doing business and their contributions to the public health, are generally much less than those of the innovator companies.

The Innovator vs. the Non-Innovator

It is not an exaggeration to say that much of the misunderstanding that exists with respect to the drug industry arises from the failure to distinguish between these different types of manufacturers. The company which has the complex and extensive facilities and the highly-trained personnel necessary to discover and develop drugs which someone else has not already marketed maintains cost burdens which are reflected in its prices. The non-innovator does not support such effort and therefore does not incur the expense in time and dollars necessary to make comparable vital contributions to the health of mankind.

The innovator must assemble and support a highly specialized team of research scientists such as physicians, pharmacologists, toxicologists, virologists, biologists, chemists, biochemists, pharmacists, engineers and other technical specialists. When their knowledge and skills are applied to a disease problem, there is no way to tell in advance how much time and money will be required to find a solution, if, indeed, one is found at all.

The discovery of a new potentially useful product moreover is merely the beginning. It must then be developed, another long and costly procedure which often requires more people, more processes and more time than the original discovery. This stage requires years of animal and clinical testing, and the submission of a New Drug Application, plus exhaustive supporting data to the Food and Drug Administration.

The approval of the NDA, clearing the product for marketing, marks the point at which the manufacturer may begin for the first time to recoup his investment. This step, alone, from the time the NDA is filed, can take from 18 months to five years, sometimes longer.

Once cleared for marketing, an extremely costly, but necessary effort is then required to make the product known to the physician, the pharmacist, and other professionals who will be working with the new agent. While there are those who would suggest that the promotion effort is too costly, or not necessary, the fact is that advertising is the most economical and efficient means of getting the facts about the new product to the physicians who need them. Journals of medicine, pharmacy and nursing provide the vehicles. These promotion costs cannot be avoided if information is to be communicated. It is a necessary cost that the innovator must bear.

Because the innovator discovers new compounds and health-saving uses for them that have never before existed, he must be particularly sensitive to, and capable of, assuring purity, potency and safety through the uncompromising high quality of his products. Quality control and quality manufacture are the *sine qua non* of the research-oriented pharmaceutical industry. These precise disciplines are inextricably linked with the operation of the innovator firm. Briefly, they consist of indispensable specifications and tests for each ingredient in the formula, proper design and formulation of the product, multiple inspections and tests during processing and packaging, final product checks, and the preparation of detailed and meticulous records to show the complete manufacturing and control history of each batch, and to enable the manufacturer to trace his products after shipment. Quality firms are well organized to recall with precision from all commercial channels any particular lot of a suspected drug product at any time, or to provide emergency advice as to where a particular drug product can be obtained when needed.

The medical profession not only demands quality in drug products but it also expects the product to be available in every form and dose that might be needed to treat a wide variety of conditions—including capsules, tablets, injectables, oral and topical liquids, concentrates, suspensions, suppositories and ointments. Not all are commercially profitable, but a capsule cannot be used to fill a prescription for an ointment, nor a cencentrate when an injection has been ordered.

Innovator firms accept this responsibility as a matter of course. The non-innovator, in contrast, frequently does not feel obligated to provide the drug product in every possible form. Rather, his tendency is to concentrate on the most heavily prescribed and the simplest and most economical forms to produce.

Beyond the production process, the drug product, in all its forms and dosages, must be available when it is needed, where it is needed. Through his system of distribution points, the innovator reaches the entire nation. Furthermore, through the same system, he can cover an emergency within hours in virtually