general or toward specific drugs. I have some comments about editorial policies.

FDA has received complaints from some authors that when they prepare an article unfavorable to drug products the articles are rejected by the controlled circulation journals even when they were solicited by the journal in the first place. The reasons given for rejection are that the article does not meet some unspecified technical standard, but whether or not this is the entire reason is difficult to determine.

Members of our staff have had several meetings with editors of controlled circulation journals asking specifically about editorial policy regarding articles adverse to the product of an advertiser. A common answer is that such articles rarely are received because physicians are more interested in reporting successes than failures and that, furthermore, successes make more interesting reading than failures. Another common answer is that the journal sells space on the basis of reader interest and to sustain this interest the journal must contain objective articles. Usually, however, it is acknowledged that whenever material severely adverse to a sponsor is received, that sponsor is given the opportunity to rebut that material before it goes into the journal.

Mr. GORDON. What happens if the advertiser does not like the material?

Dr. CROUT. I am told another article rebutting it would be placed next to it.

Mr. GORDON. Do you have any specific examples?

Dr. CROUT. This is information that is hard to come by. Let me relate a personal experience, which I feel comfortable about discussing, rather than relating what I have heard from someone else.

I was interviewed on FDA policy in relation to bioavailability and my interview was sent back for editing and I did get a chance to edit it. It was then without my knowledge sent to the Pharmaceutical Manufacturers Association and published in association with an article from the PMA, so they got the chance to publish their point-by-point rebuttal to my interview from their standpoint. But I got no chance to see their rebuttal prior to publication.

Mr. GORDON. Sort of a one-sided deal.

Dr. CROUT. That is the one personal experience in this area that I have.

Mr. GORDON. Mr. Chairman, I ask that a letter from Dr. Schumacher, University of Vermont to Dr. Alan B. Lisook, of FDA's Bureau of Drugs be inserted in the record of these hearings. Apparently he was invited by Modern Medicine to write a piece on headaches. He was told that it does not make any difference how you feel about this subject. You can take a radical position or any kind of position. So he wrote the article and the editors knocked out or tried to knock out a section in which he decried the use of a drug called Fiorinal, which, incidently, the National Academy of Sciences said, had no evidence of efficacy. I would like to put the whole series of letters between him and the journal into the record.[1]

[1] See letter dated April 8, 1974, to Alan B. Lisook, M.D., Bureau of Drugs, FDA, from George A. Schumacher, M.D., Professor of Neurology, University of Vermont, page 14022.