Cosmetic complaints climb but products still on market

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Many cosmetic products entice consumers with active ingredients that will plump, lengthen and boost.

But the cost, depending on the product, may be serious injury or worse, according to a new Northwestern Medicine study.

The study reports consumer complaints more than doubled for cosmetic products from 2015 to 2016, with hair care products being the biggest offender. But consumers remain at risk because the industry receives little regulatory scrutiny and does not require pre-approval from the Food and Drug Administration (FDA).

"The FDA has much less authority to recall cosmetics from the market in stark contrast to drugs or medical devices," said corresponding author Dr. Steve Xu, a resident physician in dermatology at Northwestern University Feinberg School of Medicine. "It's harder for the FDA to get harmful cosmetics off the shelves."

Since cosmetic manufacturers are not required to submit adverse health events to the FDA, the current data sources to track product safety are significantly limited. Even though there were more than 5,000 events reported to the FDA from 2004 to 2016, it's likely only the tip of the iceberg, Xu said. He suspects many events are not reported by consumers or doctors.

The study will be published June 26 in *JAMA Internal Medicine*.

"This is really a wake-up call," Xu said. "The point of the paper is to broaden the awareness of this database and the need for everyone to participate in reporting adverse events from cosmetics."

The most common complaints in the database were for hair care products, skincare products or tattoos, the study found. The number of overall adverse events jumped from 706 in 2015 to 1,591 in 2016, with hair care products seeing the largest increase. Baby products, unclassifiable products, personal cleanliness products, hair care products

and hair coloring products had the highest proportion of self-reports of a serious adverse health outcome, such as serious injury, death, disability.

The research highlights the need for better data.

"This is a $430 billion-a-year global industry with millions of products on the market," Xu said. "But we are only getting, on average, between 200 and 400 adverse events per year. That represents significant under-reporting. If we want more public safety and to keep dangerous products off the market, the first step is the make sure we have reasonably good data. The key point of our results is we don't have it."

An ongoing investigation

In 2014, the FDA sent letters to manufacturers Chaz Dean and Guthy Renker LLC in response to 127 consumer complaints of hair and scalp problems related to the WEN by Chaz Dean Cleansing Conditioners. Only then did the FDA discover that the manufacturers had already received 21,000 consumer complaints of scalp irritation and alopecia.

"If this was a drug, the story would be much different in regards to regulatory action," Xu said. "Three or four people can be wrong, but it's hard to ignore 21,000. It's concerning when 21,000 people complained to the manufacturer, and the FDA received only 127 of those due to poor reporting from the manufacturer."

The FDA's investigation on WEN by Chaz Dean Cleansing Conditioner products is ongoing, and the products are still available, Xu said.

The problem with cosmeceuticals

What concerns Xu the most are products that contain cosmeceuticals,

which market themselves as cosmetic products but with an "active ingredient."

"Although not explicitly studied, this cosmetic product class is becoming a growing problem," Xu said. "Many of these products are really making drug-like claims but are skirting the FDA approval pathway by presenting themselves as a cosmetic. At the very best, these products are making unsubstantiated marketing claims for products that may or may not work. At the very worst, there are actual drug components in these products that can cause real harm."

Additionally, Xu said he hopes the study's findings raise awareness of Sen.Dianne Feinstein's (D-CA) Personal Care Products Safety Act, which aims to tighten cosmetic regulation.

"Feinstein's bill is a first step forward in the right direction," Xu said. "I would have liked an explicit push towards cosmeceutical regulation. Overall, the FDA should have the power to order recalls and mandate that manufacturers declare their products' ingredients and report every adverse consumer health event to the FDA."

More information: *JAMA Internal Medicine*, doi: 10.1001/jamainternmed.2017.2762

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