They said they did not have to run it in England because the law did not require it. I asked what about the underdeveloped countries? They said that England has a sophisticated system for medical protection. I presume we have a sophisticated one here. But 4 million people are getting Chloromycetin who should not be getting it. Then you get to the underdeveloped countries where there is no protection at all, and you can see what is happening.

All I am saying is that it is one thing if a warning has not worked for a couple of years, but we are talking about 2 decades. I think we have to do something dramatic about this now.

That is my whole point.

Mr. GORDON. Dr. Goddard, you referred to the California study. Now, as I understand it, this study for the first time indicated that the risks were higher than were known at the time that the drug was put on the market; is that correct?

Dr. GODDARD. That is correct.

Mr. GORDON. The California study came out in January of 1967?

Dr. GODDARD. That is correct.

Mr. GORDON. Did the Food and Drug Administration notify all the doctors in the United States about these new risk estimates?

Dr. GODDARD. No, we did not.

Mr. GORDON. Why not?

Dr. GODDARD. The California report itself, which was known to us at that time said, and I quote:

> No reasonable basis exists for the enactment of special legislative category to restrict the use of the drug chloromycetin by a licensed physician in California. Our data indicate that this antibiotic is being administered in accordance with good medical practice, and the risk use factor does not provide a sufficient basis to single out this drug for special legislation.

They did not—and there are a number of other statements here—they did not recommend any additional steps be taken at that time.

Senator NELSON. Who is "they" in this case?

Dr. GODDARD. CMA, California Medical Association—joint study group.

As you know, Senator, we have had a number of groups of qualified physicians meet on the subject of this drug over the years. The latest one met last week to advise us on what steps could be taken and should be taken. And the question of restricting the drug to hospital usage has come up in almost every one of these meetings. Also the question as to whether or not the drug should be withdrawn from the market. Both of these suggestions have been rejected by advisers who included people such as Dr. Dameshek, eminent physicians in their own fields of specialization who have detailed knowledge of the risks involved in the use of the drug.

Senator NELSON. I believe Dr. Dameshek is prepared to say that some very tough regulations should be made—possibly treating it as you do morphine, or confining it to hospital use. His posture on what we should do about this now is much stronger than anything the FDA is recommending.

Let me read what Dr. Dameshek said in testimony before us:

> The numerous warnings regarding indiscriminate use of chloromycetin have been practically without effect. It is now about time to consider more radical measures such as complete restriction of the drug for a few specific indications.