Mr. GORDON. What would be your attitude regarding new legislation that would make it a misdemeanor for any detail man or other representative of a firm to make a false or misleading oral statement about a drug?

Mr. GOODRICH. We wouldn't have any recommendation on legislation and couldn't until it went through the regular system, you know, through the agency, and so forth. But in terms have we considered that as a legislative need; we have not.

We have in regulations already the authority to classify a drug as misbranded if it is orally represented for a condition for which it is not labeled, and that would result in the product being misbranded and it would be a misdemeanor. So we would think that legislation you are talking about would not be necessary.

Mr. GORDON. You think it is covered now?

Mr. GOODRICH. I think so.

Mr. GORDON. How many legal actions has the FDA initiated in the last 5 years based on violations of section 502(f)(1) in advertising of prescription drugs?

Mr. GOODRICH. None, I believe.

Mr. GORDON. Can you tell us why?

Mr. GOODRICH. Because we have been concerning ourselves with the higher priority problems, one, with the full disclosure regulations, second with the advertising, third with review of effectiveness for all drugs approved between 1938 and 1962.

We have initiated an exploratory program into the field of detailing, and when those results are in, we will be ready to move into that area.

But we considered our first priority to deal with the adequacies and the truthfulness of the claims, and second, the kind of promotion that was going to the physician in great volume both in direct mailing and in advertising. That has occupied our attention in terms of priorities. We did learn about this oral detailing in the case of Vibramycin by a report from a physician, and the Commissioner took it up with the president of the firm.

Senator HATFIELD. Would you state your name, please?

Dr. MCCLEERY. I am Dr. Robert S. McCleery. At the moment, I am Acting Deputy Director of the Bureau of Medicine, Senator Hatfield.

At the time of the events in question, I was in charge of the Division of Medical Advertising. I, too, am interested that the record be correct, and show the events and the nature of what it is we are discussing.

For the sake of the record, I think it should be pointed out in relation to your last statement, Senator Hatfield, that we this morning submitted a series of documents which I have reason to believe you have not had the opportunity to see.

The judgment that you reached as to the quality of the decision of the Bureau of Medicine in its agreement to allow Pfizer to use this in their training sessions I think could not be well informed until you had a chance to study the documents.

We feel that the record would show that the company made an agreement and that we have documentary evidence to show that we have reason to believe that the top management of the company kept its commitment to make sure that this improper detail piece was not used by their detail men.