We find it helpful to explain this situation by saying that the USP and the NF provide the yardsticks against which the FDA measures the quality of drug moving in interstate commerce. This recognition is in keeping with the three-way separation of powers in our Government, since it results in having the standards set up by an agency other than the one charged with applying them. Mr. Walter G. Campbell, who served as the first head of the Food and Drug Administration and was its head for a longer period than anyone else, often expressed the view that the existence of the official compendia and their creation by an independent agency relieved the FDA of playing the dual role of sitting as a council that promulgates ordinances that it must, acting later as police, proceed to enforce. Regrettably, this concept was disregarded when batch certification of the antibiotics was decreed in the 1962 amendments to the Food, Drug, and Cosmetic Act, and we are aware of more recent suggestions that the Congress should authorize further extension of batch certification. If this course is followed to any significant degree, it will sound the death knell of the Pharmacopeia and the National Formulary as non-Government sources of drug standards.

Senator NELSON. I don't exactly follow that. Are you saying that the Government should not batch-test antibiotics, or that nobody should batch-test antibiotics?

Dr. MILLER. That is a two-way question. If I answered the second part first I would probably be answering the first part. We don't think batch certification of antibiotics is especially necessary, because we don't think antibiotics, as a class of drugs, are particularly different from other classes of drugs. There are many reasons why they came to be regarded as special and different, but penicillin is just about as stable as sugar, and it was on the basis of a lack of stability that the certification program was set up in 1944 as an exigency measure, a wartime measure, then it got written into law later, and was extended in 1962.

We do not think that as a class the antibiotics are particularly different from any other drugs that we use. Now that view is in conflict with that of the Food and Drug Administration, but there are obvious reasons why they should have an interest in retaining an authority that they have been granted, and of course don't want to give up.

Mr. GORDON. Dr. Miller, in the FDA drug recall list that we have, it seems as though penicillin contamination is one of the most frequent causes for recalls.

Dr. MILLER. But that is not an antibiotic certification problem whatsoever.

Mr. GORDON. Is it not?

Dr. MILLER. No, of course not. If you were to look for it, you would probably find other drugs contaminating other drug products just as much as you can find penicillin in other drugs. But it happens that penicillin contamination of other drugs is an important public health problem, because many people are sensitive to penicillin, and they should not be subjected to penicillin willy-nilly. It is just good manufacturing practice not to mix drugs, and penicillin was a particularly bad one to have mixed in with any other drugs.