

Now, we, as you know, have required warnings to be sent out in "Dear Doctor" letters and other ways. We have not had a controversy over any of that activity so far. It is possible we will have sometime.

Senator NELSON. But of course they have successfully promoted chloramphenicol over and against the best expertise of the medical profession for 18 years.

Mr. GOODRICH. They have been required since 1952 to put on the warning which Dr. Goddard was just about to read you; in 1960 to strengthen that warning. And any promotion contrary to that warning would be a violation.

The company was allowed to use reminder advertising, and we are in the process of revising those regulations to discontinue that.

Now, as you know yourself, I am sure, from the Kefauver hearings, there was evidence that Parke, Davis used detailing pieces outside the labeling. We did contact the company about that. They assured us that that was unauthorized and contrary to company policy, and that they would instruct their staff accordingly.

Now, detailing is a difficult practice to deal with. But if we have evidence that a product is being offered orally, or in any other way, in excess of the authorized claims or without the required warnings or in derogation of the required warnings, we have the procedures to take action.

Senator NELSON. We will get to that a little later, because I want to ask you what you are doing about the most recent PMA ad in the Reader's Digest.

But what puzzles me about this is that we have required them to include this warning in their ads. Dr. Dameshek approved it, he advised me—apparently he was on the ad hoc committee.

Dr. GODDARD. Not on this one. He was on the one in 1960, 1961.

Senator NELSON. Yes. And so that warning was put on. And Dr. Dameshek's testimony is that it has been a total failure. So the fact is that everything that has been done has not worked.

Would you not agree that if Dr. Dameshek and the experts who testified here are correct, that somewhere around 90 to 99 percent of the cases receiving chloramphenicol should not, and that our methods of controlling advertising and cautioning physicians have been a colossal failure?

Dr. GODDARD. Yes—I think we would agree that the methods of informing the physicians and getting them to act on that information have been a failure.

Senator NELSON. We will get to your recommendations later. Go ahead.

Dr. GODDARD. The warning that was then required was:

Warning—Blood dyscrasias may be associated with intermittent or prolonged use. It is essential that adequate blood studies be made.

The following warning was to appear at the top of the package insert:

Certain blood dyscrasias (aplastic anemia, thrombocytopenic purpura, granulocytopenia and pancytopenia) have been associated with the administration of Chloromycetin. It is essential that adequate blood studies be made when prolonged or intermittent administration of this drug is required. Chloromycetin should not be used indiscriminately or for minor infections.