scientific journal or some other journal which is not entirely supported by drug advertising, then it could not be controlled by the FDA?

Dr. CROUT. I think it is important to emphasize that any piece of material distributed with a drug, or information sent by a manufacturer about a drug can be called drug labeling, so we have to look at both the content and its distribution. I can't answer your question clearly for every case. It would depend a little on what the physician wrote in the article, his independence from the industry, and whether it was distributed by the industry as a promotional effort.

Now the guidelines we have proposed here are an attempt to separate out what material we believe should properly be called drug labeling and what should properly be called medical education that is not under the Federal Food, Drug, and Cosmetic Act. The policies on this will be in our proposed regulations that are coming out.

Senator NELSON. You say the Food, Drug, and Cosmetic Act poses no threat to scientific communication, reporting research or to the voice of any medical opinion, providing industry funding of that communication is not involved.

Suppose a physician simply disagrees with, say, the FDA approved indications for the use of a drug as included in the labeling. He writes that he has been using the drug for many, many years, and in his judgment and experience, the FDA is wrong. The drug has been, in his judgment, very effective in controlling a certain illness. He writes an article on this subject and takes a very strong position, also recommending to other physicians that they use it in nonindicated cases, or at least he argues the case.

If that is published in a nondrug publication with no drug advertising involved, I assume what you are saying is that the act does not affect this kind of a situation.

Dr. CROUT. That is correct.

Senator NELSON. If I have such an article published in a magazine wholly supported by the drug industry, would that be controllable.

Dr. CROUT. That is the marginal case in which our policy is being developed at the present time and will be in the proposed regulations. We are not acting against those cases per se at the present time.

Let me cite one extension of this, however, which we do take action on. Once an article is used in a promotional effort, meaning literally distributed by a detail man in association with the drug, then that article becomes drug labeling and if the article references to unproved uses and so on, we will take action against it.

Senator NELSON. Is it another level of case if the physician or scientist is paid for writing the article as contrasted with one writing it totally unsolicited and not paid for.

Dr. CROUT. That is an important issue in our view, yes.

Senator NELSON. Go ahead.

Dr. CROUT. Under present law, FDA has regulatory authority over some of the materials I have been using as illustrations. Cassettes which discuss a particular drug, for example, must meet standards for drug labeling and may not promote nonapproved uses of drugs, minimize hazards, or make comparisons not supported by evidence. This still does not, of course, mean that they are neutral educational materials as their formats might suggest.