First, by subjecting products to pharmacopeial tests, they can comment on the legal acceptability of these products.

Secondly, by using more sophisticated procedures and relating these to *in vivo* activity, they can show that legally acceptable products do not always meet the criterion of being "highly efficacious medicinally".

I. COMPLIANCE TO PHARMACOPEIAL STANDARDS

Our technology is such that products containing the same drug should be chemically and physically equivalent. But are they? To answer this question, it is first necessary to outline the procedures that the pharmaceutical analyst uses to assess products. For tablets, three basic procedures are used.

1. *Assay*

The analyst selects 20 tablets from a bottle, weighs them, reduces them to a fine power, assays a portion of the powder, and then calculates the amount of drug in a tablet of average weight.

2. *Weight Variation Test*

The analyst selects 20 tablets from a bottle, weighs each of these individually, and then checks for compliance to the standard. For example, if the average weight of the 20 tablets is 200 mg., two of the tablets may deviate from the average by more than 7.5 per cent but none may deviate by more than 15 per cent.

The object of this test is to control dose variation. If a tablet is too light, it will contain too little drug. If it is too heavy, it will contain too much drug.

3. *Disintegration*

The analyst selects six tablets and places these in a tablet disintegration apparatus. Disintegration is considered to be complete if the tablets have broken down into particles that pass readily through a No. 10 mesh screen. The mean maximum disintegration time for compressed and coated tablets is 60 minutes.

There are, of course, certain other tests that are used in specific cases. For the moment, we will set these aside and concentrate on these three basic tests. The first two deal with drug content and weight uniformity. A product could easily pass these tests and still not be therapeutically effective. It is only the last test that even pretends to judge products for their therapeutic effectiveness. However, it is a physical test and, because of this, is subject to much criticism.

Approximately a year and a half ago, I began to test the generic equivalency hypothesis. Our studies are just beginning but the results, to date, to say the least, are interesting. However, before I begin to discuss these, I would like to present some data that was recently released by the Food and Drug Administration in the United States.

The Food and Drug Administration assayed 4,573 drug samples and found that 8.2 per cent failed to comply with minimum standards. (PMA Newsletter,