Dr. LEY. I would like to ask our General Counsel, Mr. Goodrich to respond to this question, if I may, Senator.

Mr. GOODRICH. When we were here last spring we did have this conversation about imputing the responsibility to the company Dr. Goddard and I concluded that before making any recommendations we should get PMA and Dr. Smith, the president of Parke, Davis, in to find out what the relationship was. The facts that we developed are as stated in this statement. It is possible legally to argue that mere membership, contribution to this PR fund is the causing tof the dissemination of the ad, but this would be a very difficult point to make in a criminal case, and Dr. Goddard accepted the explanation on this ad.

In the future, of course, we are going to try to avoid this sort of thing. We expressed both to Parke, Davis and to PMA our displeasure with this ad, and you had done the same thing. I do not think it will occur again, and it has not in the future advertisements of this type which appeared after this ad in the Reader's Digest.

Senator NELSON. Well, I suppose as lawyers we may have a difference of opinion as to what may or may not be difficult to prove.

Mr. GOODRICH. Right.

Senator NELSON. I would think it would be almost automatic if the facts are as stated here, where the company itself, and 99 or so other associates own the PMA; it is their creature; next, all the ads are paid for by contributions to the PMA, it has no independent status of its own at all, then the ad is reviewed by Parke, Davis, and it makes broader claims than the FDA would approve. I don't think there would be any question in the world but what the firm would be assigned a responsibility for that ad in any kind of a lawsuit. You may, of course, differ on that. My concern would be, at least, that they be notified that in any future case you will try it.

Mr. GOODRICH. Right.

Senator NELSON. You will try a lawsuit and then find out what the law is.

Mr. GOODRICH. That was done.

Senator NELSON. You did try it?

Mr. GOODRICH. That we have told them that this kind of practice in the future would be considered for possible prosecution.

Senator NELSON. I see. All right. Please continue.

Dr. LEY. Let me turn now to another problem associated with chloramphenicol. In May 1968, after reviewing all the blood-level data in our files on chloramphenicol for parenteral use, we concluded that chloramphenicol sodium succinate injection produced lower blood levels than the oral preparations. We suspended certification of chloramphenicol succinate pending resolution of the question about the therapeutic effectiveness of these lower blood levels. Certification was resumed in September 1968, as will be explained shortly when I discuss revision of the labeling of parenteral forms of chloramphenicol.

Senator NELSON. May I interrupt for a moment?

Dr. LEY. Certainly.

Senator NELSON. As I recall it, the issue was raised a year ago in December; is that correct?

Dr. LEY. September 1967.