

WELL

For Cosmetics, Let the Buyer Beware

Personal Health

By JANE E. BRODY AUG. 7, 2017

When you wash your hair, clean or moisturize your skin, polish your nails, or put on makeup, deodorant or sunscreen, do you ever think about whether the product you're using may do more harm than good?

Maybe you should. Thanks to a lack of federal regulations, the watchword for consumers of cosmetics and personal care products should be caveat emptor: Let the buyer beware.

To be sure, these products are not nearly as worrisome as drugs, which require extensive testing and premarket approval by the Food and Drug Administration. Still, disasters can and sometimes do occur from the use of cosmetics and personal care products, and the government is powerless to act until a slew of consumer complaints raise a red flag about a product.

In a recent editorial in *JAMA Internal Medicine*, Dr. Robert M. Califf, who served as F.D.A. chief under President Obama, noted, "The cosmetic industry remains largely self-regulated. History has repeatedly shown that when there is insufficient regulatory oversight, a few unscrupulous people or companies will exploit the vulnerable public for profit."

Even when a hazard comes to light, a product can remain on the market for years until negotiations make their way through the legal system or the company decides to halt sales. (Although the F.D.A. finally banned antibacterial chemicals like triclosan from soaps, triclosan is still in toothpastes and other consumer products.)

A current case is a classic example. The F.D.A. normally receives about 300 to 400 complaints a year about bad reactions to cosmetics and personal care products, all of which are sold over-the-counter without prior government scrutiny. When in 2013 the agency received 127 reports of adverse effects from a single line of hair-care products called WEN, it discovered that the manufacturer, Chaz Dean, Inc., had been sitting on more than 21,000 complaints of hair loss and scalp damage associated with the products' use.

A class-action lawsuit filed by more than 200 women against the company and its infomercial producer Guthy-Renker was settled last year for \$26.3 million. Yet the company claims that WEN hair care products are "totally safe" and continues to sell them.

Unlike drugs, cosmetics can be sold based solely on manufacturers' tests (or no tests at all) and claims for effectiveness and safety. Even the ingredients don't have to be filed with the government. (Only color additives require premarket approval.)

"The F.D.A. must wait for clues to accumulate from voluntary reports suggesting that a product may not be as completely safe as presumed," Dr. Califf, a cardiologist, health policy expert and vice chancellor at Duke University School of Medicine, wrote.

Asked in an interview whether more can be done to protect the public, he said, "It's highly unlikely in the current administration. There's a tiny work force at the F.D.A. to deal with an enormous industry that's currently self-policing. Voluntary reporting of adverse events linked to cosmetics and personal care products is a lot better than nothing, but it's way inadequate for the job. There's no legal requirement for manufacturers to forward reports of adverse events to the F.D.A."

(Only manufacturers of drugs and medical devices are required to submit reports of hazards associated with their products to the federal agency.)

The Federal Food, Drug and Cosmetic Act defines cosmetics as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance.”

Dr. Califf’s editorial accompanied a rather startling report in the journal by Dr. Shuai Xu, a dermatologist, and two colleagues at Northwestern University Feinberg School of Medicine. On the heels of the thousands of complaints uncovered about WEN products, the F.D.A. made publicly available its Center for Food Safety and Applied Nutrition’s Adverse Event Reporting System, a repository of adverse events related to foods, dietary supplements and cosmetics.

This enabled Dr. Xu and colleagues to analyze all the adverse events associated with cosmetics and personal care products voluntarily submitted from 2004 through 2016 by consumers and health care professionals. Through 2014, they averaged 396 a year. There was a 78 percent increase in reports in 2015 and a 300 percent rise in 2016, largely driven by complaints about WEN products.

“Over all,” the researchers found, “the three most commonly implicated products were hair care, skin care and tattoos,” and “significantly higher than average reports of serious health outcomes” involved baby, personal cleanliness, hair care and hair coloring products.

Consumers who experience bad reactions to such a product might consult a physician or contact the manufacturer, “but they rarely think of going to a government agency,” Dr. Xu said in an interview.

The F.D.A. wants to encourage consumers to submit reports to it directly and has created a website to do so at:
www.fda.gov/cosmetics/complianceenforcement/adverseeventreporting

At the same time, Senator Dianne Feinstein, Democrat of California, and Senator Susan Collins, Republican of Maine, have proposed a bill, the Personal Care Products Safety Act, that would require manufacturers of cosmetics and personal care products to submit a list of all ingredients and reports of adverse events to the F.D.A. and give the agency authority to order product recalls.

Dr. Xu said, “As a dermatologist, I live and breathe personal care products day and night. Patients ask me about them all the time. I warn patients that labeling can be very tricky. One needs a Ph.D. in chemistry to be able to interpret all the terms. What does it mean for a product to be labeled ‘natural’? That doesn’t make it safe. Poison ivy is perfectly natural.”

However, Dr. Xu said, “I’m not alarmist – I haven’t thrown out all the soaps and creams in my house. I’m not in favor of overregulation that could result in higher costs for products like moisturizers. But it should not be controversial to ask for better reporting and a better data system that includes information from consumers, doctors and manufacturers. That’s important not only to detect problems but also to allay public fears.”

Dr. Califf said that technological mechanisms for gathering such information already exist, in particular through electronic health records. As a member of a family prone to melanoma, he said he is especially concerned about sunblocks, found in myriad cosmetic products as well as those sold specifically as sunscreens.

“It’s not known how much of these chemicals is absorbed through the skin and what effect they may have over a lifetime of use,” he said. “The right studies of health effects have not been done.”

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