

business | the controversy continues

by Rob and Carol Trow

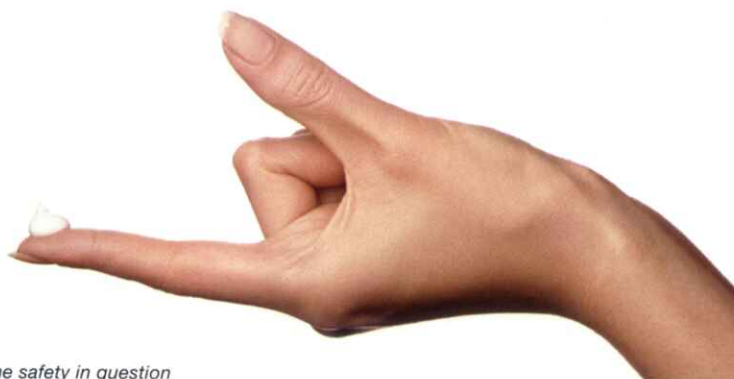
Australians have long been familiar with boomerangs. When thrown properly, they fly away only to return. In the classic horror movie *The Goonies* everyone thinks the monsters are gone, but when they awaken the little girl exclaims, "They're back." The iconic baseball player Yogi Berra once said, "It ain't over til it's over." Like these examples, the hydroquinone safety debate is back with additional funding. The use of hydroquinone in over-the-counter cosmeceuticals has been banned in many countries. However it is still allowed in the United States.

The Center for Food, Safety and Applied Nutrition, which oversees the Office of Cosmetics and Color, has obtained \$66.8 million, a part of which will be used to again address the safety of hydroquinone in skin bleaching products.

Hydroquinone has been acknowledged as a potential carcinogen. It is currently banned in European, Asian and African countries but not in the United States. What do we know that the rest of the world doesn't?

The history

The debate about the safety of using hydroquinone as a skin lightening ingredient in over-the-counter products has been going on for 40 years. The Food and Drug Administration (FDA) has recently been hearing comments in response to a proposed ruling issued August 29, 2006 that would require products containing hydroquinone to lose their over-the-counter status. The



hydroquinone safety in question

FDA has simply stated that over-the-counter products containing hydroquinone are not generally recognized as safe and effective and are misbranded.

In response to this proposed ruling, the FDA received untold numbers of responses from skin care manufacturers, dermatologists and physician associations, such as the American Academy of Dermatology, taking issue with the FDA's safety concerns. The majority of the responses to the proposed removal of hydroquinone as an over-the-counter skin bleaching ingredient came from physicians who felt that their frequent use of hydroquinone had not resulted in any apparent health problems and that it is a cost effective and efficacious way to treat skin conditions such as hyperpigmentation. The group urged the FDA to withdraw its proposed ruling.

Flip side of the same coin

On the other side of the debate, there are groups of physicians who strongly agree with the FDA's proposed decision to ban hydroquinone as an over-the-counter ingredient. In a letter to the FDA Alan Fleischer, M.D., a noted professor of

dermatology, urged that the testing requirements for approval be conducted pursuant to a new drug application. City of New York's Commissioner for Consumer Affairs, Mark Green, entered the ongoing debate as early as 1992 by calling attention to 15 studies that questioned the safety of bleaching creams. Again, in December, 2006 when the hydroquinone issue resurfaced, The City of New York strongly supported the FDA's proposed rules to limit access to hydroquinone.

The FDA received a letter in December, 2006, from the American Academy of Dermatology Association signed by Stephen Stone, M.D., opposing the potential ban.

We can only hope that additional studies will shed light on the subject. To learn more go the www.fda.gov and type in "hydroquinone." ■

Rob and Carol Trow, his wife, own *Derma-Concepts USA*, the eastern U.S. (excluding metro NYC) distributors for *Environ® Skin Care*. In the skin care field for more than 10 years, Rob has authored multiple articles for trade publications.