

physician would prescribe by indicating, without regard to the producing source, only the generic name of the drug and the dosage form he wanted his patient to have. This would introduce the possibility of a number of variables which could affect the course of treatment of some patients.

For one thing, the physician would not know, unless he made a later check, exactly which one of any number of preparations the patient actually received from the pharmacy. Since different products purporting to contain the same ingredients may have different effects, the physician could not properly judge the patient's responses.

Not only may products which purport to contain the same active ingredients have *therapeutically* significant differences, there are significant differences between such products at least in terms of patient convenience and acceptance. If a medication is relatively pleasant and "easy to take", the patient is more likely to follow the regimen outlined by the physician.

Then too, most patients and most physicians, under ordinary circumstances, prefer to avoid the potential uncertainties of generic prescribing. The long-range trend of drug therapy has been the search for precise treatment—matching the particular therapy to the individual patient and disease. Even with the same finished form of the same drug, there are variables in patient response. Further unnecessary variations in the drugs themselves only serve to reduce the control of the physician over the circumstances he seeks to correct or prevent.

The members of P.M.A. do not contend that all patients would in every instance be adversely affected by "blinde" generic name prescribing nor that the physician should never elect to govern his choice of product by price differences in cases where they exist. However, the fact that variations occur in products purporting to contain the same active ingredients makes it advisable that only in exceptional circumstances should the physician fail to designate by trademark or manufacturer's name the source of the product he intends for his patient.

A. Product differences

Here, in brief, are selected aspects of drug formulation that affect the action or patient-acceptance of drug products.

Liquids.—Among drug preparations administered as liquids, by injection, ingestion, or application to sensitive tissue membranes, there can be distinct variations in particle size, stability, sterility, surface tension (which determines wetting or spreadability), and viscosity (which controls resistance to flow, or adherence).

Solids.—Important variables among tablets include the maintenance and effective release of potency; absorption characteristics of ingredients; tablet disintegration and dissolution rate characteristics; uniformity and biological behavior of delayed and sustained release compositions.

Lotions, creams, ointments.—Factors important to therapeutic effectiveness and patient tolerance include skin permeability, ease of application and removal, and lack of local irritation.

Other therapeutic variables.—For certain types of patients, specialized formulations provide significant elements of safety or tolerability. The allergenicity of the additive (filler or binder) substances in some brands of a pharmaceutical preparation may be reflected in undesirable reactions on the part of sensitive patients. Also, a quality manufacturer will design his formulation, if possible, to be compatible with other medications that may be added to it or taken with it.

Subjective factors.—A patient's acceptance of a drug preparation is also important. If the product is in some way obnoxious or uncomfortable to the patient, he will tend to avoid taking the prescribed medication. Liquids require palatability, freedom from nausea, pleasant "feel", freedom from grittiness and ease of swallowing. Odor and flavor can be of considerable importance, particularly when medications must be used over long periods of time.

Packaging.—Pharmaceutical products are frequently in direct contact with their containers for long periods of time. The choice of proper grades and types of glass, plastics, metal, rubber foil and other materials to prevent interaction with the components of a drug preparation, and to provide adequate protection for the contents requires specialized tests and skills of the highest competence.

Stability.—A drug product should be compounded to maintain its labeled potency throughout the expected period between its production and consumption by the patient. Care must be taken to assure reasonable shelf stability when