GENERIC EQUIVALENCY

The arguments for retaining brand names prescribing have been shrouded and wrapped in that nebulous cloud referred to as "generic equivalency." The paucity of convincing and well-documented data of clinical significance causes one to suspect that this situation has been grossly exaggerated. Should a product of one pharmaceutical firm be chemically equivalent and more effective biologically, then this would be a selling point which a pharmaceutical firm could use in its advertising. The firm could, with justification, capitalize upon this point in its advertising and utilize it as a reason for selecting the drug of that particular firm. The firm thus could boast that its product is superior and has this advantage over that of competing firms. Considerable stretch of the imagination is required for one to see the justification for the use of an alias for designation of a product merely on the basis of generic equivalency. For example, should ether be prepared by Squibb be found to be biologically and clinically more effective than that of competitive manufacturers, and I doubt that it would, a physician who is aware of this would request ether—Squibb. In the event Lidocaine U.S.P. prepared by Astra were demonstrated to be biologically and clinically superior to products distributed by a competing firm, this wold not necessarily interfere with a physician's choice to prescribe Lidocaine—Astra instead of the alias, Xylocaine. Neither would there be interference of the physician's prerogative to prescribe the product he deems most effective clinically, if indeed he can make such a distinction, and the best interest of the patient will still be served. The question of generic equivalency has been "ballyhooed" with both scientific and pseudoscientific data, so that it is virtually impossible to determine what is fact and what is fancy. The situation is almost laughable. Much is said about crystal size, the effect of binders and mordants, coating, etc. This all sounds impressive and has some basis of fact, no doubt, Mr. Chairman, but no one has said what happens to one of these elite "non-generic brand name drugs" when it is introduced into the stomach of a patient, the contents of which are not known, the acidity of the juices in the stomach are not known and other variable factors which are bound to exist are not known. What happens to one of these pills or capsules after they are introduced into the stomach and are followed by a martini, potato chips, shrimp remoulade, turtle soup, a steak, potatoes, some wine, salad and dessert. If a drug is readily soluble, the chances are excellent that chemical equivalency equals biological and clinical equivalency.

One cannot deny that in some cases biologic potency may vary from one product of one manufacturer to another or even from batch to batch of a given drug by a given manufacturer, but how much is known about all of this which is factual and clinically significant? It appears to me that no one has given this matter much thought over the years and now the matter is being called to the attention of the scientific community and we are becoming aware of something that only time will prove whether or not is important. The effectiveness of a drug taken before breakfast may differ from that of taking the same drug before lunch or before supper or at bedtime, or from one day to the next. Such variable factors as fever, the presence of other drugs, hydration and liver and kidney function may influence the efficacy of a drug. Generic naming must not be confused with generic equivalency. The two terms are distinct, separate entities and not synonomous.

ACCEPTABLE STANDARDS

Standards formulated by the U.S. Pharmacopeia, the National Formulary and other agencies are acceptable, reliable standards and should be adhered to at this time until additional well documented information is available, at which time these agencies and scientific groups can revise their standards. As time passes we will no doubt learn more about the so-called "biologic equivalency" and its clinical importance. The standards will then be modified in accordance with our added knowledge, but until such a time the present-day standards are adequate.

There must be a beginning to make order out of chaos, and now is the time to effect changes. The vociferous displeasure which will be voiced will be intense but it can be readily parried by asking, "Is what is being done in the public's best interest?" How can full disclosure of all details pertaining to a drug be anything other than in the patient's best interest?