THE FORTUNES OF ECONOMIC REFORM LEGISLATION: THE CASE OF THE DRUG AMENDMENTS ACT OF 1962

(By Henry Steele 1)

I. INTRODUCTION

On April 12, 1961, the late Senator Estes Kefauver introduced a bill (S. 1552, 87th Congress, first session) to amend the antitrust and food and drug laws with regard to the prescription drugs industry. This bill, the outcome of extensive hearings held by the Subcommittee on Antitrust and Monopoly of the Senate Judiciary Committee in 1959–1962 regarding administered prices in the drug industry, embodied provisions to prevent monopolistic abuses in drug marketing. The Report issued by the Subcommittee established the existence of considerable monopoly and oligopoly power on the part of major drug firms, and indicated the extent to which such market power was obtained by virtue of patent privileges, excessive advertising, and other marketing practices which tended to augment the imperfection of market information in the interests of the larger firms.²

II. ANALYSIS OF DRUG MARKETING PRACTICES

An economist would briefly summarize the drug marketing situation as follows: demand for many prescription drugs is almost perfectly inelastic. Supply can be restricted by drug firms which secure product patents and refuse to license them. The resulting enormous profit margins on such products (factory costs may be less than 10 percent of wholesale price 3 stimulates entry, which take the form of imitative research activity on the part of other drug firms, aimed at devising a substitute for the patented drug which they can patent and advertise as superior to the original. Rivalry is thus diverted from price competition to product differentiation, as rival patented drugs attempt to take over the prescription market for a given group of disorders by intensive advertisement to doctors (the only agents qualified to prescribe) through direct mail, itinerant salesman (detailmen), and the sponsoring of medical conventions. High unit profit margins can finance large (and often imitative, duplicative, and wasteful) research programs, overpowering advertising campaigns, and still yield very high profits on investment. Since costs are low, and economies of large scale production apparently unimportant, small firms might be able to compete with large firms on a cost basis, but they suffer from two disabilities. Being unable to finance sales campaigns, their products do not come to the attention of the prescribing physician. Furthermore, the detailmen employed by the major firms make a practice of disparaging low-priced drugs, inducing the physician to equate low price with low quality. At best, the physician may not be very price-conscious, since he does not pay for the drugs he prescribes.

The situation is aggravated by weaknesses in patent laws and practices, and in the regulations governing drug advertising. Patent protection is absolute as regards a given compound, but weak as regards slight variations from that compound. The game of "molecular manipulation" is a popular one with drug firm research personnel: the goal is to devise a derivate compound which has the same therapeutic effect as some primary patented compound, but which by virtue of its marginally different chemical structure can be patented as a different drug and advertised as a "new and superior" healing agent. Patents can also be obtained for naturally occurring substances if never previously isolated, for processes occurring in nature, such as fermentation, and even for combinations of existing patented drugs. But since most major drug firms have research programs which substantially duplicate each other, near-simultaneous discovery of the same drug is a not infrequent occurrence. When several patent applications covering the same compound are received by the patent office, an interference is declared, and the parties attempt to assist in resolving the question of priority to the satisfaction of the patent office. There is, however,

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² Study of Administered Prices in The Drug Industry, Report of the Subcommittee on Antitrust and Monopoly of the Senate Judiciary Committee, Pursuant to Senate Resolution 52, Eighty-Seventh Congress, First Session, Washington, D.C., Government Printing Office, 1982

^{1961.} 3 *Ibid.*, pp. 15–16. 4 *Ibid.*, p. 16.