9. Quality companies have the facilities and will to move quickly to meet *emergency situations*, which might involve massive shipments to disaster areas or the formulation of a special dosage of a product to treat rare individual cases.

10. Quality companies as a service to physicians and patients frequently *stock lifesaving medicines* for which there is no profitable market, medicines such as an anti-venom for the black widow spider bite.

11. With an established company, the public is assured that there will be *continuity* of its high-quality products, an especially important point for persons with long-term chronic illness helped by a particular medication.

12. With no reference to its contribution to health, an established company usually represents a significant *contribution to the economy*, in terms of employment, purchases, payments of taxes and general desirability of an entire area.

VI. THE ALTERNATIVE TO ABSOLUTE GOVERNMENTAL REGULATION

Earlier sections discussed the limitations of existing standards and government regulation of the pharmaceutical industry. The intent of these sections was to show why these measures alone cannot be relied upon to provide the best medication and the best therapy. Nevertheless, they are an indispensable part of our present productive system. On one hand, they provide restraints against gross actions contrary to the public interest. On the other hand, they represent a base from which competitive companies build toward ever higher levels of total quality performance in production and in service.

In fact, it frequently happens that the companies in the vanguard introduce advanced standards and techniques that are later codified into the regulations. In this way, the regulations keep moving ahead. The ultimate effect of this process may be the virtual elimination of companies in which little or no effort is made to pursue the goal of total quality. For once a company makes a significant commitment to quality performance, as outlined in the preceding section, its course tends to move steadily upward.

It might be argued that, if regulations and enforcement have this beneficial effect, why do we not upgrade all the regulations and increase their enforcement?

To begin with, it has been shown in other sections of this statement that no amount of regulation could possibly cover all the important aspects of drug discovery, production and therapy. In addition to what has been said before, it should be recognized that the complexities of drug production make it not only impractical but completely unfeasible to develop such detailed standards and such complete enforcement as to oversee the the detailed operations carried out in the production process. For instance, raw materials and intermediates for the production of drug ingredients may be collected from a number of sources, the active ingredients manufactured in various stages and even in more than one plant, and incorporated in a number of products and a number of dosage forms of each product. During this process, literally hundreds of laboratory tests may be conducted. The most complete government regulation attempted to date has not been sufficient to oversee all details of production and testing. Government regulation simply cannot substitute for competition in stimulating the achievement of superiority in discovery and production. Unless legal standards set by the government permit the free play of competition such as that evidenced by the trademark system, it could easily result in higher economic costs without providing additional benefits.

Instead of considering ways to place research or production of pharmaceuticals, or any other consumer products, under airtight governmental domination we should work toward further perfection of the present balanced and flexible system which is the foundation of the most inventive, productive and quality-conscious pharmaceutical industry in the world. It is clearly in the interest of everyone concerned to keep it that way.

VII. SUMMARY

In briefest summary, the position of the Pharmaceutical Manufacturers Association with regard to the responsible identification of product and manufacturer in drug therapy, is as follows:

Pharmaceutical products, even those with the same principal therapeutic ingredients, differ from manufacturer to manufacturer in terms of quality and formulation, either of which may influence proper therapy.