

Senator NELSON. I want to make it clear for the record that I was responding to a statement in your testimony that had nothing to do with indomethacin in particular, or any drug in particular. The sentence was: "It is equally certain, however, that promotion cannot persuade them"—that is, the doctor—"to continue prescribing the drug unless they themselves find that it fills a real need in their practice."

Part of these hearings is directed to the question of the promotion. The point I was making is that you, again, persuade them by promotion to use a drug in their practice that is effective for the purpose for which they use it but should, for the sake of safety, be used with much greater discretion. That is my comment. I was not comparing it with indomethacin at all.

Mr. GADSDEN. There is one other point that you made, Senator. Referring to the quote which did, in fact, appear in our ads—this was a factual quote from a recognized authority.

Senator NELSON. Which quote?

Mr. GADSDEN. The one about "a drug of choice." In fact, the actual quote says, "the drug of choice." Under AMA editorial policy, they do not permit you to say "the" drug of choice; so if you check our advertisements, you will find that we ran both advertisements. In the JAMA, we said "a drug of choice"; in the others, we used the language of the quote itself, which is, "the drug of choice."

I would furthermore like to call your attention to a quotation of 1967 from the recognized publication, *New Drugs*, as published by the AMA. It says that because "Indocin" has produced relief in acute attacks within 48 hours, and because it lacks the untoward effects of Colchicine, some physicians consider it to be the drug of choice for these attacks.

Shall I proceed, sir?

Senator NELSON. Yes, go ahead.

Mr. GADSDEN. Mr. Chairman, Indocin has demonstrated its ability to fill this need in the practice of physicians, both in this country and around the world. If it did not fill a need, the past 3 years of experience with it would have clearly demonstrated this fact.

I do not challenge the sincerity of some who have said that in our promotional efforts we made some errors. Language is not a perfect method of communication, and it may well be the words and phrases that we used in the belief they meant one thing may have been interpreted by some physicians to mean something else. Such are the complexities of semantics. But this was never done purposely, and whenever any possibility of misunderstanding was called to our attention, we moved promptly to correct it. If we have made errors, they were only minor ones, and to the degree that they existed they were hemmed in by the total emphasis given to the relative effectiveness, safety, and limitations of the drug.

We responded immediately to negative comment by the FDA, and the advertisement which they complained of has not appeared since November 1966. We took this action primarily from a prudent desire to cooperate with the Agency. We hope that upon the completion of the computer tabulations of our entire patient data, we can discuss with the Agency the renewed use of such claims as "Extends the margin of safety."

Senator NELSON. What does the phrase, "Extends the margin of safety," mean?