

When you get to this point, you run into disagreements between physicians. For example, the one who may have used the drug for years and who has never had a side effect, the other who, by virtue of scientific, laboratory and other facilities available, and greater exposure to literature, is well aware of them.

These are basically conflicts. There is no reason on the basis of a difference of opinion to castigate anyone or told them up as though, by virtue of this, they deliberately misled the profession.

They are still advertising a product that our Government's FDA admits is acceptable for manufacture, sale, and distribution. So if there are objections to certain of the facts that are contained in ads, the Food and Drug Administration has full authority at the present time to bring about any necessary changes. This is neither the responsibility nor the prerogative of the medical profession.

Senator DOLE. In other words, the FDA could require—

Dr. ANNIS. They could require, in big red letters on the front page, if they so desire, "This is a dangerous drug except under certain circumstances." Even its danger may be ignored because it is the only, or one of the only treatments available for certain conditions.

Anything they could put in there. All they have to do is do it by regulation, and they have the authority right now.

Senator DOLE. But instead, they require a letter, as I understand it.

Dr. ANNIS. No, they set up certain standards. Then, if the advertising that we receive and the rest of the drug advertisers receive, they put it in print, assuming it meets the basic requirements of the law. The FDA, after reading it, says to the manufacturer, "look, you have exceeded what we have allowed or, you have failed to comply with the law; you must send out a 'Dear Doctor' letter." And the FDA requires it to be in a special envelope.

I do not care how busy you are, these envelopes doctors have come to recognize and they read them. Because whether you prescribe these drugs or not, the drug may come to your attention and you want to know which ones are involved.

Senator NELSON. I repeat, Doctor, at the risk of being boring, that I am talking about the case where the ad was misleading. I will find an example or two here for you.

Dr. ANNIS. I am satisfied you could find these, Senator. You have indicated that.

Senator NELSON. When you carry an ad and it is educational; it is intended to convince the doctor of something.

Dr. ANNIS. Senator, here are six or seven publications. You see how thick they are. If you would pick them up, you would see how heavy they are.

I do not doubt that we have errors in there. But they are not errors of commission; they are not errors deliberately made. They are errors inherent in human beings, and by virtue of our desire to bring up to date knowledge in an obviously changing area of communication and knowledge. What appears to be true today experience will prove is not true 6 months from now, even in the use of other drugs.

Senator NELSON. I am not saying that it is an error of commission for the Journal not to notify its readers that false claims have been made in an ad in its Journal. It is an error of omission. All I am saying is, since doctors to a large extent do prescribe on information they get out of the ads, the Journal has the obligation immediately to cor-