

Fifty-one patients who have experienced hair loss have been reported by 31 physicians. Of these, 4 are males, 42 are females, and in 5 cases the sex is unreported. It will also be noted that regrowth has occurred in 10 patients, 9 female and 1 male, beginning as early as 10 days after discontinuation of therapy. In 2 additional female patients, regrowth occurred despite continued therapy. Color changes have been reported in 3 males and 2 females of the group, and change in texture (usually dryness and brittleness) has been reported in 5 females and 1 male. No consistency in relationship with other medications can be defined from this tabulation. Dose relationships, where reported, are also of no particular help.

As addendum to this tabulation, the following paragraph from a letter of March 16 from Gordon McHardy, M.D., is of interest:

"Since your recent request in regard to hair thinning, I have gone over 200 of our cases who have been on MER/29 continuously over a period in excess of 12 months. In this series there was included the one patient of hair thinning on whom I reported to you and on whom we discontinued MER/29. Additionally, there were 6 patients in the group who reported a definite increase in hair growth. These, however, were all males. The increase in hair growth is obvious in 1 particularly obese individual who has grown a nice forehead flock of wavy black hair. We have encountered a second patient who has hair thinning, a female, age 52, who was on MER/29, 250 mg. daily for a period of only 42 days. During the same period, this patient had received intra-articular and oral corticosteroids. On noticing her hair loss, this patient 22 days ago discontinued MER/29 and has had a definite regrowth of new hair."

The 2 patients reported here by McHardy who have exhibited hair loss are included in the tabulation. However, the tabulation does not include the 6 males who grew hair in alopecic areas.

In view of Dr. McHardy's report, and the original reports of growth of hair in 2 elderly alopecic women by Kountz and Toro, we must also conclude that there are better classed as hair changes rather than simply as hair loss. It is, therefore, recommended that the words "changes in color, texture, or amount" be substituted for "loss" in the new brochure side effect statement. It is the feeling of the Department of Medical Research that there can be no doubt of the association of MER/29 therapy with these changes.

Enclosure [omitted].

[Inter-Department Memo, Mar. 24, 1961]

To: Mr. H. Smith Richardson, Jr.
From: R. H. Woodward.
Subject: MER/29—Complaints of Hair Changes.

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Before Frank left for vacation, we had initiated a review of reported thinning of the hair of people taking MER/29. It is our feeling that we are morally and legally bound to include our findings in the side effects statement in the FDA approved brochure—even though the reported incidence is only 51 cases of roughly 300,000 treated.

Attached for your review is a memo from Dr. McMaster setting forth the facts as we have them, together with a copy of a proposed letter to FDA by Joe Murray which has not yet been sent.

The reason for bringing this to your attention, Smith, is that we have made no changes to this point in any of our MER/29 literature, basically because we were afraid to "stir the pot" in Washington. We have heard from several sources that FDA at times has considered reopening our NDA file but, frankly, we do not know whether this is true. The risk we run in admitting this additional side effect must be realized, however, and weighed against our moral and legal obligations referred to earlier.

Frank and I both feel that the approach should be made. Further, we feel that to protect ourselves against possible damage suits, we should make the approach promptly. I thought it well to inform you, however, so that you may express your own opinion since, after all, the future of MER/29 is of interest to you and to others in the Enterprise as well as to Merrell.