Senator NELSON. Dr. Goddard thinks it may be impractical to require hospital reporting. Maybe you cannot enforce reporting in the civilian hospitals, so we do not get very good statistics. But 16 years ago the ad hoc committee made a recommendation, and over that period we could have accumulated all kinds of statistics. Yet, we cannot seem to do anything about that.

The President of the United States and the Secretary of Defense could settle that in just about 5 minutes. Have you ever asked the Secretary of Defense?

Dr. GODDARD. Not to my knowledge.

Senator NELSON. Here is one arm of the Government worrying about the problems, and ad hoc committees making recommendations, and 16 years later these recommendations have not been implemented.

Now, it does not surprise me—I have seen lots of bureaucracies in my lifetime. But 16 years seems like a long time on an important matter.

Dr. GODDARD. I would agree.

Senator NELSON. Go ahead, Doctor.

Dr. GODDARD. Senator, just a followup point. Dr. Ley tells me they have been pushing this with the medical heads of the various military services, and VA, and it has been very slow. Dr. Ley feels somewhat more optimistic that they will give us this kind of information to a greater degree than they have in the past. So we have made the effort to get this kind of data from them.

Now, the chloramphenicol was to be marked following this meeting with the label warnings as follows:

Senator NELSON. Can you clarify for me the present legal authority that FDA has over prescription drug advertising?

Dr. GODDARD. In 1962 the Kefauver-Harris amendments gave us authority to regulate drug advertising. Then in 1963 we promulgated regulations which require drug companies to provide information to physicians through the various media that they use to advertise their products. They must present the information in fair balance, with the bad along with the good, and the information on advertised effects—important information required for prescribing. And that is the basic authority we operate under. I do not know the section.

Mr. GOODRICH. Section 502(n) as amended by the Kefauver-Harris drug amendments required that in the case of prescription drugs, the manufacturer, packer, or distributor must include in all advertisements which he disseminated or caused to be disseminated, the established name of the drug, the formula, such information about effectiveness, side effects, and contraindications as should be specified in regulations. The regulations have been promulgated, put into effect in 1963. They are in the process of being revised, elaborated, and improved at the present time.

Dr. GODDARD. We think improved. There is some disagreement on that, I might say.

Senator NELSON. You have stated the general basis of the law. The law then authorizes the FDA specifically to go how far? Does the FDA have the authority to say that, "You shall put exactly this language in this way in your package insert, in the advertising in medical journals and elsewhere?" Do you have that power?