has to know whether the drug exists as such in a base or whether it has undergone sime reaction with it. And, is the resulting product therapeutically active?

With respect to ointment bases Lafferty and Gross (15) reported that it had been established that the particle size of medicinals dispersed in ointment bases has a direct influence on tissue irritation, drug absorption and the therapeutic efficacy of the medicament, but that, "The examination of competitive products indicated a wide range of control or lack of control of particle size between various manufacturers of the same product." They studied many ointments, to name but a few, boric acid, zinc oxide and mercuric oxide, all U.S.P. They conclude by saying that here is another example where dosage forms can meet official requirements in active ingredient content yet vary widely in certain important characteristics, depending on the skill of the manufacturer.

To me, this is not surprising since we have no regulations governing such things as the type of fillers one can use, the size of the drug particle permissible, and so on. Yet such things are of extreme importance with respect to the performance of the finished drug product.

These are but a few examples of how drug products can be generically equivalent and yet be so generically unalike with resepct to their biological activity or performance.

Now that we have established the fact that there is a definite difference in similar drug products and that this difference may exist with respect to trade name products and generics let us examine the point even more closely. Let us take a common drug product—a generic one, Prednisone.

An examination of the Red Book reveals that some eighty-seven drug firms produce, not the drug chemical itself but the finished dosage form. Pharmacists have eighty-seven different sources for this product and the price for this product is going to vary.

How then could I be sure of any of these eighty-seven products? This I'll try to answer later.

Getting back to these eighty-seven companies producing the tablet form of this drug, how many of these same companies market an ophthalmic ointment or an injectable?

The answer is very simple—only a few.

Why? Again the answer is simple.

It costs money to produce sterile ophthalmics and sterile injectables, the profit margin would be too small when compared to a trade name product. And, of course, the market for this type dosage form isn't as great as that for tablets. There is more money to be made in the tablet area and also one doesn't have to bother with sterility control or special equipment and manufacturing procedures.

Thus, when pharmacists handle generic products or trade name drugs unfamiliar to them, they must consider the following:

(*a*) Is this product "equivalent" in all aspects to an established and therapeutically effective product they are familiar with.

(*b*) They must not be misled by some company advertisements which state that all its products are chemically assayed or that analytical data will be sent on request. This, in itself is meaningless with respect to the therapeutic activity of the drug product.

(*c*) They should ask for absorption and excretion data, blood level data or any clinical data available. This is usually available for quality products. Only with this type data can the pharmacist be reasonably assured that the product is therapeutically active.

Pharmacists have a responsibility, not only to the physician and patient, but also to the drug industry which is in business to develop new drugs and to produce quality drugs and therapeutically effective drug products.

Let me, at this point, touch briefly on some of the comments which have appeared over the past seven months in the Green Sheet of the publication "Weekly Pharmacy Reports" concerning this generic equivalent controversy. Since time does not permit any discussion, I'll just capsulize these.

Enforced generic system for welfare prescriptions under federal-state medicare program by-passed by HEW Department after fifteen months of vigorous internal discussion.

The cheapest or lowest-cost-drug concept has been all but eliminated for generic drug legislation in the 90th Congress. Senator Montoya's bill introduced January 11 would pay for the lowest cost drugs * * * which is of a quality acceptable to a Formulary Committee to be established under a separate bill.

Compulsory generic prescribing on government programs not feasible until *clinical equivalency* is proven. Both F.D.A. Commissioner Goddard and Surgeon