Dr. GODDARD. Yes, sir.

Mr. GORDON. These are merely advisory committees.

Dr. GODDARD. Yes, sir.

Mr. GORDON. You have the authority to make the ultimate decision.

Dr. GODDARD. Yes, sir.

Mr. GORDON. Now, considering all these things we have been talking about, for weeks, and for years as a matter of fact, have you reached a decision that, on balance, it would do more harm than good if the drug were taken off the market completely?

Dr. GODDARD. Yes, sir. It is a preferred drug in Hemophilus influenzae meningitis—principally typhoid fever, and these other infections which are often life-threatening. The number of these cases in my opinion far exceeds the number of fatalities that occur because of the drug being misused.

Now, I am not minimizing the risk involved in misuse. I am simply saying that on balance, we have asked this question—this is the first question we have asked every advisory group, and they, every time, say that it should be left on the market.

Mr. GORDON. But they do not know the statistics, do they?

Dr. GODDARD. They have the same information we have, sir—the same that you have.

Mr. GROSSMAN. Which is not very good, is it?

Dr. GODDARD. No; not very good.

Mr. GORDON. If you have the authority to go all the way, to take a drug off the market, are you saying that you do not have the authority to go part way, to confine it to hospital use?

Dr. GODDARD. We could only try to confine it to hospital use by a change of labeling. I have read the new labeling we are going to discuss with the company, that portion of it which recommends the drug be used in the hospital. We have no way of enforcing this.

Senator NELSON. Is that going to appear on the new label?

Dr. GODDARD. Yes, sir.

Senator NELSON. How will that be worded?

Dr. GODDARD. I will read the warning in toto.

Warning, serious and fatal blood dyscraias (aplastic anemia, hypoplastic anemia, thrombocytopenia, granulocytopenia and leukemia) are known to occur after the administration of chloramphenicol. Blood dyscrasias have occurred after both short-term and prolonged therapy with this drug. Bearing in mind the possibility that such reactions occur, chloramphenicol should be used only for serious infections caused by organisms which are susceptible to its antimicrobial effects. Chloramphenicol must not be used when other less potentially dangerous agents will be effective. It must not be used in the treatment of trivial infections or where it is not indicated, as in colds, influenza and infections of the throat, or as a prophylactic agent to prevent bacterial infections. (Last sentence underlined.)

Precautions. It is essential that adequate blood studies be made during treatment with the drug. While blood studies may detect early peripheral blood changes, such as leukopenia or granulocytopenia, before they become irreversible. such studies cannot be relied on to detect bone marrow depression prior to development of aplastic anemia. Because of the necessity of repeated blood studies during therapy, it is desirable that patients be hospitalized if possible.

Senator NELSON. Read that last sentence again, please.

Dr. GODDARD. "Because of the necessity of repeated blood studies during therapy, it is desirable that patients be hospitalized if possible."