

believable and informative. This was our advertising and full disclosure regulations.

Now, as we move into problems of detailing, no detail men sent us any bulletins. Senator Nelson sent us the bulletins. If some detail men would be good enough to send us the bulletins, we would know how to react to them.

Senator HATFIELD. Do you feel you have enough authority then in the area of—

Mr. GOODRICH. Of inspection.

Senator HATFIELD. Of inspection and review of promotional and advertising materials.

Mr. GOODRICH. I think we do, but of course there are going to be controversies over this.

Senator HATFIELD. Yes.

Mr. GOODRICH. We have taken some steps to learn more about detailing. The companies, some of them, take the view that this is a private matter that is none of our business. We, of course, couldn't agree with that. We think it is public business.

Senator HATFIELD. The law doesn't agree either with that viewpoint.

Mr. GOODRICH. Yes.

Senator HATFIELD. Now, in the case of chloramphenicol, did you approve this drug in its original presentation to the market?

Mr. GOODRICH. Yes, Senator.

Senator HATFIELD. Its introduction?

Mr. GOODRICH. That product was approved. We made a full statement on this before the committee.

Senator HATFIELD. Yes.

Mr. GOODRICH. It was approved, I believe, in 1949. By 1952, the first alarm had been sounded about aplastic anemia. We did have a review by the National Academy of Sciences and modified the labeling. That was reviewed again in 1961 at the time of the Kefauver hearings, and a further tightening up of the labeling was considered.

Senator Nelson was good enough to bring out that there were now available incidence figures of aplastic anemia to give us a measure of how often the aplastic anemia side effect occurred. This new information was incorporated into a much stronger warning to the profession, which went out, I believe, last spring.

Senator HATFIELD. So the original introduction of the drug was then under the approval of the FDA?

Mr. GOODRICH. Yes.

Senator HATFIELD. And that included the packaging instructions and claims?

Mr. GOODRICH. Yes, sir.

Senator HATFIELD. Made by the pharmaceutical house, and then you had also review of their promotional and advertising material as it related to this particular drug?

Mr. GOODRICH. Yes.

Senator HATFIELD. There were none of these things along the way then that would indicate to you that there had been misrepresentation?

Mr. GOODRICH. We knew from the oral detailing to one of our own physicians, I mean the issue of oral detailing was divulged by our own experience. One of our physicians on the west coast was detailed for chloramphenicol by one of Parke, Davis' people, and he was told