Of these proven cases, one involves a product believed to have been distributed only in Canada—namely Bishydroxycoumarin by Charles Frosst and Company. Even counting this case in, however, the "deficiency ratio" is six in 900 or less than 0.7%.

It is U.S.P. policy to correct at once every form in inadequacy that is possible with the scientific information available. The U.S.P. Revision Committee is responsible for putting this policy into effect. The Committee consists of 60 members, each an expert in his own field. The members charged with the revision of standards are mostly chemists who are associated with pharmacy schools or pharmaceutical firms. At present, the number in each group is 17 and 12 respectively.

It should be stressed that regardless of the nature of his bread-winning job, each member serves as an individual, not as a representative of his school or firm. The members consult other experts widely. For example, as a matter of long-standing policy no F.D.A. staff members serve on the U.S.P. Committee. However, the closest sort of cooperation exists between the F.D.A. and the U.S.P., so the progress on drug standards is shared early and fully. In fact, Arthur F. Flemming, speaking as Secretary of the Department of Health, Education, and Welfare, observed in 1960, "I do not know of any organization that has a more interesting and significant relationship to the government of the United States than your organization."

The same relationship exists with scientists within the industry. Avenues of contact with industries are kept open in many directions. It is always possible that thoe who produced the drugs will discover better ways of testing them. Although the U.S.P. standards are generally regarded as being the highest in the world, they are also looked upon as subject to improvement as technical advances from it. A good example is that of the standards for thyriod tablets which, as indicated above, have been known to be deficient for years. These standards are about to be made as exacting as those for any other drugs through the application of findings made in the last few months and not yet published.

In summary, U.S.P. standards form the bedrock upon which the quality of American drugs rest. But like any foundation, the standards can be made broader and stronger as science progresses.

We trust that these comments will be helpful.

Senator NELSON. In any event, the insistence by USP and others is that there are rare cases where although these standards are met a drug may be produced that is not therapeutically equivalent. Everybody knows that you can coat a tablet so that it does not have any effect at all, even if you have the same active ingredients and the same excipients. But then it would not be within the USP standards. If USP set a standard that didn't guarantee absorption, they would correct it just as soon as the knowledge was available.

Dr. LUECK. Mr. Chairman, I respect the gentlemen you mentioned, Dr. Miller, Dr. Feldmann, Dr. Modell. But I believe there is quite an element of opinion in their statements. Now, I respect their opinion, but I think that to prove the opposite, the products must be tested side by side to prove the affirmative as well as prove the negative.

The fact is that there is an appreciable amount of information showing that products that meet certain chemical standards are not equivalent, and Dr. Slesser will cover that point; it is a long, laborious process to compare products.

For example, the study that we are engaged in presenting right now, Mr. Chairman, required something like 8,000 analytical tests just for this small study.

Senator NELSON. You say Dr. Slesser is going to address himself to this precise question?

Dr. LUECK. Yes, and provide additional information in that area.

Senator NELSON. I know he did from his prepared testimony, but