

The University of Vermont

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July 1, 1974

Dr. Alexander M. Schmidt
Director, Bureau of Drugs
Food and Drug Administration
5600 Fischer Lane
Rockville, Maryland 20852

Dear Doctor Schmidt:

On April 8th, I sent a letter to Dr. Alan B. Lisook summarizing a situation which I thought constituted unethical action in drug promotion, or at least in suppressing criticism of a manufacturer's product, by one of the so-called "throw-away" journals, namely, Modern Medicine, distributed free to hundreds of thousands of physicians and supported financially solely by advertisements.

The Editors of this publication solicited a manuscript from me on the treatment of migraine, an area in which I have had considerable experience and originally did research work when still associated with Dr. Harold G. Wolff at Cornell Medical School in New York years ago.

The essay was solicited without promise or expectation by me of any compensation, and I was happy to provide what I thought was a statement based on sound scientific opinion. I enclose a copy of the original letter of solicitation.

In my treatment of the subject, I frankly minimized the value of certain drugs, particularly Fiorinal, cast doubt on the entity, "tension headache" for which it had been promoted for years as an almost specific remedy and in general suggested that the reliance on a variety of drugs instead of other more time consuming, and more effective approaches represented simply an easy way out for the doctor. It was only after I had submitted the manuscript that I learned to my surprise that Fiorinal was being subjected to critical investigation by the FDA and that Sandoz was under some compunction to prove its allegedly specific value, and providing handsome financial grants to physicians to carry out allegedly controlled experimental trials of therapy (this after the drug had been on the market for 20 or more years).

My manuscript was initially modified by the Editor, deleting some of my critical comments about the drug approach to headache treatment and especially omitting the statement that, "The mystique of the therapeutic specificity of Fiorinal for 'tension headache' needs to be dispelled with the realization that it is merely APC combined with barbiturate". Because of my strenuous objections to this deletion, it was re-instated and I subsequently softened some of the harsher criticism I made of the usual approach to the treatment of headache.