and development needed to devise the cures for the many serious disease problems which still plague us.

However, I would like to feel secure, and I think this is almost the main point that I wish to make here today, Senator, I would like to feel secure for our hospitals and our doctors, and all of our people, that when a drug is ordered, it will be of the quality, purity, potency, and safety that it is purported to be.

Senator NELSON. Under the present law, all drugs are required to meet USP standards; isn't that correct?

Dr. CHERKASKY. Yes.

Senator NELSON. The issue you are raising here is that they do not meet those standards with sufficient consistency so that physicians can rely upon them all over the country?

Dr. CHERKASKY. Well, I think that that is one of the points, but there is also I think we are dealing partly with fact and partly with fiction, but the fiction in some ways is as disturbing as the fact. We are told that even if it meets USP standards, that does not necessarily mean it has a therapeutic efficiency that it should have. Maybe the granules should be of a different size.

As I say, partly in fact and partly in fiction, the whole climate has been created in this country with regard to drugs, primarily generic drugs, and with drugs as well from some of the major houses which makes us feel very uneasy about the use of a drug, depending upon its source of manufacture and so forth, and this to me is an intolerable situation.

Senator NELSON. You cite quality, purity, potency. Those are all factors for which USP sets standards. I don't know exactly what you mean by safety.

Dr. CHERKASKY. Make sure that it is not contaminated.

Senator NELSON. Those are all factors for which the USP sets standards and, according to the law a drug must meet those standards before it goes onto the market. Now we know from some tests conducted by the FDA that around 7 percent of the generic and trade-name drugs in a 4,600 sample test they made did not meet the standards. They were either under, or over potency or deficient in some other ways.

But you also claim that even if all drugs meet USP standards, they may not necessarily be therapeutically equivalent. Dr. Lloyd Miller of USP testified here that it is his opinion that if drugs met USP standards, there is no reason to believe or evidence, as I recall, that would show that they are not therapeutically equivalent. Do you have any observations on that?

Dr. CHERKASKY. Well, the drug companies, the major drug companies, should be authorities; I don't necessarily mean that they are. On the plane coming up, one of my colleagues gave me this handsome red book, which is entitled "Statements on Chemical Equivalence and Therapeutic Efficacy of Generic Drugs," given to us by Warner-Chilcott Laboratories, and the first item in the first section says:

> It has been shown by means of several examples—

This quotes an article—

> that neither USP or NF standards nor FDA regulations assure the therapeutic equivalency of generically identical pharmaceutical products.