Ethical pharmaceutical manufacturers perform definitive stability studies of their products. Not only are they studied in a total quality control system during developmental research and manufacture, but also subsequent to distribution.

Recently, Parke, Davis & Company initiated a study to compare a product originated by the company with several products containing the same active ingredient now available from other firms by nonproprietary and brand names. This study was undertaken to determine whether there are any significant differences between these products and the Parke-Davis product. Preliminary information on this study, available at the writing of this statement, indicates that differences were found between products in commercial distribution. More details on the study will be available shortly. They will be submitted as soon as they are received.

The company which has developed a drug product knows it intimately and is continually learning and studying new information concerning it. Its systems of manufacture and quality control are designed to meet the particular needs or requirements of the specific product. All the control procedures that are needed in duplicating the product as determined during the research phase are rigidly followed.

These methods of control are what make the drug clinically effective, batch after batch.

In summary, Mr. Chairman, analysis has its limitations. There are many factors that can produce errors, and therefore, can produce varying results.

Analysis of a drug product is useful, and in most cases essential, but it should only be used as a guideline in determining if the controls established for the manufacturing and the packaging operations are sufficient to insure the quality of the product.

Analysis alone is insufficient to assure quality. Thus, a rigid program of totally controlling all the steps involved in producing a final product is the only way a manufacturer can assure the clinical effectiveness of his drugs.

General Principles of Total Control of Quality in the Drug Industry

(As approved by P.M.A. Board of Directors on June 22, 1967)

INTRODUCTION AND DEFINITIONS

The quality of a product is its degree of possession of those characteristics designed and manufactured into it which contribute to the performance of an intended function when the product is used as directed. The quality of medicinal and related products is the sum of all factors which contribute directly or indirectly to the safety, effectiveness, and acceptability of the product. Quality must be built into the product during research, development, and production.

Total control of quality as it applies to the drug industry is the organized effort within an entire establishment to design, produce, maintain, and assure the specified quality in each unit of product distributed. The effort should not only establish specifications for product acceptance but should provide procedures and methods for achieving conformance with such specifications.

The large variety of substances used in this industry, the complexity of its products, and the various types of company organization make it impossible to design in detail a single universally applicable system for the total control of quality.

OBJECTIVES

The ultimate objective of a program for the total control of quality in a drug company is the attainment of perfection in meeting specifications for a product of high quality. It is a program designed to assure the professional user or ultimate consumer that every lot of a product conforms to specifications and that each dose distributed will fulfill the representations made in the labeling and will meet all legal requirements and such additional standards as the management of a firm may adopt.