptoms, and outcomes

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Paraphenylenediamine (PPD) became 1 of the 5 chemicals labeled as “strong sensitizers” by the Consumer Product Safety Commission (formerly designated by the Food and Drug Administration [FDA]) in 1961,¹ but reports of reactions date back to the late 19th century, when it first appeared in hair dye.² Currently, PPD in cosmetics meant for the skin is prohibited, and is limited in hair dye to 6%; however, it continues to be found in unregulated temporary tattoos and black henna products at alarming levels—ranging up to almost 30%.³⁻⁵

Topical exposure to PPD may lead to primary sensitization or allergic contact dermatitis in patients. Cutaneous and mucosal reactions may vary but are frequently characterized by erythema, pruritus, and vesicular to bullous dermatitis. Systemic reactions, frequently stemming from oral ingestion of hair dye in literature, include generalized hypersensitivity reactions such as angioedema, asphyxia, and rhabdomyolysis.⁶

In 2001 the FDA, prompted by an escalation of reported severe allergic reactions to PPD-laced temporary tattoos, launched an informational World Wide Web site and a reporting hotline to provide consumers ease of reporting of such events (MedWatch, 1-800-332-1088).⁷ In 2006, *Dermatitis*, the official journal of the American Contact Dermatitis Society (ACDS) named PPD as “Allergen of the Year” in an attempt to increase awareness (both professional and public) regarding its continued use and heightened allergic potential.⁸ Ultimately, in 2008 the ACDS and the American

Abbreviations used:

AAD: American Academy of Dermatology
ACDS: American Contact Dermatitis Society
FDA: Food and Drug Administration
PPD: paraphenylenediamine

Academy of Dermatology (AAD) jointly advised a ban on the practice of using PPD-enhanced henna tattoos.⁹

Despite the attempt to increase awareness, black henna use continued to rise worldwide, especially among children and adolescents.¹⁰ Severe allergic contact dermatitis reactions,¹⁰ and even fatalities¹¹ have been reported to PPD-laced black henna tattoos. To assess the incidence of such reactions within the United States an inquiry was made to the FDA regarding the data maintained since the initiation of their MedWatch hotline. Within the last 12 years, 70 cases of adverse reactions to temporary tattoos (n = 6) and black henna tattoos (n = 64) were reported.¹²

The majority of cases occurred in 2005 (40%), which precedes the AAD advisory notice, possibly suggesting that such organizational promotion may have partially contributed to an increased public and physician awareness of PPD and overall lower use of temporary tattoos. The most common symptoms were local reactions (pruritus, rash, pain, erythema, swelling, inflammation) consistent with allergic contact dermatitis (67%). Urticarial reactions were reported in 12 cases (17%), and systemic symptoms such as dizziness, syncope, and gastrointestinal

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Table I. Review of Food and Drug Administration—reported events in 12 years

	N (%)
Total cases	70
Product type	
Black henna	64 (91.4)
Temporary tattoo	6 (8.6)
Symptoms	
Local*	47 (67)
Blister	23 (33)
Hypersensitivity	18 (26)
Nervous†	13 (19)
Urticaria	12 (17)
Scar	8 (11)
Infection	3 (4)
Systemic‡	5 (7)
Outcomes	
Health provider/emergency department visit	37 (53)
Required intervention	12 (17)
Life-threatening event	6 (9)
Hospitalization	3 (4)
Disability	3 (4)

Data provided by Food and Drug Administration MedWatch reporting hotline: FOI 14-4014: Center for Food Safety and Applied Nutrition Adverse Event Reporting System reports allegedly related to temporary and black henna tattoos containing paraphenylenediamine, between March 2002 and May 2014.

*Pruritus, rash, pain, erythema, swelling, inflammation.

†Paresthesia, burning.

‡Lymphadenopathy, syncope, influenza-like symptoms, gastrointestinal upset.

discomfort were reported in 5 cases (7%). The majority of the cases prompted a health provider or emergency department visit (53%); 6 cases were deemed life-threatening and 3 required hospitalization. Three cases were also reportedly linked to a “disability,” however no further information was provided as to the type and severity of the diagnosis. No information on the patients’ patch-test results was available (Table I).

Contact urticaria is the rarest form of contact dermatitis and consists of an IgE and mast-cell-mediated wheal and flare reaction. It has been associated with various allergens including rubber latex and nickel.^{13,14} This form of hypersensitivity has also been associated with the potentially deadly anaphylactic reactions.¹⁵ Anaphylactic reactions to PPD have also been reported in the past.¹⁶⁻¹⁸ The urticarial reactions in the FDA data highlight the dangers of PPD and the potential for deadly anaphylaxis.

PPD ingestion has been linked to systemic reactions such as respiratory, muscular, and renal failures.^{6,19} The information provided in the FDA

database is limited, and thus, the reported 5 patients with systemic symptoms may have theoretically had additional (undisclosed) nontopical exposure to PPD that prompted systemic symptoms. However, this report of such severe reactions to presumably topical PPD-containing agents suggests a significant associated risk of unregulated black henna products containing high concentrations of PPD. These data support the need for continued public awareness of the dangers of PPD to decrease use and increase reporting of such events. Moreover, collaboration between physicians and policy makers is necessary for the development and progression of legislation to regulate and ban the use of PPD in henna and temporary tattoo products.

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