Let me note that under FDA regulations pharmaceutical manufacturers may not promote their drug products prior to approval for marketing. In this case, although it was not noted in the program, the investigator was a full-time employee of the drug manufacturer which had developed prazosin. Prazosin had not been approved for marketing at the time of either meeting.

In the AAFP program, there are two scientific exhibits on Tolmetin, a drug developed by McNeil Laboratories for treatment of rheumatoid arthritis. At the time of the AAFP meeting, Tolmetin had not been approved for marketing in the United States. In response to the Agency's questions, a representative of the firm stated that the construction of both exhibits was financed by McNeil. The representative went on to state that his company customarily financed such exhibits when its medical monitor was pleased with an investigator's results. He stated that such scientific exhibits were shown at two to four conventions each year and that while attending the convention, each exhibitor received an honorarium of about $250 per day plus reimbursement of all expenses.

Mr. GORDON. You mentioned that under the FDA regulations, pharmaceutical manufacturers may not promote their drug products using certain marketing practices.

Was this a violation of the law and what can they do about it?

Dr. CROUT. I should point out that we have recently looked into the issue of scientific exhibits and are reporting to you some of the things we have found. In our view this type of thing is a violation of the current regulations on drug labeling.

But, as I pointed out, moving into that area would, according to the testimony of AMA, essentially wipe out 80 percent of the scientific exhibits. So I am reporting to you this problem that we have recently identified. We will attempt to address it in the advertising regulations, but we have not moved against specific cases at the present time.

Mr. GORDON. When are these advertising regulations going to be put in the Federal Register?

Dr. CROUT. We had hoped—it always seems to take longer than one hopes; I must say at this point it is unlikely before late summer.

Mr. GORDON. Is it true that, as Dr. Moss of the AMA stated, if these regulations being proposed are finally adopted, about 80 percent of their exhibits would be wiped out?

Dr. CROUT. If the guidelines which are stated in page 30 are adopted in final form, I believe that is what the AMA would say; yes.

So those regulations, which will make it clear that drug labeling laws extend to scientific exhibits and multimedia systems, will have an enormous impact in this area.

Mr. GORDON. Will you please explain briefly how you distinguish between scientific exhibits and commercial exhibits?

Dr. CROUT. At a medical meeting there is usually a large hall reserved for exhibits and there are a large number of commercial exhibits by drug manufacturers, instrument manufacturers, book salesmen, and so forth. These are little booths and displays with representatives there.