

Dr. MILLER. Yes, but we do not provide any standards.

Senator NELSON. You don't provide any standards?

Dr. MILLER. We don't provide the standards. We simply say, "Look to the Food and Drug Administration for the standards, because our standards would have no force."

Senator NELSON. Thank you.

Dr. MILLER. I was about to talk about standards of clinical performance or equivalency.

Senator NELSON. Yes.

Dr. MILLER. While standards of chemical purity or potency are now highly developed, a need is recognized in the case of a limited number of drugs for some measure of clinical performance. This reflects a desire for a demonstration that a given lot of a drug product, or preferably every lot of each brand of that product, is capable of performing as effectively as any other lot or brand of it. To satisfy this desire fully might require going so far as to use human beings who were ill with the disease for which the product was intended. Needless to say, this is scarcely practical and something short of that is being sought.

The scientific principle involved here is physiological availability, and standards for clinical equivalency rest in large measure upon clearer elucidation of the factors that affect it. Physiological availability is a characteristic of a drug product that determines the extent to which the active ingredient of the product may be absorbed by the body in a useful form. It is thus a measure of the utility of a drug product to the sick patient when and where needed.

USP STANDARDS AND PHYSIOLOGIC AVAILABILITY

It is perhaps not surprising that scientists and laymen alike generally pay more attention to the spectacular natural phenomena, such as an eclipse of the sun or the appearance on schedule of a comet, than they do to other less breathtaking and more frequent events. Some of the latter may actually have enormously greater effects on man and his environment, as for example a prolonged drought or deluge. Similarly, in pharmacy, the failure of some drug products, mostly tablets, to yield the expected effects has stimulated pharmaceutical scientists to undertake studies that have generally explained the failures in a fairly satisfactory way.

A whole new sub-branch of pharmacy thus sprung up for which the term "biopharmaceutics" has been coined. Without doubt, the world is much better off as a result of these biopharmaceutic studies, for the drugs concerned are important and physicians now can use them more intelligently and effectively. However, an aura of mystique arose that has tended to blur our perspective at times. In consequence, there has been a tendency to extrapolate the findings unduly; indeed, there are some among us who would cast doubt on every drug offered for the physician's use.

Regardless of the complexity of the pharmaceutical aspects, a very simple physiologic fact is concerned here. That is, some patients get less benefit from certain oral medicinal products because, contrary to expectation, the helpful part of the medicine stays in the gastrointestinal tract and fails to get into the blood. Obviously, this applies