

Senator NELSON. Now, is there any place in this ad where the warning or precautions is made that it is not to be used in the treatment of children?

Dr. McCLEERY. Yes.

Senator NELSON. Where is that?

Dr. McCLEERY. The statement in the package insert is the one that was under considerable discussion yesterday, but includes among other verbiage the statement that the drug should not be administered to children. Those words are contained in the original package insert for the drug, under the contraindications section.

Senator NELSON. Are those the exact words? What are the exact words in the package insert?

Dr. McCLEERY. That the drug shall not be administered to children. That is in the contraindications section.

Senator NELSON. And is some reference made to that under contraindications in this ad?

Dr. McCLEERY. Yes. In the ad it is transformed into another style of transmitting information, and in the ad you will find near the bottom of the contraindications section the statement "safety in pregnancy and pediatric age groups has not been established." That is the only reference to children in the ad.

Senator NELSON. So instead of saying it should not be administered to children, as it says in the package insert, as required by the FDA, in the ad it says "safety in pregnancy and in pediatric age groups has not been established."

Dr. McCLEERY. That is right.

Senator NELSON. You consider that to be a much weaker cautionary statement.

Dr. McCLEERY. Yes, I do. I consider it is not the same information. Deficiencies in the ads were publicly noted in a speech before the Pharmaceutical Advertising Club in New York, on October 20, 1966, by our General Counsel, Mr. Goodrich. The firm quickly protested, and shortly thereafter on November 11, 1966, a sort of "Armistice Day," the firm's principal officers met with Dr. Goddard and his staff to go over the problem. The problem took into account all of the elements of the advertising that we have discussed.

At that meeting, the firm reported that on hearing Mr. Goodrich's comments in New York concerning Indocin advertising, that it had immediately ordered that ad discontinued, and was taking a close look at all of its promotional efforts.

Later on, not too much later, its physician and counsel responsible in the area of advertising came down to go over some ads for other products, that Merck makes and advertises, with us. And I must say in defense of the company that from that point in time on, they have behaved in a very exemplary way. We have watched their advertising on Indocin carefully subsequent to this point. We have watched their advertising on a number of their products for tranquilizers and anti-depressants. We have seen them introduce two major new products subsequent to the meeting in Dr. Goddard's office, and we could find no serious objection to those. And so I am glad to say this concerning the performance of Merck & Co. And I regret I cannot say it very broadly concerning a number of other companies with which we have dealt.