Senator NELSON. Do they hand out this type of promotional piece and so forth, like the JAMA ads?

Mr. GOODRICH. Sure. The same kind. You will see in the ads you have before you some of them run several pages—it is not unusual to see an elaborate ad running several pages, that is suitable for reprinting, either for direct distribution or handout by the detail man. The companies also use attractive visual aid type of promotional material to make their detailing more effective. And they use a great many other promotional techniques. I am constantly amazed at the creativity of the people on Madison Avenue who think up these ideas. But they certainly have a lot of ways of getting the message across. It could not be better stated than you did, that the problem of competing with a message such as the ad you have in front of you is a difficult problem.

Senator NELSON. In the event that some promotional material being handed to the doctor by the detail man exceeds the claims in the package insert, do you have the authority to make them correct it?

Mr. GOODRICH. Yes, sir.

Senator NELSON. Do you ever do that?

Mr. GOODRICH. Oh, yes.

Senator NELSON. You say the material is very massive. You do not review it all—or do you?

Mr. GOODRICH. We just physically cannot review it all. I would certainly recommend a substantial increase in the amount of effort we have on this. But Dr. Ley is the one who has to put the medical resources into it, and I believe the judgment has been made by him and by Dr. Goddard that we are at the level of maximum now that we can put into it—although it could stand some more help.

Senator NELSON. Do you require the detail man to submit any piece of literature, the contents of which you regulate, like the package insert, to the doctor on each occasion that he is detailing the drug?

Mr. GOODRICH. Only in the sense that every piece of written material, written, printed, or graphic material that he leaves or shows to the doctor in the course of his detail, is required to have a full disclosure of the effectiveness, side effects, contraindications, warnings, precautions, and so forth, applicable to insure safe, effective use of the drug by that physician—every piece of it.

Senator NELSON. That is the requirement as to advertising.

Mr. GOODRICH. The advertisement requirements differ only in the sense that a brief summary of information related to side effects and contraindications is permitted in general advertising. In direct mailing pieces and other labeling material the discussion must be in greater depth and detail.

Senator NELSON. Well, is it in as much detail as the package insert?

Mr. GOODRICH. Not completely, but it has to be substantially the same—not in the same words, not in the same unattractive form as that you see in the package insert. But the message has to be substantially the same. That is, all of the side effect, precaution, warning, contraindication ideas that are presented in the package insert, must be presented in the mailing piece.

Senator NELSON. And you do review that?

Mr. GOODRICH. To the extent of the facilities available for surveillance, yes.

Senator NELSON. Do you ever find any of this literature that does not comply with your requirements.?