the case we have had under consideration today, the length of time involved here? Is this exceptional?

Mr. GOODRICH. We were requested to present this case to give the committee something of the feel of what goes on between the agency and the sponsor in first assaying the clinical data to decide how good the clinical drug is and what can be expected of it, and what goes on between us in terms of developing a proper promotion. In this instance, there were two public-spirited physicians who called our attention to detailing that was beyond the appoved labeling. This is not the usual experience for us, but this case was chosen by the committee staff to give some idea of how we were doing our job and what sort of pressures back and forth were involved.

Senator HATFIELD. By this committee staff?

Mr. GOODRICH. Yes.

Senator HATFIELD. But this would not be what you would call a typical case. If I understand you correctly from what you said, if you have a case in which you are concerned about the advertising practice, you could stop it just in the matter of days.

Mr. GOODRICH. This case, Senator, involved a drug about to be introduced into the marketplace. Where we have a drug that has been approved, the regulations on advertising say that you can only advertise an approved drug for the conditions that have been approved.

If we find in our surveillance of the advertising copy, such as we see in journals like the Medical World News or the Journal of the American Medical Association, our technique is to work up in a scientific way what we regard as the defects in it, to communicate with the company and go over with them the failures in that message, and to discuss at that time an appropriate corrective action.

Senator HATFIELD. What length of time does that normally take?

Mr. GOODRICH. That normally takes a very short time, the matter of a few days to a few weeks.

Senator HATFIELD. What I would like to make certain that I understand correctly, and if I do then I want to make certain that it is in the record as such, that this case as it has been presented to me impresses me as one in which the procedures are very clumsy, that it appears to me that there are a lot of examples in here of poor administrative practices. Let me just point out one or two.

When you had something very definitely questionable in your mind about the visual aid, you said to this industry, "Go ahead and present it to your detail men, but warn them." I mean it is like in a court when a witness has said something in front of a jury and the judge says "strike that." Well, it has already heard this. I think this is analogous.

Mr. GOODRICH. Let me just react to that in the real world. We were sitting down with Pfizer to go over this visual aid, and they suddenly present us with a final printed copy. We thought it was still in development. We said to them, "this visual aid is no good. It can't be used."

They say to us, "but we have all of our detail men coming to a meeting. Many of them are en route. Can't we use this as a piece and then explain that changes will be made?"

Whether for good or bad that was the human part of the decision.

Senator HATFIELD. I just couldn't disagree with you more. I think you have not only the authority, you have the responsibility to tell them no. Maybe it is not more law. Maybe it is a little more aggressive attitude toward the law that you now have.