THE IMPORTANCE OF MANUFACTURER IDENTIFICATION

A review of the issue influencing the choice of drug products in the interest of more precise therapy and greater assurance of reliability

(By the Pharmaceutical Manufacturers Association, October, 1965)

I. INTRODUCTION AND BASIC POSITION

The member firms of the Pharmaceutical Manufacturers Association (P.M.A.) believe that competition in prescription drug production and distribution, under a system whereby physicians' prescriptions and drug labeling and advertising prominently identify the source of products by company name or product trademark, accelerates the pace of drug discovery, and encourages the highest standards of safety and effectiveness and the most economical medical care.

This statement outlines the bases for this belief and discusses the public health importance of a drug identification system.

As the statement will show, there are variations in finshed drug products resulting from the different formulations and production methods of individual manufacturers—differences that exist even though the pharmacologically active ingredients may be chemically identical. These differences are not necessarily related to product quality, but they may be. In any event they can affect the therapeutic value and physician or patient acceptance of a given finished drug. The system of using trademarks or brand names is the best known and most effective means of providing *responsible identification* of finished products, thereby giving the greatest assurance of reliability and predictability in drug therapy.

And, for the same reasons that prevail throughout all American industry, the trademark or brand name system fixes the responsibility and the reputation of the manufacturer, causing him to seek ever higher levels of excellence in his total performance.

Modern medical care owes much to pharmaceutical advances. Medical and pharmaceutical scientists have turned one key after another in the search for specific remedies to treat the myriad ills responsible for suffering and premature death. P.M.A. member firms alone have contributed more than $2 billion-worth of research to this quest since 1945.

Thirty years ago, for instance, there was only a small handful of drugs which would safely cure an infection in man. Today there are many, ranging from the broad-spectrum antibiotics to a compound so selective in its action that its use is restricted to a specific virus infection in the human eye.

Around one billion prescriptions are written by the nation's physicians and dentists every year in the United States. Practically all of the products prescribed and used come from the nation's pharmaceutical manufacturing laboratories. Precise dosage forms and formulations usually identified by trademark or brand name are made available to the physician and are dispensed by a pharmacist to his patient.

The proposition that the use of drug trademarks or brand names is in the public interest is based on three principles that are fundamental to the continuance of excellence in drug discovery, production, and therapy. They are:

1. *Therapeutic Control.*—The physician responsible for the care of the patient must determine which drug product is needed in each case. Many important and widely used drug products do not have legal standards. Even when drugs are covered by such standards, there are difference among individual formulations of products of different manufacturers which can be significant for some patients. The physician must decide whether therapeutic precision, reliability, or convenience calls for a particular formulation for a given patient, or the extent to which the selection can be delegated to another member of the health team, e.g., the pharmacist.

2. *Reliability of Product.*—A physician should be in a position to judge and select products on the basis of his knowledge of the reliability of the product and experience with the past performance of the producer. This method gives added protection to the patient—who should be assured that high standards of quality and reliability are being used in prescribing and dispensing pharmaceutical products for his use—and promotes high standards of production and control that go beyond minimal enforceable levels.