

the profession—so they failed to disclose in this connection that Indocin has some of the major side effects of these steroids themselves—for example, an ulcer-producing effect.

The ad goes on to claim that the drug extended the margin of long-term safety without any evidence in our view to support the claim, and it quoted from isolated pieces of literature to support this—one an excerpt from a symposium sponsored by the company—and to claim that the drug was “the drug of choice” in gout and in osteoarthritis of the hip, neither of which claims had been approved for inclusion in the package labeling of the drug.

It also quoted from two leading English authorities to the effect that the drug was useful in most cases of rheumatoid arthritis, when these authors had used the tablet and not the marketed capsule, and when their actual opinion, known to Merck, was that the drug was useful in only selected cases of rheumatoid arthritis.

It featured the claim of one of the participants in a Merck-sponsored symposium. This is attributed to Dr. Englund—they featured a claim, quoting from him at this symposium, that he had had 500 patients on the drug for 3 years, when Merck’s own records would have told them this was not true.

And finally, in the “brief summary” of information on side effects and contraindications, some of the major warning information was left out, such as the fact that indomethacin itself had caused ulcers of the stomach and so on, and that the drug should not be administered to children.

Now, how they did this is a very interesting operation—

Senator NELSON. Which ads were they? In which ads were the two warnings left out?

Dr. McCLEERY. They were left out in both of the ads. Most of these features that I have been discussing are common to the July ads and the November ads, Senator. You see at the bottom of the page of the ad that you have in front of you what we call “the brief summary,” and it contains information from the package insert that summarizes the warning information on the product. We say that, in practical fact, they had left out significant warnings which they are required to include in that brief summary of warning information.

Because it is a very subtle, but very important, advertising kind of language—I would like to point out why we say this.

Senator NELSON. You are saying that in no place in the fine print of this ad do they include the warnings that indomethacin may cause ulcers, and that the drug should not be administered to children.

Dr. McCLEERY. Yes, sir.

Senator NELSON. And that was well known at that time, was it not?

Dr. McCLEERY. Yes. But the issue is much more subtle, because there are references to both of these subjects in the ad which we have found fault with, and I would like to stress this kind of advertising technique which appears to fulfill the requirements of law, but in our view does not, because it is a very common practice, one which we are trying to fight. It is often called nit-picking by our opponents, as a way to denigrate the significance of changes in words, which we think is very important.

Senator NELSON. I have not read all the fine print. Are you saying that in this JAMA ad of July 18, 1966, somewhere in the fine print, there is the warning that it should not be used for children?