

4272 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

[Inter-Department Memo, Aug. 3, 1960]

To: H. W. Werner.
From: F. J. Murray.
Subject: Mer-29.

I called Frank Talbot at the FDA to discuss the status of our liver function follow-up studies on MER-29. Talbot did not seem particularly worried about the liver problem and while data should be made available to him as quickly as possible, there is no emergency situation.

Dr. Talbot expressed concern at our promotional literature and indicated claims appear to be getting excessive. He strongly suggests that we avoid stressing potential uses and stick to approved claims.

Talbot asked whether we have any more information on the spermatogenic offset of MER-29. He pointed out that there was an indication in our animal data that this might be a problem and he would like to know the effects of MER-29 on sperm count of young men taking the drug for extended periods.

Dr. Talbot stated that he has been annoyed by letters and personal visits by physicians complaining about MER-29. In each case the complaint has been based on reports of hepatitis with the original information coming from Dr. Corday. Dr. Pollock was one of the visitors. Talbot wrote Corday some time ago making complete details and has received no reply (we likewise have been unable to get details from Corday. Talbot plans to write him again and we state that since Corday has been unwilling to document his claims, Talbot must assume the reports of Hepatitis are just rumors.

[Inter-Department Memo, Sept. 20, 1960]

To: Medical Department.
From: Frank Belknap 13350.
Subject: MER-29 Alopecia.

During a recent discussion of MER-29 with Fred S. Badman M.D., 2746 N. 2nd St., Harrisburg, Penna., the doctor mentioned that he is and has been very interested in the product but in discussing the drug with some of his medical friends in the western part of our state, one a dermatologist mentioned that a side effect that some of his patients might experience complete alopecia even pubic hair. The doctor asked if I would check to see if such was the case or whether it may be strictly a rumor.

FRANK BELKNAP.

[Inter-Department Memo, Oct. 5, 1960]

To: Drs. E. F. Van Maanen, H. W. Werner.
From: T. R. Blohm/mc.
Subject: Publication of Toxicology Studies on MER/29

There seems to be a general acceptance of the idea that MER/29 is reaching a sales volume which is worth protecting. According to all the information we can get, MER/29 will soon be challenged by one or more thyroid products. Our strategy in combatting this competition will be based on the danger associated with thyroid medication in cardiac patients. In order to be effective, we must be able to point to a clean bill of health on the same score. For this reason, I believe it is more important than ever that our safety data on MER/29 get in print. Of course, publication of this information will also spike the "liver toxicity" rumors which continue to circulate, and will render less effective certain private communications from bureaucrats to the effect that MER/29 "must be toxic." We also have data showing that desmosterol cannot be excessively atherogenic, since no arterial lesions were found in any of our chronic animals.

I realize that Dr. King is pushed to the wall with studies on potential new products, but I believe this is of sufficient importance to receive a high priority. Dr. King concurs with me on this.