A Nationwide Outbreak of Alopecia Associated With the Use of a Hair-Relaxing Formulation

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Objective: To study the long-term outcome of adverse effects reported by persons who used a commercial hair-straightening product known as the Rio Hair Naturalizer System (World Rio Corporation).

Design: Survey of individuals who contacted the Food and Drug Administration in 1994 and 1995 to report adverse effects linked to using the product.

Setting: Persons residing in the United States.

Patients: A total of 464 (59% of 790 eligible) patients who returned a completed questionnaire.

Main Outcome Measures: Adverse effects associated with using the Rio Hair Naturalizer System products (neutral or color enhancer).

Results: Ninety percent of respondents were African American women between the ages of 15 and 55 years. The most common complaints associated with the use of the products were hair breakage and/or hair loss, reported by 95% of respondents. Three quarters of those experiencing hair loss reported losing 40% or more of their original hair. The median time between the loss of original hair and the growth of new hair was 8 months; however, 40 (9%) respondents reported having no new growth at the time of completing the survey, some 2 years after using the product. When mixed according to package instructions, the mean pH of a sample of 20 neutral product kits tested was 1.39 (range, 1.1-3.15). For the 21 color-enhancer products tested, the mean pH was 2.82 (range, 2.29-3.08).

Conclusions: A nationwide outbreak of alopecia and scalp injuries involving tens of thousands of women (and some men) occurred following the marketing of a chemical hair-relaxing product. Most of those affected reported substantial hair loss, with a majority indicating growth of new hair that was abnormal in both quantity and quality.

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METHODS

Reports linked to the use of Rio hair products were obtained from FDA’s Consumer Complaint/Injury Report System in 1994 and 1995. This reporting system is a passive surveillance system that uses a standard report form to record adverse effects consumers attribute to FDA-regulated products, including foods, drugs, and cosmetics. In addition to collecting an individual’s name, address, telephone number, and date of complaint, the form queries consumers about the nature of the complaint or injury as well as details about the implicated product (name, manufacturer, size, and date purchased).

During March and April 1997, we attempted to telephone all 3244 persons who contacted the FDA in late 1994 or early 1995 to report Rio hair product–associated adverse effects. The calls were placed after 4 PM on weekdays and throughout the afternoon and evening on weekends. Because more than 2 years had elapsed since the FDA received the complaints, a large proportion of telephone numbers were no longer viable. Consequently, we invited into the study only consumers who were contacted by telephone and who agreed to participate in the study (fewer than 5% of those who were invited to participate declined to do so). Thus, a questionnaire was mailed to a total of 790 consumers from the original cohort.

The questionnaire elicited details about the demographic characteristics of complainants and the adverse effects they experienced after using Rio hair products. In addition, it asked consumers about any preexisting scalp conditions they might have had prior to using Rio hair products, whether they visited a physician for treatment of Rio hair product–associated adverse effects, and what measures, if any, they took as a result of the adverse effects.

To investigate possible mechanisms by which Rio hair products could have exerted their adverse effects, we reviewed the results of pH tests that FDA chemists performed on samples of both types of products. Each package consisted of 2 plastic packets stapled together to form 1 application unit. The plastic packets contained dry powders. Users were instructed to mix the ingredients vigorously in a bowl of measured hot water and then to apply the resulting paste to the hair for up to 45 minutes. In addition, the manufacturer recommended heat activation (blow dry, thermal heat, or roller dry). After preparing the products according to package instructions, FDA chemists conducted pH testing on a sample of 20 neutral products and 21 color-enhancer products. The pH values reported were obtained immediately after mixing the contents of the 2 packets.

Prompted by a surge in the number of adverse event reports the FDA received in the last 2 months of 1994 from persons who used the Rio hair products, on December 21, 1994, the FDA issued a public warning “Talk Paper” regarding the potential of the products to damage the scalp and hair. By the end of January 1995, the FDA had received more than 3000 reports of adverse effects linked to the use of Rio hair products, the largest number of complaints the agency ever received for a cosmetic product. In January 1995, the FDA initiated a seizure action against World Rio Corporation alleging the products were adulterated and misbranded. The agency argued the products were adulterated in that they bore or contained an allegedly poisonous and deleterious substance that could render them injurious to users under conditions of use prescribed in the labeling. The products were misbranded in that the labeling was allegedly false or misleading because it declared the pH of the articles to be 3.4 when in fact the products were more acidic; in addition, whereas the labeling stated that the products were chemical free, they allegedly contained ingredients commonly understood to be chemicals.

In view of the number and seriousness of complaints FDA received from Rio hair product users, a sample of the original cohort of complainants was contacted in the spring of 1997. The goal of the study was to assess the long-term outcome of the adverse effects reported initially in late 1994 and early 1995. We present our findings here.

RESULTS

SURVEY FINDINGS

From August 1994 through May 1995, the FDA received 3244 reports of Rio hair product–associated adverse effects (Figure 1). Of the 790 consumers to whom we sent questionnaires, 464 (59%) returned a completed response.

The majority of respondents were African American women between the ages of 26 and 55 years (Table 1), and a preponderance lived in the southeastern United States (Figure 2). More than 90% of respondents reported purchasing Rio hair products between July and November 1994 (Figure 3). Sixty-three percent reported using the neutral product, 29% used the color-enhancer product, and the remaining 8% used both formulations.

In our survey population, there were no differences in the nature or frequency of adverse effects re-
reported by the type of product used (ie, neutral vs color enhancer). **Table 2** summarizes the adverse effects that were most commonly reported. Hair breakage and/or hair loss, reported by 95% of respondents, were the most common adverse effects. The median interval between the first application of the product and the onset of hair breakage and/or hair loss was 2 weeks (range, 1 day to 6 months). Hair loss was described as patchy by 63% of respondents, diffuse by 28%, and both patchy and diffuse by the remainder. When asked where the hair loss was greatest (some respondents specified multiple sites), respondents cited the temples as the most common site (66% of respondents), followed by the crown of the head (63%), and the front and back of the head (36% each). However, almost a quarter (22%) of respondents reported losing some hair from the entire area of the scalp.

Among those who experienced hair loss, the quantity lost was substantial. Three quarters (n = 246) of the respondents reporting losing some hair from the entire area of the scalp. Almost a quarter (22%) of respondents reported losing more than 50% of their hair from the entire area of the scalp.

Eighty-three percent of respondents reported using the product on 3 or fewer occasions. Forty-nine percent of respondents reported that they used some form of the product more than 3 times the month of purchase. Median time between the first use of the product and the onset of hair breakage and/or hair loss, reported by 95% of respondents, were the most common adverse effects. The unintended color of hair, was reported by a total of 128 respondents (28%). Both types of products were clearly unintended color of hair, was reported by a total of 28% (28% of respondents). Both types of products were associated with this adverse effect. The unintended colors acquired included green (103 respondents), or a red, orange, or yellowish hue (25 respondents). In addition, a quarter of respondents reported changes in fingernail color, with approximately two thirds of these persons stating that their nails turned green or yellow.

Hair discoloration, defined as the acquisition of a clearly unintended color of hair, was reported by a total of 128 respondents (28%). Both types of products were associated with this adverse effect. The unintended colors acquired included green (103 respondents), or a red, orange, or yellowish hue (25 respondents). In addition, a quarter of respondents reported changes in fingernail color, with approximately two thirds of these persons stating that their nails turned green or yellow.

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of heat (either a hair dryer or heating cap) during the application process. The use of heat during the application process was not associated with a higher rate of reported hair breakage and/or hair loss.

Survey respondents reported taking a variety of actions to compensate for the adverse effects they experienced. The course taken by most respondents (76%) was to keep their hair cut short; the median length of time people resorted to this practice was 1 month (range, 1 day to 10 months). In addition, 45% of respondents reported wearing a wig (median duration, 8 months), with 26% (6%) individuals reporting they still wore a wig at the time of completing the survey, more than 2 years after using Rio hair products. Thirty-five percent of respondents reported getting a hair weave, with a median duration of keeping the weave 1 year. Five percent of respondents reported using topical minoxidil on their scalp. Finally, 18% of respondents reported visiting a physician specifically because of adverse effects resulting from the use of Rio hair products.

Fifty-five percent (254 of 464) of respondents answered a question designated as “optional” that queried them about emotional and social consequences resulting from adverse effects linked to using Rio hair products. The most commonly reported consequences were feeling embarrassed to be seen in public (81%), being insulted or teased by others (63%), and experiencing a feeling of helplessness (60%).

**pH TEST RESULTS**

The FDA chemists measured the pH of a number of samples to determine the acidity of the Rio hair products. When mixed according to package instructions, the mean (SD) pH of the 20 samples of neutral Rio hair product tested was 1.39 (0.43) (range, 1.1-3.15). For the 21 color-enhancer products tested, the mean (SD) pH was 2.82 (0.15) (range, 2.29-3.08).

Previous reports have described cases of chemically induced cosmetic alopecia that followed the use of highly alkaline hair products commonly referred to as “relaxers” or “straighteners” in the parlance of the hair care industry. In addition, an earlier report described scalp burns in 6 children who used an acidic permanent wave treatment. However, the numbers of subjects described in these studies were far smaller than the number of persons who experienced adverse effects after using Rio hair products. The FDA Office of Cosmetics and Colors believes it receives only a small percentage of cosmetic complaints reported by consumers. Rather than being directed to the FDA, complaints may be filed with poison control centers, state and local agencies, or with the product manufacturer and/or distributor, which are not required to submit their complaint files to the FDA. Past experience at the FDA suggests that for every adverse reaction report the agency receives, the manufacturer may receive 50 to 100 such reports; consequently, it is conceivable that many more people experienced adverse effects than those who contacted the FDA.

We do not know the mechanism(s) by which Rio hair products exerted their adverse effects. However, 2 factors may have contributed: first, based on FDA sample testing, the pH of the products was lower than indicated on the product label (3.4) and differed significantly from the alkaline pH typically found in other hair straightening products. Second, the products were labeled to contain a complex mixture of metallic salts and botanical extracts.

Low product pH may have been one factor that contributed to the deleterious effects of the Rio hair products. As described earlier, after mixing the products according to package instructions, the mean pH of the neutral products was 1.39, whereas the mean pH of the color-enhancer products was 2.82. The low pH of the products may explain why some individuals reported experiencing a burning sensation upon applying the product. It is also possible that the low pH contributed to hair damage in some instances; a study of the effects of exposure of hair to solutions of pH less than 2 found a permanent weakening of hair fibers by up to 30% of their original strength.9

Interestingly, although the adverse effects reported by users of the 2 products were similar, the mean pH of the samples of the neutral products that were tested was lower than that of the color-enhancer products. Consequently, it is possible that some factor other than pH, or perhaps in addition to pH, contributed to the adverse effects.

The ingredient lists for both products differed somewhat. The neutral product specified the following components: purified extract of cherry of Antilles (Malpighia Globe), mineral salts (copper, ammonium, and chloride), nipagin, and fragrance. The color-enhancer product listed the following ingredients: concentrated extract of Coulteria tinctoria pods, mineral salts (copper, ammonium, and chloride), and fragrance.

Because no literature references to an entity called “Malpighia Globe” were found, it is possible that the manufacturer misidentified this botanical ingredient in the neutral product. More likely, the ingredient was either Malpighia glabra or Malpighia punicifolia, a West Indian cherry plant that produces a fruit that is believed to be one of the richest natural sources of ascorbic acid known (containing 1300 mg of ascorbic acid per gram of fruit). This ingredient, sometimes referred to as “Acerola,” is also used in other cosmetic products as a source of ascorbic acid.

The presence of copper in both products may have contributed directly to adverse effects, including hair discoloration and hair breakage. Green hair, reported by 28% of the respondents in this study, has been reported previously among persons who consumed tap water with elevated copper levels, or bathed in water that had been acidified with sufficiently high levels of fluoride to cause copper to leach from household piping.

The presence of copper in the products may also have contributed to the hair breakage. Hair is composed of kera-
tin, a protein characterized by a high level of the amino acid cystine. The mechanical strength of hair is due, in part, to the disulfide bonds of cystine cross-linking adjacent protein chains within the hair fiber structure and to the presence of salt linkages resulting from the electrostatic interaction between positively charged protonated amines of one protein chain and negatively charged carboxylate groups of adjacent protein chains.

It has been reported that hair absorbs large amounts of copper, causing hair fibers to contract in length and absorb moisture. The presence of copper may have other effects. Copper salts have been reported to cleave the disulfide bond of cystine and copper ions have the ability to form complexes with amine and carboxylate groups, such as those found on hair protein chains. Copper, therefore, may interfere with the participation of these groups in salt linkages within the hair. In summary, low pH and various copper-keratin interactions may have resulted in diminished mechanical strength of hair fibers, and been a contributing factor for hair damage caused by the Rio hair products.

In their series of patients with chemically induced alopecia linked to the use of alkaline cosmetic hair agents, Nicholson et al suggested that the adverse effects their patients experienced were most likely a result of a combination of physical and chemical insults rather than just the alkaline nature of the products used. Consequently, to address the possibility that other cofactors may have played a role in contributing to the morbidity experienced by Rio hair product users, we queried individuals about several other hair care practices that potentially could have affected the degree of damage inflicted by the Rio Hair Naturalizer System (specifically, whether they had applied any permanent wave, dye, or relaxing agent in the year preceding the use of Rio hair products and whether they used a hair dryer or heating cap at the time Rio hair products were applied). We found no relationship between adverse effects such as hair loss or the presence of bald spots with any of these factors.

Unlike drugs, cosmetics are not subject to premarket review and approval by FDA. Consequently, in this situation, many consumers may have been led to believe the products they were purchasing were chemical free when in fact a reading of the ingredient lists would have revealed the presence of several substances commonly recognized as chemicals. However, such a reading would not have disclosed the fact that at least some of the products had a pH level significantly below that listed on the label. The nationwide outbreak of hair-related problems described in this report underscores the need for individuals to maintain vigilance when contemplating the purchase or use of cosmetic products, especially from companies that tout claims such as “chemical-free” or other claims that may be difficult to substantiate.

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REFERENCES