Senator NELSON. May I interrupt you? You say no more so, although this study indicates that it is quite a bit less so.

Dr. EDWARDS. The studies vary considerably. There are others that show that it has an effectiveness that is comparable to that of aspirin.

Dr. Simmons, would you want to say something on that?

Dr. SIMMONS. Mr. Chairman, Darvon is an effective analgesic, but no more effective than two aspirin tablets. There are some situations where it would be inferior to aspirin. To go further in the comparison with codeine, the best available evidence indicates that Darvon is about two-thirds as potent as codeine, and the 32 mg. of Darvon in general has been found to be indistinguishable from placebo.

Senator NELSON. This study used 65 mg. tablets, not the 32 mg.

Dr. SIMMONS. Right.

Senator NELSON. I looked at other studies, but they refer to placebo, that is, Darvon being not much more effective than placebo. All of them, I think, conclude that aspirin is more effective; isn't that correct?

Dr. SIMMONS. Many studies do. I am not aware of studies that show Darvon is superior to aspirin. I think in fairness you have to say that analgesic studies are difficult to perform and evaluate.

Senator NELSON. The "Dear Doctor" letter went out in response to a scientific study. Is that a common practice?

Dr. EDWARDS. No.

Senator NELSON. No?

Dr. EDWARDS. It is not a common practice.

Senator NELSON. Did the letter go out in the same form as the ordinary "Dear Doctor" letter that goes out at the FDA's direction to correct misleading advertising claims?

Dr. EDWARDS. Again, Mr. Chairman, let me say we have not officially received a copy of the letter. We have gotten it elsewhere. We have seen the letter, and it is in the general format of a "Dear Doctor" letter that would have been issued by a company at the request of the Food and Drug Administration.

Senator NELSON. Well, isn't it probable, if not almost inevitable, that the physician who is used to receiving "Dear Doctor" letters that are sent at the direction of the FDA, likely to interpret this as a correction in advertising and, therefore, is an accurate statement of what Darvon is and its effectiveness?

Dr. EDWARDS. I think that is a fair statement, yes. And as I mentioned a little earlier, the "Dear Doctor" letter does not present any reasonable degree of balance, in our judgment, and as a result we are taking this action to require that a corrective letter be sent by the company to physicians.

We think it is generally a bad policy, that any time a critical article comes out in major accredited journals, for a company immediately to send out a "Dear Doctor" letter. I don't think this is a good practice.

Senator NELSON. Well——

Dr. EDWARDS. Then the third action, if I might, will be a letter sent by the Food and Drug Administration stating that the Food and Drug Administration will not allow the use of unapproved labeling that deviates from approved labeling in any significant respect.

These three actions we are taking in an attempt to avoid similar repeats of this particular happening.