

## BIOLOGICAL POTENCY AND ITS RELATION TO THERAPEUTIC EFFICACY

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### SYNOPSIS

The relation between the biological activity of drugs, expressed in terms of international units, and their therapeutic efficacy is neither simple nor constant, varying with the patient, the disease, and the drug, together with a number of other factors. Yet clinicians and pharmaceutical manufacturers understandably demand as simple a relation as possible between unitage and efficacy. The authors examine the implications of that demand and consider how far bio-assay in terms of units can be adapted to meet it. For this purpose they select three substances whose standardization is under consideration by the WHO Expert Committee on Biological Standardization: adsorbed diphtheria toxoid, delay insulin, and corticotrophin. In their conclusions, they consider that unitage should be regarded simply as a statement of the amount of active principle present, and that it should be taken as an indication of efficacy only when the efficacy depends on the content of active principle. Where different dosage-response relationships of an active substance, and of the same substance compounded to increase efficacy, entail the establishment of a standard for the "compound", the unitage of that compound must be expressed in terms of the number of units of starting material compounded. Finally, they consider that unitage, apart from indicating the amount of active substance, cannot be very useful to the clinician in his estimate of a drug's efficacy.

The most practical and widespread use of an international unit of biological activity is in characterizing therapeutic preparations, which may