terial, and he is going to do it in accordance with the criteria which we have established, what he is doing is providing us with a grant of funds and allowing us the opportunity to produce a fair, balanced, and honest educational program which has been reviewed by as many groups and as many different people and in as many different ways as we possibly can before the educational program is provided to the physician.

Now, I think the very important thing here is who supports these kinds of efforts. I think the answer to that question is the manufacturers with the better products, the high-quality products.

Mr. GORDON. What do you mean by "high quality products?" Is there anyone with a low-quality product on the market?

Mr. CALESA. Let me state it differently.

People who are leaders in a particular therapeutic field, people who have, let's say, the better recognized products.

Mr. GORDON. You are talking about the brand name companies, the trade name companies, are you not?

Mr. CALESA. Yes, sir, I am.

Mr. GORDON. The members of the PMA?

Mr. CALESA. Yes; I am.

Mr. GORDON. OK.

Let's not talk about high-quality products, because according to the Food and Drug Administration, all of the products on the market are high-quality products.

Mr. CALESA. OK, fine.

Did I answer all of your questions?

Should I go on?

Mr. GORDON. I think you have answered them.

Mr. CALESA. It must be pointed out that there is a difference between what I have described as education which does not meet all drug labeling requirements and education which does meet all drug labeling requirements and is considered as advertising.

If all education supported by pharmaceutical manufacturers is to be considered as advertising and thus subject to all drug labeling requirements, serious shortcomings will occur.

First, that automatically means that the pharmaceutical manufacturer will be involved in the selection of physician participants and that they will review, edit, and have final content approval of all content. The reason is that by Federal requirements they must protect themselves against physician participants saying that may be considered accepted medical practice or the individual physician's opinion but deviates from the approved labeling.

The editorial board participants do not accept this infringement by Federal Government authority over what they want to say. In addition, package inserts in the educational material are a tacit endorsement of the manufacturer's products. The effect of drug labeling on education is an infringement on free speech and presupposes that content control cannot be achieved by the medical profession.

The Food and Drug Administration has proposed a series of guidelines to differentiate education from advertising to overcome these problems. As you can see, we agree with all but one of these guidelines and have introduced additional guidelines.