sible producers know that their products are so judged, they strive to achieve and maintain the best possible reputation for quality. The physician and his patients obviously benefit greatly from this system in which the needs of medical care are matched by the aspirations of the producer.

Standards and legal enforcement, as a practical matter, can concern themselves only with certain major aspects of product specification. Only through the active desire and efforts of the producer to excel can the principle of "voluntary compliance" give the assurance of quality that the public must have. This desire to excel is a built-in feature of the responsible identification system.

The P.M.A. defines quality control as follows:

"Control of quality in the formulation, manufacture, and distribution of pharmaceutical, biological, and other medicinal products in the organized effort employed by a company to provide and maintain in the final product the desired features, properties, and characteristics of identity, purity, uniformity, potency, and stability within established levels so that all merchandise shall meet professional requirements, legal standards, and also such additional standards as the management of a firm may adopt." [1]

Testing a finished pharmaceutical product for quality is a difficult and complex laboratory problem, because quality is often a hard-to-trace feature that must be built in—during production, from raw materials to formulation, through in packaging and all intervening operations up to the delivery of the products to the consumer. As an example, long-range stability is a feature of quality made possible by careful research, formulation, and production. The only completely valid test of this feature is time. Any short cut or lack of skill during manufacture that results in deterioration of the product months later often cannot be detected until the weakness appears. And only fortuitous spot-checking would pick up the inadequacy before many patients have received the faulty medication.

For these reasons, federal regulations are now stressing standards of good manufacturing practice, even though such standards are difficult to enforce unless the company itself it motivated to meet them.

The storage facilities for raw materials; the facilities for bulk formulation; the layout of the plant; the work-flow process; the precision of the equipment; the training and experience of supervisors and workers; the standards and disciplines of internal quality inspectors; the attention to quality control technology; the searching for solutions to, rather than avoidance of troublesome problems; the willingness to assume the costs of detecting and correcting error; the intelligence of information flow, and record keeping—these are among the elements of responsible, quality production.

These elements are recognized by most experts in drug production. However, they emphasize the difficulty encountered by an individual physician or pharmacist in making quality judgments without the advantage of relying on the producer's known reputation. The drug standards regulatory system (see pages 7 to 14) is clearly not designed to replace private manufacturing responsibility.

It is therefore clear that the system of competitive stimulation to quality, through responsible product identification, provides a service of inestimable value.

V. THE VALUE OF TOTAL COMPANY PERFORMANCE

The third positive value of the brand name system, which goes beyond reliability of product, has been expressed in this way:

Company Total-Value Product.—The prescription pharmaceutical manufacturing industry is in competition for excellence. Responsible and identified pharmaceutical concerns, under the stimulus of our competitive system commit themselves to expenditures and accomplishments in creative research, reliable marketing and production, and high standards of management, personnel and comprehensive service. 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 alone.

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[1] General Principles of Control of Quality in the Drug Industry, adopted by the Board of Directors of the P.M.A., May 3, 1961.