

Senator NELSON. I assume when we get to the area of Government procurement of drugs, we will hear testimony from the appropriate person from the Defense Supply Agency. Go ahead.

Dr. SLESSER. This on page 10, Mr. Chairman.

I will read his direct words.

In our quest for quality pharmaceuticals, we found that we had to go one step further—

He is talking about a 10-step program which he described nine steps of, one of them involving laboratory testing—

we had to go one step further to complete our ten point quality assurance program. Therefore, a few months ago the Department of Defense approved the concept of requiring proof of pharmacological equivalency. The literature is replete with studies of factors, both biological and physiological, chemical, influencing the biological activity of drugs and drug products. This includes dissolution rates, disintegration rates, comparison of dosage forms of the same drug, and particle size as they affect biological activity, and blood tissue levels, absorption rates, and metabolism and excretion rates for drugs. This plus our complaint history on a score of select pharmaceuticals indicated a dire need for pharmacological equivalency testing. In essence DPSC will formulate a proposed testing procedure with the cooperation of government personnel, universities, or industry. This procedure will be submitted to the DMMB—

Which is the Defense Medical Materiel Board—

for professional evaluation and approval. The DPSC will include the pharmacological equivalency testing procedure in the specification. We will also document the bidders or offerors method of manufacture, specifications, procedures, and quality control for the production of the specific lot of materiel subjected to the testing required in the specification.

Now, this, of course, is over and above U.S.P. or N.F., because I think you can easily see that no compendium, irrespective of its nature, can cover all those links in the quality-control chain—the essential links—in order to make sure that each batch is safe and effective—when you consider the differences in the selection of nondrug components, differences in formula, in manufacturing procedure—the quality control differences and so forth.

Senator NELSON. If I understood correctly what the captain was saying, he was reciting careful procedures which must be followed to assure that U.S.P. standards were met, is that not correct?

Dr. SLESSER. No. He was in effect stating the inadequacy of U.S.P. or N.F. standards, because he found it necessary to convince the DSA policymaking people that another specification was necessary—namely, proof of pharmacological activity.

Senator NELSON. This puzzles me a little bit.

Today Dr. Lueck testified that the U.S.P. standards are the highest in the world, if I understood him correctly.

Dr. SLESSER. That is correct.

Senator NELSON. A week or so ago, the president of one of the major pharmaceutical corporations said that the U.S.P. was the highest standard in the world. Does this captain know of standards higher than those we have in this world?

Dr. SLESSER. No standard, Mr. Chairman, can suffice in lieu of or instead of the test for safety and effectiveness on human beings in a clinical study.

Senator NELSON. What we are talking about—the captain, and you—