Abstract

Background/Objectives: Despite their ubiquitous use and several recent health controversies involving cosmetics and personal care products for children, the FDA has very little oversight for these products and relies on consumer submitted adverse event reports. We sought to assess the recently released Center for Food Safety and Applied Nutrition’s Adverse Event Reporting System (CAERS) database for adverse event reports submitted to the FDA for baby personal care products and to determine whether useful insights can be derived.

Methods: We extracted the CAERS data file from 2004-2016 in December 2016 and looked at the subset classified by the FDA-designated product class as a baby product. Events were manually categorized into product type and symptom type to assess for trends.

Results: Only 166 total adverse events were reported to the FDA for baby products from 2004-2016. The majority of reports indicated a rash or other skin reactions. 46% of reported events led to a health care visit.

Conclusions: Pediatric dermatologists should consider submitting cosmetic adverse event reports or encouraging consumers to do so in situations where patient harm is identified.

Discussion: Implications for Pediatric Dermatologists

- Reports are up-trending, however this still likely represents significant under-reporting
  - Baby personal care products represent $30 billion industry globally
  - FDA investigation of 127 adverse event reports for one product in particular unveiled more than 21,000 reports reported to the company directly

- Opportunity for pediatric dermatologist to participate in adverse event reporting for baby products

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