I think there is no question that if Darvon in whatever dosage is claimed to be an effective analgesic, there must be evidence that it performs better than a placebo as an analgesic.

Dr. EDWARDS. As I indicated, Mr. Chairman, we are in the process right now of negotiating with the manufacturer to further revise the labeling on this particular product.

Senator NELSON. I shall put in the appropriate place in the record the news release [1] from the Eli Lilly Co. in response to criticism of that drug. There are a couple of interesting sentences in it. I will not bother to read it all, but it says:

> The fact that some investigations fail to show a difference between 32 milligrams of Darvon and a placebo or "sugar pill" is not surprising. All analgesics give similar results at their lower ranges of effectiveness. Thus, a placebo often performs as well as a single aspirin tablet. This does not mean that the aspirin tablet is a placebo. It merely shows that analgesia research, being based on subjective evidence, is not at all that precise at the lower ranges of dosage.
>
> As for the view that Darvon should not be prescribed "routinely" in preference to other analgesics, we agree.

The evidence is that we prescribe Darvon routinely as the analgesic of choice in Veterans hospitals around the country. All you need to do is look at the amount. But it is being studied further, is that what you are saying?

Dr. EDWARDS. Absolutely, and as I said, the labeling on this drug will very shortly be changed again. Dr. Simmons, do you have any other comments in that direction?

Dr. SIMMONS. No.

Mr. GOODRICH. I might make one more point. In our adequate and well-controlled study regulation, there is a requirement for comparing the drug, the claims of effectiveness, either with a placebo or with something else and if it is claimed to be an effective drug, it must be and is compared with a placebo. Of course, it must perform substantially better in order to have any claim supported.

Senator NELSON. Have the physicians been informed that the 32 milligram propoxyphene hydrochloride is not more effective than a placebo?

Dr. SIMMONS. Mr. Chairman, Darvon is a very interesting subject from its inception. If you ask us, has the physician been adequately informed of the late changes in Darvon, I think we would honestly have to say no, and we are taking steps to see that that gets accomplished.

Dr. EDWARDS. I think that Dr. Simmons did not go quite far enough. When Darvon was initially placed on the market and it was promoted as a drug compared to codeine, and as having the potency of codeine, and yet was a non-narcotic drug, I think that this was probably the first error as it relates to the subject of Darvon.

We have come to grips with that particular problem in labeling. We have not as yet come to grips with this problem of its effectiveness relationship to aspirin, and so forth, but I think very shortly we will have that problem corrected, at least as far as the labeling is concerned.

Senator NELSON. Thank you. Go ahead.

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[1] See p. 7993.