There is one serious difference of opinion. They propose that the intent should not be for ultimate distribution by the pharmaceutical industry. If the manufacturer supporting the program meets all of these criteria, why can't he give it away? He has the distribution channels and can use them to get the program to the doctor. If he paid for the program and has the ability to help get it used correctly, why shouldn't he do this? If he can't do this, why should industry pay for it?

Finally, our opinion is that if the manufacturer is forced to produce educational materials as advertising, we will all lose—the medical educators, medical schools, organized medicine, the pharmaceutical manufacturer, the doctor in practice, and because of these losses the patient and the American public loses.

Mr. GORDON. Sometimes, Mr. Calesa, the line between education and a subtle form of advertising is rather thin. The FDA has to make that determination. Is it a subtle form of advertising, or is it really education?

Mr. CALESA. I think the FDA has spelled out criteria to define how that line should be evaluated, and we, as I just mentioned, are in full agreement with the criteria that they have spelled out, with the exception of one, which is distribution.

So, I accept that problem, and I accept the way they propose to handle that problem.

Mr. GORDON. One thing that puzzles me is why will the doctors not pay for this? Lawyers and economists and other occupations pay for their education. Why would a doctor not want to do that?

Mr. CALESA. Well, they perhaps were spoiled by the industry a number of years ago. But the hospitals will; the hospitals will pay for educational material. They will pay for the hospital staff, and they will pay for the allied health professional. But physicians in private practice will not. According to our studies, the physicians in private practice never had the kinds of demands being placed on them for obtaining continuing medical education, as there are now.

We have produced programs both with and without labeling. Obviously, we favor the former as do all of our medical advisors. As a matter of fact, Dr. Crout, in his appearance before this committee, complimented Health Learning Systems for a program we are producing called, "Dialogues in Hypertension," which is developed in cooperation with the national high blood pressure education program of the National Heart and Lung Institute, the Council for High Blood Pressure Research of the American Heart Association, and the National Kidney Foundation, under an educational grant from Smith Kline and French Laboratories. This program is produced according to the criteria previously discussed.

Dr. Crout then went on to describe a program which we produced under a grant from Marion Laboratories which he said was an example of education that was promotional. In this case it should be pointed out that the program produced met the criteria for drug labeling. It contained the package insert on the films and in the monographs and was edited by the Marion Laboratories' medical and legal departments in accordance with labeling requirements.

It is exactly for this reason that we feel labeling should not be a part of an educational program, assuming the other criteria have