And just to delineate it a little further, let us take the case of chloramphenicol on which we had substantial hearings. This is a very potent drug and everybody knows it. It has in a certain incidence, some dramatic side effects involving blood dyscrasias, including aplastic anemia.

In today's circumstance, chloramphenicol, according to the National Research Council of the Natonal Academy of Science, is not the drug of choice in any disease. It is the choice only when the target organism is subject to control by chloramphenicol, when no other drug will do the job, and when the disease situation is very serious.

So clearly, if you had some disease organisms that would not respond to treatment by tetracycline or any other drug, and the patient was seriously ill and the target organism was sensitive to chloramphenicol, the drug under that situation is safe within the meaning of the law.

However, if the disease is subject to treatment by tetracycline, it is not safe within the meaning of the law or if the patient has a serious disease or if the target organism is not subject to control by chloramphenicol, it is unsafe.

Is that your understanding of what the law means?

Mr. GOODRICH. Yes. My understanding is that all safety decisions have to be made in the context of the conditions for which the drug is prescribed, recommended or suggested.

Now, going back to what Congress had in mind in 1938 when they focused on an acute episode of poisoning, it happened to be due to the vehicle and not the drug itself. But as soon as we began passing on safety from the very first drug, the sulfanilamides, that were involved there, those drugs were not safe in any absolute sense of the term but they were quite safe in treating infectious disease at that time, because many of those were lift threatening.

Now, in that class of drugs, of course, it is relatively easy to balance benefit-to-risk, which is the test here. But there are other types of drugs that we have had to deal with over the years, drugs used for prophylaxis, or that type of drug, and in each instance it is essential that the agency balance benefit to risk, because there are very few drugs that have no side effects whatever, if they do anything.

There are some inoccuous drugs that do not do anything, but if they are innocuous, then they do not have any benefit or any risk; they are just ineffective.

But from the beginning of time we had to deal with the sulfanilamides, first as a class, with the corticosteroids, and many other classes of drugs that came on the market after 1938. And this was really kind of the beginning of a new era of chemotherapy that had both beneficial effects and side effects and contraindications that were necessary to be observed in using the drug.

Now, you had drugs effective against specific target organisms and effective as prophylactic measures.

Senator NELSON. Let me ask this question, though. Is it not correct when using the word "safe" that you do not mean safe in general, you mean safe for this particular patient who has a particular