Now, the National Academy of Sciences has made their report. As I understand it, FDA agrees with that report.

Dr. LEY. We have not only agreed, but we have taken definite action with reference to this product.

Senator NELSON. The literature will certainly carry references about this. There will be some news here and there in the medical journals. But the fact is one reason for advertising is to promote the drug. General Motors made a public announcement calling back 4,900,000 cars on the ground that it is a public hazard. This is a matter of public health. Shouldn't Parke, Davis be required now to say it is a different ball game; there are other drugs, this is not the indicated drug, the drug of choice in any disease, and run ads in the medical journals saying that? This is what General Motors did. And we all agree, all the experts agree, and you do, that it appears that 90 percent of the people are getting this drug for nonindicated cases. It is no greater tragedy to die from an automobile accident than from this drug unnecessarily. General Motors has made the front page announcement. That is what the law requires. Why shouldn't Parke, Davis be required now to advertise what the fact is?

For whatever purpose the ads were valid in the past, they aren't now, and it is not the drug of choice for any disease and it ought to be called to the attention of the medical profession by ads in all the journals. Why shouldn't that be done? We aren't willing to restrict their practice, saying they can only use it in the hospitals, but a lot of doctors should be told about this. Well, you aren't doing that. Just make them tell the truth. What is wrong with that?

Dr. LEY. We have essentially through our own letters last year said, look, to the physician recipient, the indications of this product have changed. It is a different ball game. Parke, Davis has not said this. And I'd have to turn to the General Counsel to see if there is any way that FDA could be instrumental in arriving at such a statement from Parke, Davis. I have doubts whether we could.

Mr. GOODRICH. Well, I think we have required them to do that in this very ad. If you will read the box warning, it does tell them that the ball game has changed, that the indications have changed, that the warnings are stronger, and we have, by telling them to discontinue the reminder ads, required that this message go with all promotional material.

Now, we do not have the specific authority of the Automobile Safety Act to require notification of defects, but this went to every physician in the United States and keeps going in every ad used, in the detailing piece and in the Physicians' Desk Reference. So I believe we've done more than just say, just modified the labeling in terms of indications. The indications were written in a very special way in a box form, and the side effects and hazards were emphasized both in wording and in outlay and display.

Senator NELSON. Well, we are talking, of course, about two different things: One is the package insert, that aspect of the fine print in the ad that you require, and the other is to counteract the history of a whole page stating, "when it counts."

Mr. GOODRICH. That was the purpose of the letter to every physician in the United States, and rather than have Parke, Davis send it out we sent it out. We made sure it went not only to every physician but