Department of Defense formularies, they supplement that by the laboratory clinical tests of the entire medical organization.

Senator NELSON. In order to make the selection in the first place, unless they have some clinical evidence to go on, and in many instances they do not, they go on the assumption that if it meets USP standards it is therapeutically equivalent. That is the testimony before this committee.

Mr. CUTLER. The USP says right in its own introduction that meeting USP standards does not assure pharmacological availability, which, as I understand it, is therapeutic equivalence.

Senator NELSON. Dr. Miller of the USP on page 508 of the hearing record, part 2 says:

> The important point, however, is that not more than a dozen drugs have presented problems with respect to physiological availability.

Exactly your words.

> Thus, to damn the entire Pharmacopeia of some 2,000 drugs for the failure of a mere handful is unscientific in the extreme.

This is Dr. Miller's direct, flat refutation of what you have just said.

Mr. CUTLER. Here is page XVII of the preface of USP:

> The term "physiological availability" connotes attribute of the dosage form of a drug that constitutes a measure of the extent to which the active ingredient is taken up by the body in a useful form. From a practical standpoint, the attribute is of useful significance only in respect to the dosage forms intended for oral administration. Progress has been slow in developing methods to measure physiological availability that would be suitable for USP use. Consequently, however desirable it is to give assurances of complete 'availability' to every patient requiring a USP article, the problem of providing objective standards and methods remains in the exploratory stage at this time.

Senator NELSON. Nobody argues with that.

Let me quote to you from Dr. Goddard's testimony.

The problem remains. There is no perfect chemical test to guarantee physiological availability. The perfect test is in a human being. But listen to Dr. Goddard:

> I do not think anyone can provide absolute assurance that they are putting equivalent combinations for every drug in the marketplace. But by the same token, I have not seen any good evidence from any firm, large or small, that their drugs are superior to anybody else's. I hear the statement made time and time again. I have challenged firms who have made this statement, show me evidence that their drugs are superior.

The assumption when you design a formulary, according to the testimony before the committee, is that if drugs meet USP standards they are equivalent. There are a handful of cases where evidence to the contrary has been shown. You have one of the handful before us, chloramphenicol, and we are going to get at the question of how careful your testing was on that drug and the deaths that have been caused by your product.

Now, Doctor, I understand that your product, Chloromycetin, has been responsible for deaths resulting from bone marrow disorders, is that correct?