The industry's reaction to the presence of Food and Drug Administration regulation has been apparent primarily in the area of the certification of new drug applications. In order to secure permission to market a new drug, the applicant must submit a sufficient amount of clinical and experimental data to establish that there is no significant danger connected with the proper use of the drug, *i.e.*, that its acute toxicity is sufficiently low to let it be considered a safe drug. It takes time to conduct sufficient experiments and carry out enough clinical studies to determine probable toxicity in general use. It takes still more time to have the application studied and processed. In drug marketing, many firms are often working on the same product at the same time, and each desires to cut the period between discovery and marketing to an absolute minimum, for the order of priority in market appearance usually determines the relative sales ranking for different brands of a given drug. Consequently, the motivation is to limit experimental and clinical work to the minimum acceptable level,[55] to skip stages in product development, such as the pilot-plant stage, and to influence the staff of the Food and Drug Administration in such a way as to facilitate rapid approval.[57]

The response of the ethical drug industry to its specific economic framework may be summarized as follows: the employment of the patent privilege to erect barriers to entry into the production of specific patentable drugs, the substitution of product differentiation for price competition, and the use of the accompanying techniques of sales promotion to minimize the impact of the price competition that might be offered by smaller firms. This is accomplished in three ways: the vast bulk of advertising done by the major firms tends, by its mere magnitude, to obscure the very existence of small, non-advertising generic sellers; the employment of opaque brand names for advertised drugs makes it formidably difficult for buyers to detect the existence of lower-priced, generic equivalents; and the campaign of disparagement renders suspect the quotation of a low price. No price competition need ever develop for patented drugs; for non-patented drugs, product differentiation, the adoption of deliberately confusing nomenclature, and the waging of a never-ending campaign of disparagement against low-priced drugs can effectively substitute for price competition, and prevent small, low-priced sellers from taking over any appreciable amount of the prescription drugs market, even though the absence of economies of scale or other barriers to entry will permit small sellers to undersell large by remarkable margins. This has been accomplished in the face of the presence of governmental inspection to insure the quality of all drugs merely by the extension of the policy of disparagement to include the adequacy of the Food and Drug Administration's facilities for making inspections.[58]

III. EVALUATION OF MARKET PERFORMANCE IN THE ETHICAL DRUGS INDUSTRY

A. Varieties of competition among drugs

There seem to be three main dimensions of competition: price competition, product competition, and product differentiation. While price competition is not

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[56] This is naturally deplored by physicians and medical educators. Dr. C. D. Leake of Ohio State University noted pertinently: "There is no shortcut from chemical laboratory to clinic, except one that passes too close to the morgue." *Id.*, pt. 18, at 10418.

[57] Dr. Barbara Moulton, formerly with the Food and Drug Administration, testified that excessive deference was at times shown to impatient applicants. She testified that if the medical officer in charge of the evaluation of a new drug application is not satisfied as to the evidence of its safety, the applicant will frequently make an appointment with the medical director. She continued: "I have known such conferences to be followed by an order to the medical officer to make the new drug application effective, with the statement that the company in question has been evaluating new drugs much longer than the medical officer, and should, therefore, be in a much better position to judge their safety." *Id.*, addiction danger warning on the label of a tranquilizer was refused by her superior, whom pt. 22, at 12025. She related an experience of her own in which her request to place an addiction danger warning on the label of a tranquilizer was refused by her superior, whom she quotes as saying, "I will not have my policy of friendliness with industry interfered with." *Id.*, pt. 22 at 12032.

[58] The large firms, acting through trade associations, have been instrumental in contributing to the inadequacy of governmental inspection. Prior to 1953, the Food and Drug Administration had broad powers to inspect plants as well as products. The Factory Inspection Amendment of 1953, supported by the major firms, made it possible for drug makers to refuse to allow inspection of significant phases of drug operations. Large as well as small firms have not hesitated to avail themselves of this privilege. Testimony of G. P. Larrick, *id.*, pt. 22, at 12113.