

3. *Company Total-Value Product.*—The prescription pharmaceutical manufacturing industry is in competition for excellence. Responsible pharmaceutical concerns, under the stimulus of our competitive system commit themselves to expenditures and accomplishments in creative research, reliable production and marketing, and high standards of management. These organizations, who openly and widely identify their products by trademark or brand name, and in so doing identify themselves, are thus motivated to provide excellence in *total quality* of product and service. Such total control of quality of product and service is of significant value to dispensers and consumers of today's prescription medicines, exceeding by far the value of the product's ingredients.

In summary, patients, physicians, and pharmacists can best be assured of therapeutic control, reliability of product, and the value of total company service when the product is designated by trademark, brand name or other *responsible identification* of the people who stand behind it.

II. NAMES, STANDARDS AND REGULATIONS

The issues involved in drug prescribing and regulation cannot be approached intelligently unless certain terminology, references and practices are precisely defined and clearly understood. The following description of drug nomenclature, of the official reference guides to drug standards, and of government regulatory processes are presented here in brief summary.

A. How drugs are named

Most drug products have three names: the *chemical* name, the *established* or generic name, and the *trademark* or *brand* name. The first two names describe the same thing; that is, the chemical composition of the active therapeutic ingredient(s). The first is scientific and precise; the second is more convenient and concise. The relationship is analogous to that of the scientific term, *Homo sapiens*, and the more common and usable term, *man*. The third name—the trademark or brand name, on the other hand, refers to a particular manufacturer's formulation, and identifies the drug product with the originator or manufacturer. So, the completed analog would go like this: *Homo sapiens*, *man*, *John T. Jones*.

Chemical name

A therapeutically active compound, like all other matter, is composed of a combination of basic chemical elements. Once created or identified, a drug molecule is named in the laboratory according to standard practice in the field of chemistry.

Here is an example: *6-chloro-3,4-dihydro-7-sulfamoyl-2H-1,2,4-benzothiadiazine-1,1 dioxide*. This is the chemical name of a product compound widely prescribed to decrease excessive fluid content in the body—a diuretic. While long and cumbersome, this name is also precise for it serves as a complete identification of the compound to any trained chemist.

Established (or generic) name

Obviously, a drug compound must also have a shorter, more usable name. Such a name is originated by research or medical authorities involved in the possible therapeutic application of the chemical. The name is then submitted to review committees of the American Medical Association and of two standard drug references, the *U.S. Pharmacopeia* and the *National Formulary*. These three groups function through a coordinating group called the United States Adopted Names Council. If there is any conflict with existing names, or disagreement as to the meaning suggested by the proposed name, further negotiation takes place with the initial sponsor of the name. The Food and Drug Administration has veto power over final selection. If entirely satisfactory, the name is then transmitted to the World Health Organization, which works with the official pharmacopeial organizations of many nations.

Once a name for a drug compound has been approved by the Adopted Names Council, or by a regulatory body it is thereafter known as the "established" name, also referred to as the "generic," "official," or "nonproprietary" name; the most popular of these terms, and the one that will be used in the balance of this paper, being, "generic".

In the case of the compound illustrated earlier, the established or generic name adopted is *hydrochlorothiazide*. Still quite a mouthful, but much easier than: *6-chloro-3,4-dihydro-7-sulfamoyl-2H-1,2,4-benzothiadiazine-1,1 dioxide*.