Senator NELSON. Please go ahead.

Dr. LEY. In a letter dated May 1, 1968, the firm notified us that it had discontinued all "reminder advertisements" in March of 1968, with the exception of those ads that were too far along in the publication process to be cancelled.

Dr. L. M. Lueck, of Parke, Davis, also said in this letter that the distribution from Detroit of all "reminder" pieces—such as rulers, pencils, and calendars—had been discontinued. He said this practice also was being discontinued in the field as rapidly as possible. Since that time, ads for the drug have carried essentially the full disclosure information from the package insert of the dangers and side effects associated with the use of chloramphenicol and the "box warning" that is part of the labeling.

On June 27, 1968, we issued a revision of the prescription drug advertising regulations applicable to "reminder" advertising which took into account our experience with chloramphenicol. Under these regulations, if the Commissioner finds there is evidence of a significant incidence of fatalities or serious side effects associated with the use of a particular drug, he can, by notifying the firm forbid the use of "reminder" advertisements that omit warning information.

On March 12, 1968, we met with representatives of Parke, Davis and the Pharmaceutical Manufacturing Association to determine whether the advertisement which appeared in the Reader's Digest issue of February 1968 "was caused to be disseminated" by the drug firm. This ad, in our view, recommended the drug for uses that were not warranted and seriously understated the hazards, side effects, and contraindications.

As a result of the meeting, we learned that the idea for this ad originated with the advertising agency handling the public relations program for PMA. The copy was reviewed and approved by PMA. Parke, Davis was subsequently asked to review the copy and to give permission for the use of the names of Dr. Payne and Dr. Burkholder. Funds for the advertising program which included this ad were contributed by approximately 100 members of PMA. Dr. Goddard accepted the explanation that PMA, not Parke, Davis was responsible for the ad.

Senator NELSON. May I interrupt for a moment.

We discussed this at great length with Dr. Goddard in the spring of 1968 and I raised the point that it didn't seem rational to permit Parke, Davis as a contributing member of the PMA to sort of duck its responsibility since it was the advertising firm and PMA that paid for the ad with Parke, Davis, in fact, reviewing the ad. There is a further question—as a member of the PMA any member company must have imputed to it responsibility for whatever the corporation is that they really own and control. If that is not the case, then any company can escape responsibility for an ad, which really violates FDA rules and regulations, by simply saying, well, it was the advertising firm and the PMA; although they all run the PMA, in this way they escape responsibility. I thought it was a very inappropriate ruling on the part of FDA.

My question is, What is the policy as to future situations such as this? Will the company be held accountable or will they be excused?