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# An evaluation of various economic aspects of the American drug industry

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# AN EVALUATION OF VARIOUS ECONOMIC ASPECTS OF THE AMERICAN DRUG INDUSTRY

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# CHAPTER I

## STATEMENT OF THE PROBLEM

### Introduction

The drug industry, because of the close relationship between its product and the health of the consumer, represents a very important area of manufacturing. It is hardly an exaggeration to say that drug manufacturers and distributors are dealing in matters of life and death. Therefore, although the industry cannot be expected to operate without the expectation of profit, there is a legitimate area of concern surrounding the prices of the products and the possible effects upon these prices of operations within the industry.

The drug industry is said by its critics to enjoy quite high profits. In recent years particularly, high profits have derived from the fact that the industry as a whole has had a number of successful innovations, which tend to be profitable in any industry. The apparently high level of profits, the seemingly high prices of medicines, the inflexibility of prices and the economic structure of the industry have attracted the attention of investigators. The industry represents the fourth of a series of industries studied by the Subcommittee on Antitrust and Monopoly, a

subcommittee of the Committee on the Judiciary (the Kefauver Committee) with respect to prices which some members of the subcommittee thought gave evidence of being "administratively set and maintained," therefore insensitive to changes in the market.[1]

There are two important factors the Kefauver Committee made note of. As Senator Kefauver pointed out, the buyer of a product offered by the drug manufacturer is a "captive" consumer. He may not legally buy the product without a prescription. Once a doctor's prescription is written, he must buy only that product or go without the medicine he needs. Moreover, he who selects the product does not buy it; he who buys it did not select it.[2] The second factor of significance according to the committee's report is that the drug industry is characterized by an inelastic demand for its products and therefore it is unresponsive to changes in prices. Presumably there may be a few consumers who, if they are unable to buy high-priced drugs, go without them. But they are probably in the minority. The amounts demanded

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[1]U.S. Senate, 87th Congress, 1st Session, "Administered Prices, Drugs," Report of the Committee on the Judiciary, United States Senate made by its Subcommittee on Antitrust and Monopoly Pursuant to S. Res. 52 (Washington: U.S. Government Printing Office, 1961), p. 3, hereinafter referred to as "Kefauver Report."

[2]Ibid., p. 3.

of the drug industry would not in any case, be very responsive to price reductions. This means that one check on high prices which exists in many other industries, a reduction in sales volume, is absent in the drug industry. These salient aspects of the price problem with respect to drugs put a rather different complexion on the issue than would be the case with respect to some ordinary consumer item.

The importance of the problem and the magnitude of the industry may be indicated by the dramatic expansion of the drug industry especially in the last generation. Roughly thirty years ago, the total money spent for medicines in the United States was about $715,000,000.[3] Today, annual sales in the industry respresent $2.5 billion.[4] In less than two decades, moreover, total expenditures for prescription drugs in the United States increased ninefold. In 1958, an estimated $1,800,000 was spent on them. The average price per prescription jumped from $1.51 in 1947-1949 to $2.62 in 1956, a seventy-three percent increase during a period in

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[3] C. Rufus Rorem and Robert P. Fischelis, The Costs of Medicines, The Manufacture and Distribution of Drugs and Medicines in the United States and the Services of Pharmacy in Medical Care. Publication of the Committee on the Costs of Medical Care: No. 14. (Chicago: University of Chicago Press, 1932), p. 4.

[4] Kefauver Report, p. 1.

which the cost of living went up only eighteen percent.[5] This would seem to indicate particularly great inflation in the cost of drugs. But the reader must keep in mind that the drugs we are using today are frequently not only new and different but very much improved and this seemingly disproportionate rise is not necessarily genuine.

With the disproportionate rise in drug prices have come certain criticisms which were not previously made against the industry. A generation ago, at a time when there were frequent protests against doctors' fees and hospital bills, there were few complaints about drug prices. There was some concern with quality and therapeutic claims. But the only attack made at that time against the industry and its prices which approximates the charges being made at the present time was the protest that doctors wrote prescriptions for well-known proprietary medicines which could have been purchased more cheaply over the counter.[6] Such a protest was not wholly unlike the present controversial discussion of the advantages and disadvantages of prescription by brand names and prescription by generic names, i.e., according to the chemical composition of the medicine. But the issue of high price of drugs as such was not a prominent

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[5]"The High Cost of Rx Drugs," Consumer Reports, November, 1958, p. 597.

[6]Rorem and Fischelis, op. cit., p. 5.

one at that time.

It is argued by many that the present seemingly high cost of drugs is at least partly attributable to the cost of technological innovations and research. Since the development of the so-called "wonder drugs," antibiotics among them, research and innovation in the drug industry have undoubtedly made valuable and appreciable contributions to the health of the nation. It may be suggested that it is innovation and its effect on competition among drug manufacturers, together with related problems of patents and licensing, which have sent the prices of drugs up sharply and out of proportion to the general price rise. Connected to this problem is the need for extensive and expensive promotional procedures by which each manufacturer must put its new product before the physicians.

The specific issue of collusive pricing and violations of the Sherman Antitrust Law arose when in 1953 the Federal Trade Commission began to show an interest in the drug industry and authorized an inquiry into the manufacture and pricing of antibiotics. The inquiry did not get under way until 1956 and in the next year a 361-page report was issued containing data which formed the basis of a 1958 complaint of the Federal Trade Commission against six manufacturers of antibiotics. The prices of these items remained unchanged while the prices for penicillin went down steadily,

although the process of manufacture was quite similar.[7] It was also charged that the drug industry was taking unfair advantage of the public and the government in the Salk vaccine program. Bids received by the United States Public Health Service from Lilly, Pitman-Moore, Wyeth, Sharp and Dohme (of Merck Company) and Parke-Davis were identical. Price-fixing was charged and the Department of Justice took action in May, 1958, under Sections 1 and 3 of the Sherman Law, the charge being fixing prices by agreement.[8]

In 1961, two major antitrust indictments were brought against the industry, one against a pharmaceutical association and the other against three drug companies. Both were criminal indictments. The former resulted in trial and conviction. The latter indictment was dropped for lack of supporting evidence.

## Scope of this Study

The focus of this thesis will be the alleged excessive market power or abuse of market power by firms in the drug industry. To this end, it will be necessary to discuss such aspects of the industry as prices and profits, patenting and licensing, innovation, promotion and generic versus

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[7] "The High Cost of Rx Drugs," p. 597.

[8] Ibid., p. 598.

brand name prescription. But since it is essential to limit the area of investigation, these considerations will be entered into only as they relate to the main focus of the study. The drug products under discussion will be "ethical" products. These are products requiring prescriptions written by a doctor, and without which the buyer cannot purchase the drug, as contrasted with proprietary medicines, such as aspirin, which can be bought over the counter.

The specific questions to which answers will be sought are as follows:

1. Assuming administered prices, found wherever pure competition does not prevail, are these prices socially evil?

In this connection, we are concerned not with whether there is or is not sufficient evidence of price-fixing arrangements for a conviction, but whether the degree of market power is harmful to the economy. In other words, how much competition is socially and economically useful? How "pure" can we expect competition to be?

2. Are the prices in the drug industry too high in terms of unwarranted profits and the considerations of humanity related to the sale of medicines?

Here, we shall be concerned with possible solutions. If prices are too high, what specifically causes this situation? What changes could be made to put prices within reach

of the ordinary consumer without damaging the profit position of companies? What bearing does the possibility of prescription by generic names have on this situation?

In the course of answering these questions, an attempt will be made to draw some definite conclusions on these highly controversial issues. Proposals and recommendations for further study will be presented.

## CHAPTER II

## PATENTING AND LICENSING IN THE DRUG INDUSTRY

Spokesmen for the drug industry state that there are over 1300 firms in the whole industry. Whether this is precisely true or not, there are at any rate only 22 such drug companies investigated by the Kefauver Committee; these are the major companies in the United States. Differing degrees of economic concentration were revealed by these investigations, according to whether concentration of production or concentration of sales (i.e., "control of the market") was the point at issue. Thus, nine principal hormone products are produced by only 7 of the 20 largest drug companies. Diabetic drugs are produced by 5 of the 20 largest, and tranquilizers by 6. There are 3 producers of sulfas, six producers of vitamins, eight of antibiotics other than penicillin, and seven of penicillin. Small manufacturers are a relatively unimportant factor in the ethical drug industry. For instance, in three of the four leading steroid hormones, small businesses (any firm other than the 22 companies investigated) have no part at all.[1]

The weak position of the small companies is determined

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[1] Kefauver Report, pp. 69-72.

not by the amount of capital needed to engage in production, but rather by the patent restrictions existing in the industry. The United States, contrary to the practice of most countries, does grant patents on pharmaceutical products. Patents on the processes of producing drugs are also granted by the United States and most other countries. In this discussion, with some exceptions, however, reference to patent protection means patents on the drug products themselves. In drugs, as in many chemical industries, process patents are not a strong form of protection because by a slight change in the process a patent can be evaded.

The limitation of patent protection for pharmaceutical products is historically related to social thought of the nineteenth century during the period of the industrial revolution. It was believed then that if the inventor of chemicals or drug products were limited to his process others would be stimulated to find new and improved processes which would make the product more available in greater quantities and at lower prices.[2] But patents are apparently not absolutely necessary for the stimulation of research, according to one authoritative report on expansion of research

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[2]Leonard J. Robbins, "Pharmaceutical Patents in Foreign Countries," Journal of the Patent Office Society, Vol. 37, 1955.

facilities in the drug industry in European countries which do not grant them.[3]

Patents potentially may, according to one theory, become an important factor in restricting competition, rather than stimulating it, and this in spite of the legal limitations which the Sherman Anti-trust Act places on the way in which the patent holder may use his patent to control the market. A patent holder who licenses others may not, as a condition to receiving his license, require the licensee to observe his prices. He may assign territories in which the licensees may sell, but if there is a reciprocal arrangement among competing patent holders, implemented by cross-licenses, so that competition between them is effectively restricted, the Act may be violated. In the drug industry, as in others, the inventor who works in the large corporate laboratory is an employee of that corporation, and must agree in writing to assign all his future inventions to the employer. The patent becomes, therefore, an effective instrument of market control.[4]

The simplest form of market control exerted by means of patents is pre-emption of the whole market by the owner.

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[3]Paul de Haen, "European Pharmaceutical Research," Drug and Cosmetic Industry, January, 1961.

[4]Kefauver Report, p. 138.

When no other seller is licensed, the patent owner can charge whatever he wishes without hindrance by antitrust laws or other statutes. If he licenses no one and retains control of the whole market, he may retain price control over the product for at least seventeen years. The law limits the exclusive grant to 17 years, but this statutory limitation is no longer very effective. Patent dominion can be extended by means of spacing improvement patents over the years or making changes in the molecular structure of the product. For instance, the University of Toronto held the basic patent for insulin for 20 years, but by means of a series of improvement patents and licensing arrangements with Danish firms on new types of insulin, the international structure of patent control remains the same. In this country, Lilly was the first licensee and for a time the only one, and its market control over insulin has been held unassailably for 40 years.[5]

A prominent example of single-company patent monopoly is the early broad-spectrum antibiotics introduced at the beginning of the last decade. Because penicillin was first developed in England, no product patent could be secured on it here. It was also suggested by some that because the product was yielded by a mold, and was a product of nature,

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[5] Ibid., p. 141.

it was *per se*, unpatentable. But when Dr. Waksman at Rutgers discovered streptomycin in the mid-1940's, a patent was sought on the grounds that even if it was a product of nature, it was only transitory and had not been isolated and its therapeutic use had been unknown. The United States Patent Office accepted this view and thus opened the way for issuance of patents for new mold products as they were found.

When American Cyanamid introduced the first broad-spectrum antibiotic, chlortetracycline (Aureomycin) in 1948, its policy was to license no other companies in order to retain complete monopoly over the product. Parke Davis did the same for Chloromycetin and Pfizer for Terramycin. The same situation holds in the case of products originated by a foreign company granting an exclusive license to an American company for sale. Under such licensing agreements as exist, for instance, between Smith, Kline and French, exclusive American licensee of Rhone-Poulenc in France, for Thorazine and Compazine, royalty charges vary from four to ten percent. Smith, Kline and French would be entitled to a reduced royalty rate if a competitor entered the American market selling substantial quantities of the products, something which has not yet happened.[6]

An interesting variation of this arrangement is that

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[6] *Ibid.*, pp 142-3.

between Upjohn, the American firm, and Hoechst, the originator, in the case of the new oral antidiabetic drug, tolbutamide, sold under the brand name Orinase. Under this agreement, Upjohn received an exclusive, nontransferable license to make, use and sell it in America, its territories, and possessions, which means that even the originator of the product is barred from entering the market. This exclusive arrangement continues "until the expiration of the last to expire of any patents included at any time within the license patent rights, including improvement patents."[7]

A duopoly exists when a patent holder finds it advantageous to license another firm, for one reason or another. Sometimes a quid pro quo arrangement is desired and the patent owner receives a license on a different drug. Sometimes the arrangement is motivated by the desire to profit from sales made by a firm having a bigger distribution organization. When Carter received a patent to manufacture meprobamate, but did not have facilities to produce it, the company arranged with several other companies to supply the bulk finished products. They were required to sell exclusively to Carter, and any inventions or improvements in the product which they might make must be turned over to Carter on a royalty-free basis. This drug, a tranquillizer, was

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[7] Ibid., p. 143.

then introduced under the name of "Miltown" and had an enormous success.

Although Carter is a leading seller of over-the-counter drugs, it did not have enough men to promote the ethical drug and therefore entered into a licensing agreement with American Home Products Corporation, giving the latter the right to sell, but not to manufacture, meprobamate in the United States and most countries of the world. This right was limited to meprobamate as a single drug, not in combination with any others. Later, combinations were permitted in connection with drugs for which American Home Products held the exclusive rights in exploiting, but American Home Products agreed to make no sale of the bulk powder to any other companies. Subsequently, American Home Products brought out "Equanil," another tranquillizer, and its sales exceeded those of Miltown. Carter was collecting royalties on Equanil and also making profits on the sales of the bulk powder to its licensee. Carter also entered a duopoly of sorts on sales in foreign markets, owing to its lack of an established distribution organization. Since most foreign countries do not grant patents on pharmaceuticals, Carter could not control the whole supply, but did have a property in the trade name. It therefore gave to American Cyanamid a contract giving that company exclusive

right to sell the product abroad under the brand name Miltown. American Home Products was also selling the product abroad, as well as at home, under its own name, Equanil.[8]

Among other ways and possible circumstances, oligopoly may come into being when several large companies make an agreement regarding respective claims about an invention which all made at about the same time, but for which only one can obtain the patent. Instead of letting the Patent Office determine priority, the companies themselves decide which one will receive it, and the others withdraw their applications. In exchange for this, they are licensed by the company which receives the patent. This process is called "arbitration" in the trade. The best example of oligopoly resulting from such a process is the case of tetracycline, manufactured by three companies and sold by five. The story of this drug is somewhat complex. Pfizer filed a patent application in 1952. American Cyanamid applied in March, 1953, and Heyden Chemical, a small company, in 1953 also. A few weeks after Heyden filed the application, its antibiotics division was bought out by Cyanamid. In January, 1954, Pfizer and American Cyanamid made an agreement determining priority so that the winning company would license the other one. In the meantime, however,

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[8] Ibid., p. 144.

Bristol filed a patent application on one form of tetracycline, tetracycline hydrochloride. In March, 1954, the Patent Office declared another "interference" on tetracycline, involving Pfizer, Cyanamid, and Bristol. Cyanamid had already filed formal concession yielding its priority to Pfizer. Bristol approached Pfizer for a license but was turned down. In April, 1954, Bristol entered the market with its own tetracycline. A number of companies tried to buy the bulk material from Bristol, which selected Upjohn and Squibb to sell its product in addition to itself.

Pfizer had already won the patent from Cyanamid, but could not act because the patent had not yet been issued. Cyanamid then took action against Bristol, declaring that the latter infringed on Cyanamid's Aureomycin patent. In October, 1954, the Patent Office examiner stated that tetracycline had been produced in the manufacture of Aureomycin, therefore the product was an old one and was unpatentable. Pfizer kept on submitting affidavits, however, to overcome this rejection. It declared, among other things, that there was no indication of the presence of tetracycline in Aureomycin and secured a negative result by the use of certain types of "low potency" broths and "commercial tests." The patent was then granted to Pfizer and infringement actions were instituted by Pfizer against Bristol, Upjohn, and Squibb.

Cyanamid's action against Bristol was settled when Cyanamid licensed Bristol to manufacture tetracycline. Bristol agreed to pay royalties on the sale of tetracycline. Bristol then moved to abandon its patent application, still pending, on the grounds that it was unpatentable. Pfizer pressed action against Bristol, Upjohn, and Squibb, which made counterclaims. In March, 1956, the six lawsuits were privately settled. Squibb and Upjohn were licensed by Pfizer to sell, but not to manufacture, tetracycline. Bristol received a license from Pfizer to manufacture and sell tetracycline with payment of royalties. Pfizer was granted access to any of Bristol's patents in the field and, if it exercised the option, was to pay royalties to Bristol. Thus, by a private settlement, "orderly and controlled" marketing of tetracycline was finally accomplished.[9]

An important consideration in this form of compromise, according to Senator Kefauver, is the fact that the Patent Office virtually gives up its statutory function of deciding who is entitled to the award of a government grant of monopoly for seventeen years. In the opinion of Senator Kefauver, such private arrangements represent restrictions of competition and work a hardship on the small companies. For this reason, among others, the Kefauver-Celler Bill (S. 1552,

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[9] Ibid., pp. 145-7.

H. R. 6245) was introduced to provide certain amendments to antitrust, patent, and food and drug statutes. The proposed bill would reduce to three years the period of exclusive use of a drug patent. It would require an inventor to license any qualified applicant anywhere in the world after three years and would require the patentee to give with the license all the "know-how" needed to manufacture the invention; and it would prohibit private settlement of patent disputes.[10]

There is a considerable expression of opinion against this stand, however. It is contended, for instance, that such a step would effectively inhibit a company from creating any new drugs, since it would make it impossible to get back the initial investment during the brief period in which the patent holder would have exclusive use of his patent. It would deter a company from attempting to bring out its own formula or modification of an existing drug and thus eventually would tend to slow down and to stultify drug development.[11]

The pharmaceutical companies and the Pharmaceutical Association describe the bill as unfair, frankly discriminatory legislation, one which would invalidate drug patents,

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[10]Pharmaceutical Manufacturers Association, "Will It Legislate Better Drugs? A brief analysis of the Kefauver Compulsory Licensing Bill," (Washington: no date, pamphlet).

[11]Morris Fishbein, "Kefauver's Drug Bill," Medical World News, May 26, 1961, p. 40.

discriminate against large companies, institute federal licensing as a requirement for doing business, nullify the value of trademarks, and abolish trade practices which are legal in other industries.[12] Thus, for instance, Francis Brown, head of Schering Corporation declares:

> The story of penicillin shows the part that patents play in bringing scientific discovery into industrial development. Most people do not know that Sir Alexander Fleming's findings on penicillin--not patented and free to all--lay dormant for a decade. Then wartime needs and almost unlimited government subsidy stimulated industry to develop production methods which, after the war, finally brought this remarkable drug into the channels of private commerce. Had penicillin been patented, industry might have been provided with the incentive to invest risk capital in expensive exploratory techniques required for its development at a much earlier date.[13]

The whole question of patent laws is admittedly complex. Secretary of Health, Education and Welfare Abraham Ribicoff, although endorsing one of Kefauver's key proposals, that the Food and Drug Authority be authorized to see that manufacturers prove a new drug is effective as well as safe before it is released to physicians, and although supporting more stringent procedures to clear antibiotics and other drugs, has been reluctant to commit himself on the

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[12]Pharmaceutical Manufacturers Association, "The Kefauver Compulsory Licensing Bill," (Washington; leaflet).

[13]Francis C. Brown, "Profits and the Future, The Case for Business Statesmanship," (Delivered before Sales Executives Club of Northern New Jersey, "Presidents' Day," Newark, N.J., April 24, 1961) (Pamphlet, p. 12).

controversial proposal to overhaul the patent laws.[14]

The president of the Pharmaceutical Manufacturers' Association, Dr. Austin Smith, declares: "Incentive effort among the 13,000 researchers in the pharmaceutical industry could be stifled--as more attention is turned to the pricing of existing medicines than to the development of new drugs for sicknesses. . ."[15]

Kefauver's argument is that such legislation would reduce the cost of medicine, as well as prevent patenting agreements among private manufacturers from by-passing the Patent Office. But his suggestions relative to the part played by research and royalties in specific companies have been countered and contradicted by representatives of the companies themselves. Kefauver's statement that a large part of the income of Abbott came from royalties on drugs has been met by the assertion of Dr. Ernest H. Volwiler, director of research for Abbott Laboratories that:: "We could not carry on our research program on the income we receive from royalties, or any considerable share of them." Evidence has also been brought out to suggest that clinical experience which actually determines the value of a drug comes after application for a patent. Dr. Volwiler has

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[14]"HEW Lends Support to Kefauver Measure," Medical World News, September 29, 1961, p. 17.

[15]Austin Smith, M.D., "Something to Think About," Today's Health, August, 1961, p. 21.

maintained that the development and patenting of a number of compounds, even if they have almost the same properties, promotes competition rather than otherwise.[16] Dr. Theodore Kumpp, president of Winthrop Laboratories, maintained that a special study of his company had proven that research represented thirteen percent of sales, and that there was more incentive to research under the American patent system than in any country in the world.[17]

Smith, Kline and French laboratories contend that pre-patent agreements are not only the usual, and perfectly legal, method of settling patent disputes, but that they are encouraged by the Patent Office. That the Kefauver-Celler Bill should make it illegal for drug companies to arrive at such agreements, this company maintains, would compel the companies to fight each other through the Patent Office or court proceedings. This could result in important drugs being kept off the market, since no contestant in an interference suit would market the drug until the case had been settled, and such cases can drag on for years. As an example, he cited prednisone, used in the treatment of arthritis and other rheumatic diseases. Had the Kefauver-Celler Bill

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[16]Pharmaceutical Manufacturers' Association, Supplement to PMA Newsletter, Supplement to Vol. 3, No. 50, December 12, 1961, pp. 1-2.

[17]Ibid., p. 2.

been a law in 1955, he stated, it might not yet be on the market, whereas it has been manufactured and marketed under licensing agreements since that date by several companies.[18]

Kefauver's contention that to forbid drug companies to make such pre-patenting agreements would restore free competition is debated by spokesmen for the industry. Smith, Kline and French declares that such a bill could only discriminate against small companies, for larger companies can better weather such fights than small ones. The proposal would interfere with research because there is no way of knowing, until an application is filed, whether any other firm has been working in the same area. The only safe rule would be to stay out of research that competitors might possibly be working in. This company points out, too, the possibility that if such a bill were passed, a similar prohibition on pre-patent agreements would probably spread to other research-oriented industries such as electronics and chemicals. Indications that such other industries are concerned and do take much the same view has come from several sources.

Robert Semple, chairman of the board, Manufacturing Chemists Association, pointed out that definition of drugs in the Kefauver Bill would bring a wide range of chemicals

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[18]Smith, Kline and French, "Commentary, Pre-Patent Agreements," (Philadelphia: processed pamphlet, p. 2.)

under the controls of the bill. "Actually, many chemicals developed for various industrial uses also find specific application as drug components, and such use as a drug can be a very small portion of the total use."[19] Similarly, chairman of the Aerospace Industries Association patent committee, has spoken against the patent proposals of the Kefauver Bill for somewhat the same reasons.

It is clear that the patent and license provisions of the Kefauver Bill would have wide ramifications beyond application to the pharmaceutical industry. The whole problem of patents and licenses in the drug industry must be related, moreover, to the issue of pricing and to the costs of innovation and research in the industry. These, and the related problem of generic versus trade names, also brought up in the Kefauver-Celler Bill, will be discussed in subsequent chapters.

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[19]Supplement to Vol. 3, No. 50, Pharmaceutical Manufacturers Association, December 12, 1961.

## CHAPTER III

## INNOVATION AND RESEARCH IN THE DRUG INDUSTRY

There is a close interrelationship between patents, technological innovation and the degree of concentration in the drug industry. It is relevant here to cite some of Schumpeter's observations concerning innovation which would seem to be particularly applicable to the drug industry. Schumpeter notes that capitalism is an evolutionary process, rather than being of a static or stationary condition. Superficial observation of an oligopolist industry, observation which concentrates only on moves and countermoves within the industry which seem to be aiming at only high prices and restrictions of output, are based on the hypothesis that there is a perennial lull in capitalism. The point, according to Schumpeter, is not how capitalism administers existing structures but how it creates and destroys them. "Creative destruction" is the expression Schumpeter uses to denote a process of industrial mutation which constantly revolutionizes the economic structure from within.[1] Creative destruction is capitalism's great and dynamic competition, overshadowing in importance the classical price competition resting on efficiency competition.

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[1]Joseph Schumpeter, Capitalism, Socialism, and Democracy (New York: Harper and Bros., 3rd ed., 1950), p. 83.

Almost any investment, he points out, necessitates some activity to safeguard it. Long-range investing under rapidly changing conditions, especially under the impact of new commodities and technologies, requires protective devices, such as patents, or temporary secrecy of processes, or long-range contracts. What the government agent may consider evidence of price policies which are only predatory or of restrictions of output that seem to imply loss of productive opportunities are often unavoidable in the long-run expansionary process of capitalism. This, he notes, is particularly true of industries or sectors of the economy in which the impact of technology is important.

There has been an enormous expansion in recent years in the drug industry's expenses for research and development. In 1954, $90 million was spent on research and development; in 1959, $190 million, and in 1960, $200 million.[2] Whatever may be the implications for restriction of trade in monopolistic, duopolistic or oligopolistic practices relating to patents, there is at the same time a high degree of the type of competitiveness which is particularly significant in industries undertaking research and development. This type of competitiveness is perhaps more significant than price competition, since it strikes, as Schumpeter

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[2]Charles E. Silberman, "Drugs: The Face Is Getting Furious," Fortune, May, 1960, p. 130.

says, not at margins of profits and outputs but at the foundation of the business organizations themselves.

Dr. Frederick H. Meyers, Associate Professor of Pharmacology at the University of California, has remarked in this connection that when manufacturers try for a share of the market they do not "choose to use price competition." Instead, they use whatever method will establish their trade name in the mind of the doctor. Although promotion and advertising are aspects of the drug industry which will be discussed more fully elsewhere in this thesis, it is relevant to mention here the way in which innovation and promotion are closely interrelated. When a company is about ready to release a new compound, it goes in for what is called "seeding." "Seeding" is a way of getting the drug used in a medical center before it is generally released and getting a limited number of physicians to employ it as a part of a clinical trial.[3] The point to be made here is that, whether or not the company is engaging in a sincere effort to have the drug evaluated or merely in an effort to get publicity for the drug, innovation is intimately related to promotion. The technique of "seeding" and other promotional devices and activities are important to the drug company which wishes to identify its own product in the mind of the doctors.

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[3]Kefauver Report, pp. 176-7.

Since research and promotion are intimately related, it is not surprising that an analysis of financial data for the years 1949 to 1958 supplied by 50 drug companies to the accounting firm of Arthur Andersen and Company reveals that research expenditures have been a primary factor in determining a company's future share of industry sales. When every firm is using research to improve the market, increasing research spending ceases to be the decisively effective weapon in competition it once was and marketing becomes more significant.[4]

Research in the drug industry, then, can potentially serve a number of purposes. Some research is carried on in the interests of maximum growth; in this case, research is an offensive strategy. Other companies engage in defensive research of a type which can help them preserve existing markets. In most of the postwar period, for instance, Abbott Laboratories and Parke Davis engaged in defensive research, spending about four percent of sales on research. Companies with offensive strategies, such as Merck and Lederle, spent about eight to ten percent of sales on research. In 1945 before research was so extensively engaged in, Lederle was spending seven and one-half percent of sales on research. Its sales rose from about $33 million in 1945

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[4]Silberman, op. cit., p. 138.

to more than $160 million in 1959. This company also engages in aggressive marketing. In 1948, when it was promoting and introducing the first broad-spectrum antibiotic, Lederle shipped ten carloads of samples to about 142,000 doctors at an estimated cost for that product alone of about $2 million.[5]

There is a difference between basic research and product development, and a difference which has some significance for the whole problem of economic concentration and monopoly in the industry. One reason, for instance, for the "high" prices of drugs is said to be the cost of research. But some observers claim that much, if not actually most, of the research undertaken by the drug companies is not basic research, in the sense that it is aimed at really new findings, but more product development and virtually meaningless product differentiation. According to some sources, most of the significant contributions of the American drug industry, those for which it is most noted, actually were made in the late 1940's or early 1950's. Although newer corticosteroids have made their appearance more recently, cortisone was discovered in 1948 and ACTH in 1950. There is some question in the minds of authorities whether the newer corticosteroids represent much of an improvement over the older steroids. Newer drugs are said to be more potent,

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[5] Ibid., p. 140.

so that smaller quantities may be administered to achieve the same therapeutic effects. But this is not necessarily an advantage so far as therapy is concerned. One specialist in testing of pharmaceutical products, Dr. Louis Lasagna, head of the division of clinical pharmacy at Johns Hopkins, has given as his opinion before the Kefauver Committee hearings that adequate controlled comparisons of drugs are almost impossible to find in any case. Major qualitative therapeutic advantages are rarely achieved, he suggests, by minor molecular modifications of an original drug.[6]

A certain amount of research undertaken by drug companies is directed at precisely this "molecular manipulation" which enables a company to obtain a patentable derivative of a basic drug which is either not patented or on which the patent is held by another company. John McKeen, president of Pfizer, speaking of looking for minor molecular modifications, stated over ten years ago:

> . . .it is apparent that neither penicillin nor streptomycin furnishes any real indication of the outlook for the antibiotic industry. From a profit point of view. . .the only realistic solution of this problem lies in the development of new and exclusive antibiotic specialties. This. . .is an exceedingly costly and vigorous alternative; nonetheless, it is the avenue of approach being most extensively explored by certain antibiotic houses today. This is the approach being followed by Pfizer.[7]

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[6] Kefauver Report, p. 203.

[7] "Antibiotics and Pfizer & Co." Armed Forces Chemical Journal, Vol. III (April, 1950), No. 8, pp. 37-38.

Nevertheless, it would seem that even the so-called molecule manipulation appears to serve a useful purpose other than that of by-passing a patent held by another firm. One such purpose is to eliminate certain untoward side-effects which may be encountered in a particular drug and perhaps eliminated by some variation of it. Of particular interest, too, is the variation in the way different persons react to the same drug. The prescribing physician often tries one after another variety of a specific drug before he finds one suitable for a particular patient, as in the case of anti-histamines which induce drowsiness in some individuals and not in others, or tranquilizers, some of which merely stimulate instead of tranquilizing some persons.

Then, too, molecular modifications often lead to new discoveries which were not anticipated in the start. Ernest Volwiler, consultant to Abbott Laboratories and former director of research, has pointed out that Abbott created a drug called trimethadione, which was first tested for its analgesic properties. Later, Abbott learned that it had anti-convulsant and anti-epileptic value. After the drug was marketed, Abbott researchers screened 2,000 more compounds in this field. One of them, paramethadione, a molecular modification of trimethadione, was found useful to treat patients who were not adequately controlled by the earlier product. The company eventually marketed these two

products and a number of other agents that differed from them in chemical structure.[3]

It may be true, as some observers claim, that a good deal of research undertaken by the drug industry is misdirected, something which is undoubtedly true of research in a number of other areas. Thus, Dr. A. Dale Console, formerly medical director of Squibb, claims that research talent, time and resources are wasted on devising and marketing drugs which have too little or no value, whereas more significant progress could be made in other areas. He contends, too, that unlike other industries the drug industry is able to market many of its failures, i.e., drugs which are presented as new products when they are really not new but useless modifications of old ones. There is too much dependence on novelty drugs and rapid obsolescence is a sign of motion which is mistaken for progress. Against this view, it is contended by other authorities that both basic and applied research are necessary in drugs. Dr. Chester Cavallito, director of research for Irwin, Neisler and Company, a relatively small drug house that engages in a good deal of research, considers both types of investigation both necessary and useful. Dr. Vannevar Bush, board chairman of Merck, one drug house which is particularly said to

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[3]Pharmaceutical Manufacturers Association, Supplement to PMA Newsletter, December 7, 1961, p. 6.

engage in molecule manipulation, states that under the present patent system pharmaceutical houses are encouraged to improve on present drugs. When Merck developed Diuril, for instance, the competitors of the company had to try to find improvements of their own, which they did.

Much of the debate concerning the relative merits of basic research and applied research now revolves around the provision of the Kefauver-Celler Bill which would limit patent protection to three years and compel a drug house to license prescription drug patents to other companies after that time, as well as provide technical knowledge applicable to the patent. One objective of this provision is to bring down prices of drugs and encourage competition by drawing other producers into the market at a maximum eight percent royalty. John T. Connor, president of Merck, points out, however, that an increase in the number of producers and the resulting fragmentation of the market could bring about a squeezing of profit margins, since the economy of large-scale production and distribution would be eliminated and costs of distribution and production would rise for everybody.[9]

Connor's observations in this connection seem to bear out Schumpeter's theoretical formulations. Without the

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[9]Ibid., p. 5.

protection of a patent system, Connor points out, capital could not be attracted for growth, and research would tend to be devoted to improving existing processes. Money spent on research would increasingly tend to go into promotion. Connor also makes the point that without the protection of patents secrecy would be the rule.

Eugene V. Rostow, Dean of the Law School of Yale University, member of the graduate faculty of economics at Yale and member of the 1955 national committee to study the antitrust laws, observes that most of the provisions of the Kefauver-Celler Bill would actually weaken the existing forces of competition in the drug industry. Rostow maintains that there are a relatively large number of important firms in the drug industry and that undue concentration does not exist. The industry is characterized, he states, by "explosive dynamics" and a pattern of radical shifting of market leadership.[10] That the pattern in the drug industry does not conform to one of pure and perfect competition should not come as much of a surprise, he points out.

In this connection, we should remark that Schumpeter observes that perfect competition is and always has been temporarily suspended when anything new is being introduced even under otherwise perfectly competitive conditions. He

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[10] Ibid., p. 7.

suggests that the introduction of new methods of production and new commodities is not conceivable with perfect and prompt competition, because perfect competition implies free entry into every industry. And free entry into a new field might make it impossible to enter it at all.

A perfectly competitive economy is comparatively free from waste.[11] Schumpeter has pointed out, too, that progress entails destruction of capital values in the strata with which new commodities or methods of production compete. Where the impact of innovation is significant in the economy, restrictions of output are frequently unavoidable incidents in the long-run process of expansion.[12]

As has been suggested in the previous chapter, an oligopoly situation does apparently result from a patent award to a particular company for a product for which the company then engages in cross-licensing procedures with other companies. It is a fact that there are a relatively few large producers and a high degree of specialization in particular products among the major firms of the drug industry. But it is an open question whether this oligopolistic hold can be weakened, or should be destroyed if it were possible, by the type of legislation proposed by Senator

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[11] Schumpeter, op. cit., pp. 104-5.

[12] Ibid., pp. 88-89.

Kefauver. The investment required by research and innovation is so great that without patent protection there would seemingly be little incentive for any company to engage as extensively as at present in the long process either to develop wholly new products or to modify existing ones. It appears, too, that without patent protection secrecy would be necessary as a protective device. If, as Schumpeter suggests, perfect competition is incompatible with technological innovation, would liberalization of the patent laws in the direction and to the degree proposed by the Kefauver-Celler Bill increase competition?

We must also consider the extent to which promotion and distribution are allied to innovation. Merely to permit or encourage a considerable number of firms to develop products by obtaining a license from the original developer after a period of three years might mean that the product could not be promoted and distributed by the patent holder company. Would there not, perhaps, develop a situation in which so many companies potentially could develop a drug that no one company would have any incentive to invest the amount of money required to produce it? Would not, perhaps, the resulting fragmentation of the industry work against an orderly procedure for production, distribution and marketing? Is it possible that imperfect competition and a

degree of concentration are to be preferred to inflexible application of antitrust provisions, especially in this unique area?

# CHAPTER IV

## ADVERTISING AND PROMOTION IN THE DRUG INDUSTRY

Advertising and promotion of ethical drugs differ considerably from such activity in the marketing of most other products. It is, after all, the prescribing physician, not the ultimate buyer, who must be "sold." Since new drugs are being developed with great rapidity, and significant changes are being made in medicine and pharmacology, the physician must be kept constantly and correctly informed in order to be able to dispense new drugs with efficacy and safety. Even the most well-informed and well-intentioned physician finds it difficult to keep up with these developments and it is for this reason that promotional techniques in the drug industry take their unique form.

There are four main ways of promoting drugs: visits by detailmen, mailing of brochures and samples, advertising in medical journals and "throw away" journals (i.e., those circulated without subscription cost), and exhibits at medical meetings.[1] Although there is obviously nothing

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[1]Norman G. Hawkins, "The Detailman and Preference Behavior," Southwestern Social Science Quarterly, Vol. 40 (December, 195 ), No. 3, pp. 213-224.

wrong with promotion and advertising as such, there have been criticisms directed against the industry on the grounds that their promotion is excessive, adding significantly to the cost of drugs. It is also held that the magnitude of promotional and advertising costs is related to the proliferation of new, and not always necessary, modifications of drugs, modifications which are ultimately made in order to evade patents held by other firms. There is clearly some validity in this claim. We have already suggested in the previous chapter that companies which engage in extensive research also engage in aggressive marketing policies, for rather obvious reasons. This has been true especially of Lederle, as noted previously.

Aggressive promotion and advertising must go hand-in-hand with extensive innovation, whether in basic research or in patent-evading modifications. A good case in point is the experience of Pfizer. This company which has been a leader in fermentation technology, was called upon by the government during World War II to help mass-produce penicillin. At the end of that time, Pfizer was the world's largest producer of penicillin, turning out fifty percent of American output. This postwar prosperity did not last, however, because the company had no marketing organization of its own, but could only sell to drug manufacturers who then resold the product under their own names. By mid-1949,

however, some of the most important of Pfizer's pharmaceutical customers were building their own plants and canceling their contracts, sometimes without even giving notice.

Pfizer, thereupon, changed its tactics and built up its own marketing and sales organization, engaging in aggressive sales policies. Having established a good marketing organization, Pfizer was able to engage in molecule manipulating. It is a company which can now develop a competitive product within a matter of months, and can rely on its marketing methods to establish the products among the two or three variants of the drugs already on the market. One of their specialties is developing new dosages of a drug or combining a new drug with an old one. These new policies have enabled the company to increase their sales between 1947 and 1960 more than six-fold, from $39 million to $354 million. Profits are not proportionately high, however, since it costs more to promote a variation of a drug than the first of its kind in the field.[2]

It is true that drug companies spend a good deal of money on promotion and advertising. During the investigation undertaken by the Kefauver Committee, for instance, twenty-two drug companies submitted data on expenditures for all their promotional activity, direct mail and

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[2]Silberman, op. cit., p. 140.

advertising in medical journals, costs of detailmen, free samples, and so forth. For the year 1958, promotional expenses of these twenty-two companies amounted to about $580 million.[3]

The data submitted by these drug companies showed that about twenty-four percent of their receipts was spent on promotion. Selling expenses constituted the largest single item for these companies, often being even larger than cost of goods sold. On the average, cost of goods sold was a little above selling expenses, with a figure of thirty-two percent. By comparison with these figures, research and development accounted for six percent, general and administrative expenses, eleven percent, taxes, thirteen percent, and net profit after taxes, thirteen percent. Twenty of the companies supplied figures for compensation and expenses of salesmen and detailmen. This accounted for $200 million out of the total of $577 million. The twenty-two largest drug companies also spent, in addition, a quarter of a billion dollars on advertisements in medical journals, direct mail ads, samples and miscellaneous items.[4]

One official of a smaller drug company quoted an advertising director of Smith, Kline and French as an

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[3] Kefauver Report, pp. 156-7.

[4] Ibid., pp. 157-8.

authority for an estimated cost of between $9 and $10 for each physician visit made by a detailman. Since there is a total of about 150,000 physicians in the country, this comes to a cost of about $1.5 million for a single detail call on every doctor in the country.

Figures also show that the detailmen constitute a sales staff which is very large in proportion to the total employees of the company.[5] The magnitude of the selling effort made by the drug companies may appear to be "too great," but there is little doubt that, even if some of the efforts are excessive, much of it is necessary and physicians respond to it, even though they may be critical of it.[6]

The question of whether these expenses are "excessive" is, of course, a moot point. What constitutes "excessive" advertising and promotional expenditures? One critic, Dr. Louis Lasagna, head of the division of clinical pharmacy of Johns Hopkins, related these so-called "excesses" to the

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[5]The occupation of detailing has been evolved almost wholly since 1940, and is defined in the U.S. Department of Labor, dictionary of Occupation Titles (Second edition, Washington, D.C., 1949) as follows: "He introduces new pharmaceutical products and their methods of use to physicians, dentists, hospitals, and public-health officials, promoting the use of the product rather than selling it. This requires a thorough familiarity with the application of medical preparations and a general knowledge of medical practice."

[6]American Medical Association, "Effectiveness of Promotion in a Medical Marketing Area," Journal of the American Medical Association, 1956; also, Theodore Caplow and John J. Raymond, "Factors Influencing the Selection of Pharmaceutical Products," Journal of Marketing, Vol. 19 (1954).

built-in obsolescence of drugs. He suggests that each year the advertising agencies must sell to the medical profession a "whole bushel basketful of sows' ears for silk purses."[7] The physician merely becomes confused by this plethora of advertising. And each year there are product failures, that is, drugs which prove to be something less than the miracles they are said to be at the start. Another and similar attack on the industry has been launched by Dr. Dale Console, former medical director of E. R. Squibb, presently in private practice, who has pointed out that since the incidence of disease cannot be manipulated, increased sales volume in drugs must depend on the use of drugs unrelated to their actual need or usefulness. He refers to the carefully planned and skillful execution of "exploitation" which constitutes one of the costs of drugs which, he suggests, should be measured not only in dollars but also in terms of the inroads which the drug industry has made into the whole structure of medicine and medical care.[8]

This would seem to be something of an over-statement. It is a fact, of course, that competition in the drug industry exists between trade names and brands, something which is true of nearly all other American industries. Therefore promotion of all types is of vital concern to the companies.

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[7] Kefauver Report, p. 170.

[8] Ibid., p. 171.

We should also remember that drugs differ appreciably from many other commodities in that it requires a specific degree of knowledge and skill to dispense them safely. As suggested above, even the best-qualified physician rarely has the time to keep up with rapid developments in pharmacology.[9] It is detailmen who inform them about the qualities and attributes of newly developed drug products. Detailmen must be knowledgeable in the qualities of the drugs they are promoting. They must have an understanding of dosages, possible side effects, contraindications, and so forth. It follows that the cost to the company must be high, since such salesmen are performing a unique type of selling effort. It is an effort which is dependent on personal contacts with physicians. This is a time-consuming service, in itself, waiting on physicians, making fruitless calls in some instances, returning for renewed efforts to make the contact.[10]

Added to the cost of detailmen is, of course, the cost of free samples which the drug companies dispense to physicians. This is another area in which selling and

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[9]Herbert Menzel and Elihu Katz, "Social Relations and Innovation in the Medical Profession: The Epidemiology of a New Drug," Public Opinion Quarterly, Vol. 19, Winter, 1955/56, pp. 337-352.

[10]Anonymous, "Selling Drugs to Doctors," Practitioner, Vol. 179, November, 1957.

promoting a new drug obviously differs from the same effort made in regard to most other commodities. (But we should remember that free samples of such items as soap, tooth-paste and other items are constantly being given away by other manufacturers.) One difference here is that free samples cannot directly be given to the consumer. The physician is the individual who decides to dispense or not, and to whom the sample of the new drug must be given. He frequently dispenses these samples to patients who are unable to pay for such expensive new medicines. Often enough, the physician reports back to the drug companies, via the detailmen, his clinical experiences with the drugs.[11]

As to excessive expenditure on advertisements and promotional schemes attributed to drug manufacturers, we may note, for the purposes of comparison, that an investigation into administered prices in the automobile industry made a sharp attack on advertising practices in that sector of the economy. And advertising for cars is the type which may profitably be directed at the mass market and toward the whole adult population which are, potentially at least, buyers of cars. Where drugs are concerned, advertising must be channeled through very specialized media. Doubtless

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[11] Charles C. Rabe, "The Doctor Measures the Detailman," Medical Marketing, Vol. 11 (February, 1952), pp. 19-25.

the promotion costs of new medicines could be cut drastically if drug companies could exploit the usual mass media. This, of course, is impossible.

But this is not to say that perhaps, in some instances, promotional costs might not be cut down to some extent. It might be fair to suggest the elimination or reduced use of the more elaborate and expensive "throw-away" brochures or journals.[12] Actually a more serious criticism of advertising in the drug industry is that launched against the quality and integrity of drug advertising. The suggestion has been made, for instance, that drug advertising has tended to deteriorate since the competition has become so fierce, i.e., that it has become somewhat misleading and sometimes distorts important facts about possible harmful side effects. There may be validity in some of these criticisms, although each of these claims would have to be evaluated carefully, as to source, interpretation of advertising matter, and so forth.

There can be little doubt that the high cost of promotion and advertising does tend to raise the price of drugs. But this is true of any item or commodity which must be advertised, and is a normal feature of our economy. The

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[12] Theodore Caplow, "Market Attitudes: A Research Report from the Medical Field," Harvard Business Review, Vol. 30 (Nov.-Dec., 1952).

humanitarian considerations relating to the sale of drugs represent another factor, altogether. But if the drug industry is to remain a part of the free-enterprise system as a whole, advertising and promotion must necessarily play a significant role in the selling effort. Undoubtedly, too, the competition between brands sets off the promotional race between companies and this, in turn, is an inevitable feature of innovation in drug manufacture. Once money has been spent on research, an investment has been made which must be recouped. It is also a fact that some part of all research efforts fail to produce marketable drug products, so that the selling and promotional effort put upon the products that are marketable may compensate, in some measure, if successful through larger receipts, for this failure.

At any rate, so long as prescription is by brand name, so long as the present patent and licensing system remains in effect--and these are both elements of our free-enterprise economic system--a good deal of the cost of advertising and promotion is not likely to be eliminated. It is true that there have been several promotional schemes of some drug companies which have met serious objections on the part of physicians (one such was the cocktail party for the press to launch a new drug, which brought about premature release of information about the drug and put unwarranted pressure on doctors to prescribe it at a point when it was

too early to dispense it to the public). These have been disavowed by at least one of the companies criticized for the scheme. But most of the promotional efforts of the drug companies do not seem to be out of line with similar efforts made in other sectors of our economy; the most commonly voiced objection in the case of drugs relates to the charge that the drugs are then priced "too high."

There is also, of course, a fairly direct connection between the degree of economic concentration in the drug industry, the nature of the oligopolistic or duopolistic position of various firms, and the magnitude of the promotional effort. For example, if price competition between various brands of a similar drug were more of a factor than it is, the cost of promotion would seemingly have to be reduced, in order to lower the cost of the drugs, or to keep them competitive with one another. Since competition is heavily based on product differentiation, and brand-name is vital in promotional effort, advertising is tremendously important. At the same time, as suggested in the previous chapter, the very role of innovation through research itself almost precludes price competition of this sort. Innovation and research are costly and techniques must be found to protect the investments of the companies engaging in it. Without some assurance that the costs will be repaid, research itself might well be stifled.

Thus, although some degree of promotional cost might be cut down and some types of promotional effort avoided as putting undue and premature pressure on physicians, it would seem that insofar as cutting down advertising expenditures is concerned, there is a point below which this would scarcely be feasible if research is to be encouraged.

## CHAPTER V

## GENERIC VERSUS BRAND NAMES

Another method by which economic control is exerted by certain firms in the drug industry is the use of trade names rather than generic names in prescription. There is a tremendous variety of drug names in existence. The chemical name of a particular drug indicates its chemical composition. The generic name may abbreviate the chemical name and, in any case, is the name used to identify the drug in formularies and in teaching. Usually a drug has only one generic name, but there are cases in which it may have two or three. A drug also has a number of individual trade names given to it by the several companies promoting it. Sometimes the generic name of a drug is called its nonproprietary name. In addition, the American Medical Association has coined the expression, "counterpart," to indicate generic name. The trade name of a drug may be called its brand name or proprietary name.[1]

For example, the chemical name for synthetic penicillin is alpha-phenoxyethyl penicillin potassium. This is also used as a generic name. But there are two other generic names, potassium penicillin 152 and phenethicillin potassium.

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[1] Kefauver Report, p. 223.

There are six sellers of this product and each markets the product under his own trade name, i.e., Syncillin, Darcil, Alpen, Chemipen, Dramcillin-S and Maxipen.

Physicians in the course of their medical training are taught to identify drugs by generic names, so that they learn the nature of the drug and its relationship with similar compounds. Promotional and advertising material is directed by each company to induce the physician to prescribe the particular drug by the brand name or trade-mark of the company.

All ethical drugs, however, whether marketed by generic or trade name, must meet the minimum standards of the United States Pharmacopoeia or the National Formulary. If a drug differs from the standard of strength, quality or purity as determined by the tests laid down by these agencies, it is considered adulterated. The Food, Drug and Cosmetic Act of 1906 made the United States Pharmacopoeia compendium of drugs the official compendium for the enforcement of the act. The United States Pharmacopoeia also serves the same purpose for similar legislation at the state level. Authority for this program remains in the hands of a private, nonprofit organization, the United States Pharmacopoeial Convention, Incorporated, which meets regularly every ten years and in whose membership are representatives of colleges of medicine, colleges of pharmacy, agencies of

the Federal Government, and state and national medical and pharmaceutical organizations.[2] This agency sets high standards but with certain permissible tolerances. Purification beyond the limits set are unnecessary and, in fact, meaningless.

It is on some such grounds that the Kefauver-Celler Bill calls for a generic name prescription system, that is, on the grounds that brand names do not necessarily ensure high quality of drugs since qualities and potency are set by government agencies and must be met by all manufacturers equally. At present, the procedure for establishing the generic name for a newly found drug is for the company which develops the drug to submit proposals for the names to the Council on Drugs of the American Medical Association. This name is reviewed by a joint nomenclature committee of the United States Pharmacopoeia and the American Medical Association. There is a nomenclature review board to review individual negotiations when needed. Provisions of the Kefauver-Celler Bill would favor prescription by generic name by providing that the official name of the drug must appear on the label in type as prominent as the trade-mark.

There are in existence at the present time both private and government agencies which do buy their drugs in

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[2] Ibid., p. 229.

large quantities by generic name. Many hospitals purchase their drugs by generic names under what is called the hospital formulary system. When hospitals purchase by generic names, competitive pricing can frequently be obtained for nonpatented drugs. Even apart from patented drugs, on which it is almost impossible to get competitive prices, important savings can be effected on total drug purchases this way. Doctors using these hospital facilities state in writing their willingness to have such drugs used on their patients, even when the doctors' own prescriptions specify trade names. Hospital pharmacists have been in the habit of making such substitutions. The system was originally adopted at a time when trade names were almost unknown, and the hospitals were interested in insuring rational drug therapy. Over the years, the factor of economy has entered into the picture, however.

Similarly, the Military Medical Supply Agency of the United States Government buys between $30 and $40 million worth of drugs a year specifying that bids for such procurement must be by generic name in the interest of achieving economies. One official has stated that about twenty major suppliers and eighty smaller ones have been involved in these purchases. Many of the larger hospitals in the country buy their drugs in this way, awarding the business to the company with the lowest price. Federal, State and local governments also purchase for institutional use according

to this practice.

Of late, it has been an increasing practice for welfare departments of the various state and local governments to require that prescriptions for welfare patients be written in generic names. The American Medical Association late in 1960 recommended the use of generic name prescribing for welfare patients in the interests of reducing drug costs.[3] In some areas, the use of the generic name is limited to a specific group of the more important drugs in current use where there is a wide difference in price between large and small companies.

In an effort to stem this trend, the National Pharmaceutical Council was formed in the drug industry in 1953 with the avowed purpose, among other things, of providing for what is called a new concept of "substitution." A generation ago, substitution meant dispensing a wrong chemical or drug, one different from that prescribed. The National Pharmaceutical Council now seeks legislation, however, to introduce a new concept of substitution, one which would make it criminal for a pharmacist to dispense medication of a different brand from that called for on the prescription, even when the doctor may have given blanket authorization for dispensing by generic name. This group has also

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[3] Ibid., pp. 247-8.

engaged in a campaign to eliminate the hospital formulary system. Its concept of substitution, for instance, would make it criminal for the hospital pharmacist to substitute any other brand, e.g., the brand purchased under its own formulary system, for the brand specified by the physician.

This highly controversial issue of generic versus brand name is usually debated on the basis of purity, quality, reliability of well-known brand and so forth. On the one hand, it is claimed by those who are opposed to prescription by generic name that it is important for the purchaser to be certain of the insured potency of the product he is buying. The implication is made that products of small or lesser known companies are inferior to those of the large manufacturers. It is claimed in this connection that government control over manufacturing and labeling, although supposedly rigid, is not able to assure proper quality and valid identity of any drug article. It is suggested that in spite of the fact that all drugs must meet government specifications there is a great difference in the quality of pharmaceutical products.[4]

Some manufacturers, for instance, take advantage of tolerance allowances and make up their products to meet the minimum requirements. Records of the State and Federal Food

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[4]Edward S. Brady, "Only Drugs of Highest Quality..," The Prescriptionist, June, 1954.

and Drug agencies show that seizures of drug products and prosecutions of manufacturers have taken place on the grounds of adulteration and misbranding of drugs found to be below strength. There are also variations in disintegration time which may significantly affect the therapeutic effectiveness of the product. Most of these variations derive from inadequacies in production control, admittedly an expensive procedure and one of the first to be abandoned by the cut-rate manufacturer who is interested chiefly in marketing his product at low prices.[5]

In this connection, George P. Larrick, Commissioner of Food and Drugs, has stated that the authority of the Food and Drug Administration to inspect manufacturers of drugs was restricted considerably when Congress passed the factory inspection amendment of 1953. As a result of this restriction many manufacturers, large and small, do not permit inspectors of the Food and Drug Administration to inspect important phases of their drug operations. And because controls are not always exerted meticulously by a drug firm at every stage of a product's preparation, it is sometimes necessary for the Food and Drug Administration to recall products from the market and impose penalties on the

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[5] Ibid.

manufacturers.[6]

In the case of large-scale purchases of drugs by generic name, the problem of safety is nonexistent because inspection of drugs is undertaken. The Military Medical Supply Agency, the world's largest buyer of drugs, inspects plants and their operations before the companies can even qualify as bidders. After the contract is awarded and the material delivered, it is submitted to tests. Similarly, some of the large hospitals in the country do a certain amount of checking on their own and they have testing facilities in case there is any doubt of purity or potency. This is, of course, a wholly different situation from that of the individual physician who is not in a position either to know for certain or to test the quality of any drug which he prescribes for a patient.

The problem of generic versus brand names has other implications, apart from the issues of quality and potency, about which there is considerable difference of opinion. The proposal of the Kefauver-Celler Bill to deny an "official name" to any combination of two or more drugs would be difficult to put into effect. To deny a recognized name to such a preparation would mean that the name of every

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[6]George P. Larrick, "Report from the Food and Drug Administration," to Drug and Allied Products Guild (mimeographed speech, no date).

ingredient in the formula for a combination of drugs would have to be listed on the label. The present law recognizes the United States Pharmacopoeia and National Formulary names, standards and tests, and is based on the concept that such compendia are integral parts of the practice of medicine and pharmacy. Under this law, when an official title is used on a drug label, or when one official synonym is used, either with or without an official compendium designation, the product must conform to the official monograph or be considered misbranded. Using the official title or synonym is considered the same as printing the official monograph on the product's label. The physician would know the official preparations of the National Formulary if he were to use the simple prescription form and prescribe a preparation having a combination of several drugs in it.[7]

In any case, there are in most states no laws or rules which limit the use of generic names if doctors, hospitals or Federal agencies want to use them.[8] To make mandatory the printing of the generic name in type as large as the brand name would be to single out the drug industry for an unwarranted attack on trade-mark and brand name, even

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[7]"On the Witness Stand...APhA's secretary testifies at drug hearings," Appendices to statement, "Nomenclature," Journal of the American Pharmaceutical Association, Vol. NS2, No. 1, January, 1962, p. 56.

[8]Kefauver Report, p. 359.

apart from the more radical suggestion that some individuals have put forth that prescription by generic name actually be mandatory. It is true that the drug industry is in quite a different category from some other industries, so far as the importance of its products to the consumer is concerned. But it hardly seems necessary to go so far in order to prevent prices from rising too high.

Some observers predict that, should all drug products be purchased under a generic name, all drug standards would immediately drop to the lowest tolerance in the United States Pharmacopoeia, and any attempt to exceed such standards would be useless, since there would be no reward for those who make the extra effort to do so.[9] But it can be validly held that even if that were to happen, it would not materially matter, since expert opinion has set the limits of quality within which drugs may be manufactured. And the same experts have testified that there is no advantage whatever in exceeding the highest standards. Presumably, then, even if the worst should happen, and manufacturers dropped their standards to the lowest limits set by the Pharmacopoeia, no great harm would be done, since the difference between highest and lowest is neither very great nor very significant.

But there is a practical question involved. To apply

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[9]"Minority Analysis of Majority's Charges," Kefauver Report, p. 360.

the concept of prescription by generic name rather than brand name involves patents, copyrights, trade-marks and advertising. If drug manufacturers were to be deprived of the right to exploit their own brand names as other manufacturers in our economy do, there would be less incentive for them to undertake research and promotional activities. Attacks on brand names have been made at various times in our history, once during World War II when it was felt that the elimination of brand names might serve as a device to facilitate price controls. There are always individuals and groups which are inclined to criticize the brand name concept of identification of products, partly on the basis of the assumption that exploitation of brand names leads to higher prices. This may or may not be valid. But brand names are a basic aspect of American economy and free enterprise. It would be unfair to discriminate against one industry in this respect without important and valid reasons. It might also be unwise to do so since, as we have noted earlier, promotion and innovation go hand in hand.

It is undoubtedly true that innovation, promotion and the exploitation of brand names in the drug industry do intensify control of the drug market by the large companies, because such companies have more success in getting their own brands prescribed by doctors. Whether the drugs are patented or not, the small manufacturers are kept out of a

large share of the market. Price competition is not much of a factor in the drug industry. As we have seen above, it is competition in innovation which plays a more important role. Obviously, anything that causes a doctor to prescribe by brand name and to have any difficulty or reluctance in prescribing by generic name is going to magnify control by the larger companies which do more research and spend more money on advertising and promoting their products.

Still, this situation is not very different from that in other sectors of the American economy, in the sense that the larger the company the more it can spend on advertising and promoting its own brand name. In some respects, this may be an undesirable situation so far as emphasizing tendencies toward monopoly, duopoly or oligopoly in the drug industry is concerned. In other respects, it may be that the nature and degree of competition in the drug industry serve the interests of the public so long as research and innovation are stimulated and new products are developed constantly. Clearly, where drugs and medicines are concerned it is vital that the process of research continue. What is sometimes referred to as "meaningless product differentiation" in other industries can scarcely be applied as a concept to the drug industry, even though a certain amount of molecule manipulation may not yield significantly new medicines.

If, therefore, a trend toward prescription by generic name were to undermine the exploitation of brand name and thus to decrease research and innovation, this would be a heavy price to pay for increased competition in the area of pricing. It would seem, however, that where generic prescribing does effect considerable economies, as in institutional agency buying referred to above, it should continue. Insofar as prescription writing by individual doctors for their usual patients is concerned, i.e., not welfare patients who must also economize, there does not seem to be sufficiently valid reason to alter the system of prescription by brand name. Doctors are free to prescribe by generic name if they wish to. It would, perhaps, be desirable if certain effects of brand-name prescription could be minimized, however, especially the intensification of economic control by the larger manufacturers. This seems to be related to the efforts of such companies to promote and advertise their products which, as suggested in the previous chapter, also lead, in some degree, to over-pricing.

# CHAPTER VI

## PRICES AND PROFITS

One of the most controversial aspects of the drug industry is that related to prices and profits. Industry prices are usually evaluated by such yardsticks as unit production costs, prices in various markets, and profits. Unit direct or production costs, as discussed here in regard to certain pharmaceuticals, include costs of materials, labor, assay and quality control, and allocable plant overhead. These are the processes which turn out the finished drug, packaged for shipment to wholesaler or retailer.

The manufacturer has other expenses, of course, such as selling and promotional costs, research costs and general administrative expenses. Therefore, the difference between production cost of a product and its selling price is not the same as net accounting profits. But in order to trace the relationship between production cost and prices of specific drugs, it is essential to disregard here the indirect costs, administrative expenses and other expenses which must specifically be allocated to certain products. Direct costs represent inescapable costs of manufacturing a given amount of a product, apart from expenses in other areas which arise partly as a result of managerial decisions, and some of which are more variable than others.

The difference between direct costs and selling price is margin; it is not, if there are other costs, net profit. This margin may be referred to as "percentage margin" or "percentage mark-up." It can be measured either in terms of costs or prices. If the base or denominator of the division is price and the numerator the margin, the result is margin in terms of price or "percentage margin." If the base is cost, then the relative extent to which price is larger than direct costs is being determined in terms of costs, and is called "percentage mark-up relative to costs."

For instance, let us consider one of the corticosteroids, related to prednisolone, sold by Schering under the brand name, "Meticortelone"; the computed direct or production cost (in the nature of a maximum estimate) is given as $1.57 per 100 tablets. Schering sells this bottle of 100 tablets to the retail druggist for $17.90 and the druggist sells it to the consumer for $29.83. This same product is sold under a variety of other brand names by Upjohn, Merck, Pfizer and Parke Davis, all at the same wholesale and retail prices suggested by each manufacturer, except that Parke Davis' product carries a suggested retail price one cent above the $29.83 of its competitors.[1]

Similarly, for prednisone, another corticosteroid.

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[1] Kefauver Report, p. 15.

Computed production cost, except selling and distribution costs, is $13.61 per thousand. The price to wholesalers is $136 per thousand, to druggists $170.00 per thousand and the list price to consumer would be $283.33 per thousand. This is a margin of ninety percent of price to wholesalers for the manufacturer for selling, administrative, and other nonproduction costs, and profit.[2]

In the case of certain tranquilizers, a somewhat similar relationship between prices and product costs is demonstrated. For instance, Carter Products owns the patent rights to meprobamate. Carter sells the finished drug under the trade-mark "Miltown," and has licensed one firm, American Home Products Corporation, to sell the finished product in the United States. Carter itself does not manufacture meprobamate, however, but subcontracts bulk production to a number of other firms, none of them licensed to sell the drug in finished form. Carter has licensed two companies, American Home Products and American Cyanamid, to sell the product throughout the world. American Home Products offers this product for sale through its Wyeth division under the trademark "Equanil." Wyeth's role is confined only to finishing and packaging, since Wyeth buys the bulk from Carter, as much as Carter is willing to sell, and any additional amounts

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[2] Ibid., p. 16.

from sources approved by Carter.

Unit production costs, including all the costs of making the bulk powder, finishing, bottling and packaging for shipment, but excluding selling and distribution costs, are $7.32 per thousand for Carter's "Miltown" and $15.00 for Wyeth's "Equanil." The reason for the price differential is that Carter buys from subcontractors who cannot enter the finished product market, acquiring its own meprobamate at an average cost (December, 1958) of $4.35 a pound. Wyeth, compelled to buy the bulk powder from its only domestic competitor in the finished product market, had to pay Carter's price of $10 a pound. For both brands, the prices to wholesalers are $52 per thousand, to the druggist, $54 a thousand, to the consumer, $108.40 per thousand ($5.42 for fifty).[3]

In the case of the oral antidiabetic drug, "Orinase," tolbutamide, the product must be bought from the German firm, Hoechst. Upjohn secures the active drug in bulk form from an American subsidiary of Hoechst, and performs only tableting, packaging and marketing functions. Upjohn's total production costs, i.e., cost of material, tableting, and royalty to Hoechst, is $13.00 per thousand. It is sold to the wholesaler and to druggists buying direct from Upjohn

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[3] Ibid., p. 18.

at $83.40 per thousand and to the consumer at $139.00 per thousand ($6.95 for fifty).[4]

Tetracycline, one of the broad-spectrum antibiotics, is produced in the United States by three firms, Bristol, American Cyanamid (Lederle Division), and Pfizer. Squibb and Upjohn are licensed by Bristol to sell the finished products made from bulk powder purchased from Pfizer. The cost to Upjohn to manufacture tetracycline (actually, tetracycline phosphate complex capsules) is $9.30 per hundred, including royalty. The cost to Bristol is $5.03 per hundred. Bristol sells the product to the wholesaler at $24.22 and Upjohn at $30.60. Both sell to the retailer for $30.60 per hundred and to the consumer for $51.00 per hundred.[5]

It is clear from these specific instances and also from other data applying to the actual producer of the bulk drug and the manufacturer's average realised price, or price to wholesalers, that the margin (over direct costs) to prices is quite high. It varies from 80.1 percent to 88.8 percent. Again, it must be emphasized here that this is not to be thought of as profit. For out of this margin must come research expenses, the extent of which is a managerial decision; administrative expenses; distribution and promotion

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[4] Ibid., p. 20.

[5] Ibid., p. 24.

expenses; taxes and any other costs of the business. But there is a reason to distinguish between inherent costs below which the drug company cannot go when producing pharmaceuticals and other expenses which are determined as matters of policy. To a certain extent, of course, costs of administration and overhead are inherent in the expenses of doing business but they differ from the unit direct or production cost in being susceptible to variation. This is worth mentioning because in the controversy over lower drug costs, major producers frequently point out with some validity that although it would be possible to lower overhead costs, it would not be particularly desirable, if this decrease in overhead costs resulted in inadequate quality control. To a greater extent, expenses of research and promotion are the result of deliberate choices and policies of management. If prices of drugs were lower and the margins were lower there would obviously be less money for management to spend in certain other areas of production. Whether this would be desirable or not, is another matter.

It is somewhat difficult, moreover, to compare the margin in the drug industry with that in other industries, because unit cost data are available for only two industries, automobiles and bread, both of which were investigated by the Senate Subcommittee on Antitrust and Monopoly. Available statistics of this type from other industries are meager.

But in the four largest bread-baking companies, the margin between unit direct cost and manufacturers' average realized price was 29.6 percent. In automobiles, the margin for one, General Motors Corporation, was thirty-nine percent or less than half that of most of the drug products.[6]

When comparisons are made on the basis of company analysis instead of individual products analysis, even wider comparisons can be made. Among fifteen drug companies on available data for 1959, gross margin above production costs ranged from 58.6 percent to 78.4 percent. By comparison among fifty different industry groups, each company a leader in its industry, it is found that the lowest gross margin of fifteen drug companies was higher than any in other industries. Coca-Cola had a gross margin of 57.36, whereas the lowest gross margin of fifteen companies was fifty-nine percent. In six out of the fifteen companies, the gross margin was more than seventy percent of sales, whereas in forty-one of nondrug companies the margin was below thirty-five percent.[7]

The difference between the breakdown of sales dollars of drug producers and that in other industries is revealing in other areas. Although few industries in the American

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[6] Ibid., p. 26.
[7] Ibid., p. 29.

economy spend so small a proportion of sales receipts to produce the goods they sell, few industries spend so much either on research and innovation or on promotion. In 1960, for instance, the research expenditures of the drug industry as a percent of sales were about three times those of all industry.[8]

A specific breakdown of the sales dollar of several major drug firms is presented in Table 1. These figures indicate that selling (which includes promotion and advertising, of course) is by far the largest item in the sales dollar. Since the basic demand for drugs cannot be increased much, if any, by advertising and promotional expenses, selling costs are not related very directly to selling the consumer, but, as suggested in the discussion on innovation, are related closely to the need to publicize new developments to physicians. The data shown in Table I seem to suggest a positive correlation, among many of the firms, between selling expenses and research, although it is not entirely certain which is cause and which effect. Sales efforts of the companies are competitive, not in the sense of attempting to secure a greater use of the drug in question, but of securing for the firm a greater share of total

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[8] Pharmaceutical Manufacturers Association, Prescriptions, Profits and Progress (Washington, 1961), p. 5.

TABLE I

BREAKDOWN OF SALES DOLLAR FOR 15 DRUG COMPANIES (Drug Operations Only)

| | American Cyanamid (Lederle) | American Home (Weyth) | Bristol Labs. | Carter Products | Ciba | Eli Lilly | Merck | Pfizer |
|---|---|---|---|---|---|---|---|---|
| Net Profit | 15.6 | 14.7 | 9.9 | 20.4 | 12.7 | 13.3 | 12.9 | 10.5 |
| Taxes | 16.2 | 15.6 | 6.5 | 23.4 | 12.9 | 13.8 | 12.8 | 5.7 |
| Selling | 25.4 | 24.0 | 32.3 | 27.8 | 33.9 | 18.1 | 18.1 | 26.7 |
| General and Administrative | 10.2 | 14.9 | 18.0 | 6.5 | 7.4 | 10.5 | 10.2 | 7.1 |
| Research | 6.4 | 3.2 | 13.7 | 2.7 | 13.9 | 8.8 | 8.0 | 4.9 |
| Cost of Goods | 26.2 | 27.3 | 19.6 | 19.2 | 19.2 | 35.4 | 38.0 | 45.1 |
| Total | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 99.9 | 100.0 | 100.0 |

| | Parke, Davis | Schering | Smith, Kline and Fr. | Upjohn | Abbott | Hoffmann-LaRoche | Norwich |
|---|---|---|---|---|---|---|---|
| Net Profit | 16.0 | 15.9 | 17.2 | 13.7 | 11.0 | 8.7 | 11.6 |
| Taxes | 15.3 | 13.4 | 20.0 | 14.4 | 10.1 | 9.4 | 12.0 |
| Selling | 25.2 | 32.7 | 19.5 | 20.9 | 28.4 | 17.4 | 40.5 |
| General and Administrative | 6.1 | 8.8 | 10.9 | 16.6 | 10.0 | 30.0 | 6.6 |
| Research | 4.8 | 8.2 | 8.9 | 8.8 | 5.6 | 6.9 | 4.5 |
| Cost of Goods | 32.6 | 20.9 | 23.5 | 25.6 | 34.8 | 27.5 | 24.8 |
| Total | 100.0 | 99.9 | 100.0 | 100.0 | 99.9 | 99.9 | 99.9 |

Source: Kefauver Report, p. 31.

sales of the particular drug.

Taken as a whole, the gross margin of the drug industry as represented by the twenty-two representative companies examined by the Kefauver Committee came to 67.9 percent of sales, when drug operations alone are considered. Three-quarters of the margin went to promote sales or into profits. Profits before income taxes and advertising and selling expenses were about the same in size. Profits amounted to 25.8 percent of sales; advertising and selling to 24.8 percent.[9] Profits after taxes, of course, are considerably lower and by comparison with other industries are certainly high but not necessarily excessive. As Francis Brown, the head of Schering, has pointed out:

> . . .[You] must distinguish between markup and profit, because markup is on the basis of cost and percentage of profit is on the basis of the sales dollar, so that in the case of profit you can never get more than 100 percent. In the case of markup it may be less than 100 percent or thousands of percents, depending on the nature of the product.[10]

As Table I shows, net profits in the drug industry vary. Hoffman-LaRoche in 1958 reported a net profit of 8.7 percent, whereas Carter Products reported a profit of 20.4 percent.

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[9] Kefauver Report, p. 30.

[10] "The American Drug Industry," The American Forum, Westinghouse Broadcasting Company, Tuesday, February 2, 1960 (Washington, D.C., Vol. XXIII, No. 6), p. 2.

The twenty major drug companies are also among the first fifty corporations of the nation ranked by net profit as percent of invested capital and as percent of sales. Three drug companies head the list of industrial corporations ranked by net profit after taxes as percent of invested capital--Carter Products; American Home Products Corporation and Smith, Kline and French. Ten other drug companies are within the first fifty industrial corporations and four more in the next fifty. Three of the six top industrial firms ranked by net profit after taxes as percent of sales are also drug firms; thirteen of the twenty major firms are among the top fifty industrial corporations.[11]

The drug industry as a whole compares very favorably with other individual industries. It has experienced very fast rising profits especially between the years 1947 and 1959, although with a small drop in the latter part of 1960 when, for the first time in ten years, a reduction was made in the prices of major antibiotics (fifteen percent) and a corresponding reduction in the profitability of the drug industry was experienced.[12]

But the drug industry has had a strong competitor in motor vehicles which during some years in the 1950's has

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[11] Kefauver Report, p. 51.

[12] Ibid., p. 53.

surpassed the drug industry in performance. A major factor with relation to the drug industry's sustained economic growth is that it appears to be virtually recession-proof. Whether this is related to the fact that it is not dealing in ordinary consumer commodities, the enjoyment of which is a matter of preference for the consumer, and the demand for which is more elastic, or rather to the ever-increasing role of profitable innovation would be hard to ascertain without further research. It may be that the inelasticity of demand which is said to place an upper limit on sales also places a lower limit on them. And this may be especially the case when new drugs are constantly being developed which at least give promise of combating diseases.

In this connection, however, it should be stressed that, as is true of any industry which engages in considerable innovation, obsolescence is a factor in the drug industry. Many, if not most, of the newer drugs can become obsolete within five years. Indeed, it is said that thirty-three percent of prescriptions being written today could not have been written five years ago,[13] since so much innovation is bringing out newer substitutes for old drugs. In other words, the drug industry is a high risk industry, from

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[13] D. D. Stiles, 1960 Prescription Market (Mimeographed), Abbott Laboratories, July 26, 1961.

some points of view. There is a time lag between the investment of funds in a research program and the time when returns on the investment may be realized. And, as suggested earlier in this study, often enough research projects do not develop a marketable product. Lederle, for instance, had invested almost a million dollars to find a vaccine for pneumonia when the discovery of sulfa drugs wiped out the market for the vaccine. In 1959, Lederle was investing $500,000 in cancer research whereas in the same year total sales of its five anti-cancer drugs amounted to only $150,000.[14]

The drug industry is, to a greater extent than many, a high capital industry. One dollar of capital generates only $1.41 of sales, whereas many other industries are far above this level. Baking companies generate $4.72 for each $1.00 of invested capital; autos, $2.30; textiles, $1.96; tobacco, $1.59; paper and allied products, $1.57, to mention but a few.[15] It is not unusual for high profit and high risk to go together, in any case, although a high capital-output ratio need not necessarily imply high risk, so much as just high capital costs. But it is worth mentioning that one particular type of risk to which drug

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[14] Prescriptions, Profits and Progress, p. 5.

[15] Ibid., p. 7.

companies are susceptible, despite scrupulous efforts to avoid it, is damage suits for individuals suffering ill effects from drugs. In recent years, several companies have been obliged to pay out large sums in such suits. Moreover, the drug industry usually looks upon the cost of research as part of current operating budget whereas it has been suggested by the National Science Foundation that research expenditures might properly be viewed as capital investment. If this were done, the prescription drug industry in 1960 would have put 13.5 percent of total sales back into the business.[16]

Profits in the drug industry are admittedly high, among the highest in all of American industry. But to say that they are unreasonable or excessive is to lose sight of the fact that the industry is one with very high capital requirements, high risk, and, associated with the latter, rapid obsolescence. Some critics of the industry have suggested that since an average six percent net profit rate of return on net worth (stockholders' equity investment) represents what is considered a fair and reasonable rate of return, it may not be amiss to limit the profits in the drug industry as is done in the case of public utilities limited

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[16] Ibid., p. 8.

by regulatory bodies.[17] In this connection, it is suggested too that drugs might be considered in somewhat the same light as utilities, necessities of life such that the sellers have a fairly assured market. On the other hand, it is also pointed out that the drug industry does not enjoy a franchise granted by public authority and is subject to the competitive forces of the market place (if not price competition, product competition).

But there is a more important factor in the drug industry and that is the value to the consumer of a constant effort to develop new products. We may say, of course, that prescription prices are high; some observers say "too high." For the purposes of this discussion, the question of whether prices are too high will be discussed only from the point of view of economic concentration. Other considerations, relating to ethics or social responsibility, would take the study out of the area of economics which is the main concern here. Prices are high when compared with basic production costs but, as has been demonstrated, much of the margin goes into selling and promotion. These are inextricably interrelated with innovation and the competition to which innovation gives rise. Should an effort be made to place a ceiling on prices and profits, there is little doubt that a damping

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[17] Kefauver Report, p. 312.

effect on innovation would be observed.

It is a matter of managerial decision resulting from innovation to allocate so much of the margin to promotion. (The relationship is phrased in this way to suggest that promotion costs considerably more than research itself.) In other words, this is a decision relating to deliberate policy of exploiting new developments. But it is apparently a necessary one. For there have been instances in which small firms in certain production lines were able to put their products on the market and at prices substantially lower than those of large firms, but were not able to capture a share of the market. This fact stems from difficulty in distribution which results from inadequate funds to carry on competitive promotion and advertising.[18]

All these facts together suggest that there is a relationship between innovation, high prices, expensive promotion and economic concentration. Only in a very few instances has it been possible for small manufacturers offering price competition to break down the rigid price structures of the larger firms.[19] It would seem that without the promotional expenses, it would be possible to market many of

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[18] Ibid., p. 314.

[19] Ibid., p. 315.

the drug products at a lower price and still make a profit. But to do this would be to endanger the position of the firm in the market. But there is little indication that the few firms which do enjoy a monopolistic or oligopolistic position in the industry will retain that position indefinitely.

We may, then, draw these conclusions from a study of prices and profits in the drug industry:

1. Profits and prices are high in the drug industry, by whatever standard they are assessed;
2. High profits and prices are related to high risks and high capital investment;
3. High profits, high prices and high risks are partly the cause and partly the result of innovation and rapid obsolescence;
4. Lower prices and profits would tend to cut down on innovation;
5. Economic concentration is both the cause and the result of high prices, high profits and high risks.

Further implications of such economic concentration will be explored in a succeeding chapter of this study.

## CHAPTER VII

## ADMINISTERED PRICES AND RESTRAINT OF TRADE

Reference has been made earlier in this study to the several indictments brought against firms within the drug industry and pharmaceutical distributors on charges of price-fixing by agreement. One was the case of a suit brought against five drug firms by the Department of Justice on the basis of evidence that bids received by the United States Public Health Service for Salk vaccine were identical. Later, major anti-trust indictments were brought against parties in the industry, i.e., against pharmaceutical associations of Northern California, Arizona, Idaho and Utah. Both were criminal indictments. The cases against the Northern California Pharmaceutical Association and the Utah Pharmaceutical Association were decided in favor of the plaintiff, i.e., the government, on the grounds of price-fixing in contravention of the Sherman Antitrust Law.[1] That against the drug producers was dropped because there was no evidence that price-fixing agreements were made.[2]

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[1]"Utah trial verdict...government favored," Journal of the American Pharmaceutical Association, February, 1962, p. 79.

[2]Edward Ranzal, "3 Drug Concerns Indicted with Officers in Trust Suit," New York Times, August 18, 1961, 1:2.

The question for this study is whether it is valid to infer that price-fixing does take place within the drug industry and what the implications for economic concentration in the industry may be. It would seem that the lack of overt evidence to support charges of price-fixing cannot be taken as unmistakable evidence that some form of price-fixing does not exist.

It is obvious, however, that there is little or nothing in the way of price competition in the drug industry. Price leadership exists in the drug industry, as in many other industries. This is a process by which leading manufacturers set the prices and other companies, even when they may be more efficient, manufacture at lower costs and show higher profit margins, retain the same prices and change them only when the leader changes. In the drug industry there is another factor, however. When a new product is manufactured the usual procedure is to introduce it at either the same price or one very close to that of the existing product in use for treatment of the same illness. Drug industry representatives refer to this as "meeting competition." That is, they eliminate price rivalry, for as

long as the new drug is introduced at the same price as the old one, the maker of the older product does not need to lower his price.[3]

The situation which results from these factors is one in which "administered prices" exist. Prices within such an industry are "set by administrative action and held constant for a period of time." They are not, therefore, sensitive to changes in the market. Should demand fall off, prices do not fall but ordinarily are held at a particular level by a curtailment of output.[4] There may presumably occur a widening gap between production costs and prices, since under the impact of technological change the former may fall whereas the latter do not.

As suggested previously in this study, we have somewhat arbitrarily excluded the question of "reasonableness" of price per se because it would involve us in many non-economic considerations which would require extended treatment. And, as has been suggested, price competition in the drug industry, even if it existed, would necessarily be significantly affected by the costs of innovation. In the drug industry, however, competition exists rather on the basis of technological innovation itself than on the effects

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[3] Kefauver Report, p. 98.

[4] Ibid., p. 2.

which innovation might have on reducing costs. Theoretically, at least, innovation in production techniques in certain industries would enable an advanced firm to lower its costs, thus forcing other firms to meet the competition and lower theirs in turn, and so forth. The drug industry is significantly different from some others in that there is almost nothing approaching an elastic demand. This point, which has been mentioned previously, is worth emphasizing here because prices in the drug industry could not, in any case, be substantially affected by the usual "law" of supply-and-demand.

This implies that marketing techniques would necessarily differ from those in other industries. Few efforts to increase consumption in ethical drugs could be effective. It is true, of course, that if prices were not administered and price competition were active, prices would have to fall. Innovation in production methods would make it possible to produce products more cheaply, as one would suppose actually is the case, and, without artificial price rigidity, prices would tend to fall with lowered costs.

The question arises here, as to whether that would necessarily be beneficial either to the economy as a whole or to the drug industry specifically. Assuming that some degree of economic concentration exists in the industry, which appears to have been demonstrated, what are the effects

of such concentration? The economic concentration in the drug industry does not prevent competition as such from existing. What it does do is to put stress in competition on technological innovation rather than on prices as such. These technological advances are necessary in order to stimulate the development of new products. It is true that capital costs in the drug industry are far less than in other industries such as, for example, the automobile industry. But the particular type of innovation in which this industry engages requires patent protection. Rapid obsolescence of pharmaceutical products implies a significant need for promotion in order to make new products profitable for as long as they are useful and are not superseded by others. And it, in turn, stimulates further concentration by bringing about a situation in which a relatively few producers holding patents are able to effect a far larger distribution of products than smaller producers can.

Does all this constitute "restraint of trade?" It seems to the writer that this is not essentially the case. There is an oligopolistic situation for the most part in the drug industry. True, with reference to specific patents and products, there may be a monopoly or duopoly, but in the industry as a whole oligopoly is the primary character of the structure. In other words, the whole question of

competition and "free" trade, as related to prices, is a somewhat fine one. A price may lessen competition or it may, equally, destroy or prevent competition altogether. It might conceivably be possible for a manufacturer to lower his prices to one purchaser, and not lower them to another whose circumstances were different (this being quite legal), and in doing so destroy one purchaser (to cite an extreme situation) and thus lessen competition, rather than stimulate it. There is certainly ample evidence in the drug industry that producers quote different prices to different categories of buyers and there is some evidence, although admittedly not much, that some firms can quote lower prices than others when their promotional and distributive costs are lower.

In connection with drugs, more than any other type of commodity perhaps, an issue of significance is that of the ultimate benefit to the consumer. Therefore, if it could be readily demonstrated that more competition could exist in the drug industry under other circumstances, such as alterations in the patent laws, we should still have to answer the question, "Would this be to the benefit of the community as a whole?"

The answer to that question is, in the writer's opinion, no. Increased price competition in the drug

industry would do much to decrease innovation and competition in development of new products. This is not precisely the same as suggesting that prices might not be lowered to some extent, or that lowered prices might not benefit the consumer ultimately. The problem of high prices of drugs for low-income consumers is a real one and might perhaps be mitigated, to some extent, by somewhat lower expenses of promotion and advertising. However, if increased competition were to result in substantially lower prices and also in substantially decreased research competition, the eventual result would be a net loss to society.

The fact that prices are administered in the drug industry is evidence that there is nothing approaching "pure" competition. However, it would be hard to find any industry in which such competition thrives in the American economy, if by "pure" competition we denote a competitive situation determined wholly by the market and beyond the influence of any individual action by a seller. That there is monopoly and, under varying circumstances, duopolistic and oligopolistic competition in the drug industry can hardly be denied. This may not be the type of competition which, under other economic circumstances, our own society would like to foster. But it is not illegal, although somewhat circumscribed. It does not violate the antitrust laws, and the

two instances in which suits were upheld because of violations of the Sherman Antitrust Law were exceptions. Moreover, they were found in the distributive sector of the industry, rather than in the producing sector.

The patent monopolies which exist, in varying degrees according to the particular patent, licensing and cross-licensing arrangements, do not constitute violations of the antitrust laws. These arrangements are conducive to development and they provide the protection which the innovator requires in order to make up the costs of his research. They contribute in some measure to restriction of competition; this is true. But it appears to be part of the price which our society pays, or perhaps any advanced industrial society, for the risks of research. Without the protection, the innovation would be less. Innovation is obviously a basic component of an advanced industrial society and it does not seem that it would be beneficial to any society to discourage it.

In summary, there is no such thing as pure competition in the drug industry. There is, perhaps, some degree of price competition, but for the most part the competition which exists is in the area of research and in the area of selling. There is certainly evidence of administered prices in the drug industry, but no explicit evidence--except

perhaps in the case of the pharmaceutical distributors in several states--of price-fixing as such. This does not mean that there is no such thing as price-fixing, but simply that there is no evidence sufficient to prove violations of antitrust legislation, in the legal sense.

Clearly, there is a conflict between technological progress and social values. It would seem that social policy must work to get reasonably adequate progress at the lowest cost in high prices, or whatever other undesirable elements may seem to help growth. In some such fashion, at least, a balance between social values and industrial progress may be struck under the conditions of our society.

# CHAPTER VIII

## SUMMARY AND CONCLUSIONS

This study has been concerned with economic aspects of the American drug industry. In particular, attention has been focused upon the degree of concentration in the industry, the relationship of prices to profits, the extent of research and innovation and their effects on prices, patents and licensing, prescription by generic rather than brand name, and the question of administered prices.

We have concluded that there is structurally a rather high degree of concentration in the industry. The degree differs with the various products manufactured by the companies and the patent and licensing arrangements relating to each product. The pattern may be monopoly or duopoly, with respect to particular products, but more frequently it is oligopoly. Although there is no explicit evidence of this, it is probable that informal or tacit arrangements sometimes exist among the firms such that prices are established without incurring the risk of prosecution under the antitrust laws. Price leadership and live-and-let-live arrangements may be presumed to exist as in oligopoly generally.

Entry into the market is limited, not because of high

capital requirements but by the patenting and licensing arrangements which restrict the products to which the small producer is able to receive rights. Process patents are not a long-lasting form of protection because molecular manipulation, a form of product differentiation, enables some firms to avoid patents held by others. The patent system represents a socially created barrier to entry into the industry of the patent holder without which, in all probability, oligopoly would disappear or at any rate the small number would become more numerous since there are few, if any, significant natural barriers to entry in this particular field. Critics of the system suggest that patent protection should be limited to three, instead of seventeen, years and that release of information after that time should be mandatory. Against this view, this paper has suggested that patents are a necessary form of protection, even though limited in scope, if a firm is to invest heavily in research, which in the case of drugs would seem to be desirable.

The drug industry is similar to other oligopolistic sectors of the economy in which, although there is almost no price competition, there is keen competition in promotion and product differentiation. In many cases of oligopoly,

rival promotional and advertising campaigns succeed chiefly in increasing the costs of the individual sellers and often, though not necessarily, prices to buyers. This is a criticism which has been launched against the drug industry. The problem of the drug firm, like that of others, is to maximize profits as far as possible. Obviously, increased advertising costs (unless they reduce unit production costs through larger volume) do add to the seller's total costs and there is little point in increasing such costs to a level at which marginal revenue falls below the marginal cost of the advertising. The limit of social value from advertising may be reached, however, before the point at which it ceases to be profitable to the firm. When the social limit is too far transgressed, policy may have to consider ways and means to halt purely persuasive or competitive (not informative) advertising. But if legislation is to be invoked, probably it should be done for all oligopoly or even for all non-purely competitive sellers. But the prescription drug industry would do well to avert legal action by avoiding a situation in which greatly excessive competitive (over and above informative) advertising adds to drug prices even if by adding equally to costs it fails to add to profits. We

have suggested in an earlier chapter that it would be possible and desirable to cut down on some elaborate and expensive promotional campaigns (such as, for instance, the cocktail party at which drugs are occasionally "introduced" to physicians, but which has been disavowed by many firms), and efforts of this type might conceivably lower prices to some degree. On the other hand, it is necessary for the drug companies to "sell" the physician, rather than the ultimate consumer and this requires a well-informed and qualified salesman who can keep doctors informed of latest developments in the drug industry. Physicians themselves concede that they are unable to keep up with these for lack of time. This is a rather costly selling effort but effective promotion is necessary because of the rapid obsolescence of drugs resulting from innovation. This paper does not, therefore, support unqualifiedly the claim that promotion of drugs is excessive.

In the drug industry we have suggested that product improvement and in some cases even product differentiation is not without its social benefits and that it may ultimately operate in the best interests of the consumer. Nevertheless there is a significant reservation with regard to innovation and technological change. As this paper has pointed out earlier, with respect to the types and purposes

of research, some of the results of innovation are admittedly of dubious value, and at least one competent authority has suggested that drug manufacturers are sometimes able to market their research failures as well as their successes. Mere novelty in drug differentiation does not *per se* constitute progress. Although it is the opinion of this writer that innovation should be encouraged, it might be well to explore various methods of emphasizing the more basic research in preference to that which is less therapeutically useful. In this connection, the codes of ethics drawn up in other industries might serve as an example of one type of solution to the problem.

This paper has suggested, too, that the greater freedom of entry into the market which would presumably result if the patent system were altered or the selling expenditures of the larger firms restricted might well result in atomization of the market. In many cases of oligopoly, such atomization results in less efficiency and in higher unit cost of manufacture. The importance of this reduced manufacturing efficiency would be less in the drug industry in which the cost to manufacture is a relatively small part of the price in any case. But, as has been suggested above, some decrease in innovation might take place with fragmentation of the industry since technological competition would

be replaced in part by price competition.

The attack by critics on prescription by brand name rather than generic name seems unwarranted. This paper has pointed out that physicians are free to prescribe drugs by generic names if they prefer. It is true that for bulk buyers, e.g., hospitals, which can afford their own laboratory tests, prescription by generic name, and especially when secured by competitive bids, can result in significant economies without the risk of poor quality. The individual physician, lacking such means of testing, may prefer to prescribe by brand name. And certainly the ultimate consumer is wholly unqualified to judge the quality of a drug. This paper has pointed out that while qualitative differences between drugs of the same type manufactured by different firms are necessarily limited since all drugs must pass certain tests which set permissible limits, there are, within those limits, differences in quality. As is the case in other oligopolistic industries in our economy, exploitation of brand name in the drug industry is a very significant part of competition. Undermining brand names would diminish incentive toward innovation and, to an extent, toward production of products of the highest quality rather than of the lowest permissible level.

One of the most severe criticisms made against the

drug industry is that prices are unreasonably high, both in terms of cost to the manufacturer and the burden to the individual purchaser. It has been pointed out that costs are higher than may appear to be the case when costs of research and promotion, and degree of risk are taken into consideration. With respect to research it must be remembered that for every useful discovery, for every "breakthrough," little or big, for every useful new creation there are likely to be dozens of disappointments. Yet the costs of these negative results must be borne by the few marketable successes.

Still it is to be confessed as reported in Chapter Six that research costs are not the overwhelmingly dominant element in the sales dollar. (To be sure, the fraction varies from firm to firm.)

Selling costs are the dominant cost, exceeding both "production" and research costs individually and approximating them in combination. As indicated above, it is probable that selling costs distribute themselves over the whole spectrum from vital information of high social utility to competitive pressures involving high expenditures and dubious social gain.

It is not unusual in an oligopolistic industry for prices to exceed average costs and for profits to exist in

the long run. Blocked or partially blocked entry into the field has implications in regard to the organization of production in the economy. Essentially, profits indicate that consumers may desire an expansion in the output of the product under consideration as compared with the output of other products in the economy. But resources are not free to move in that direction because there is restriction of output in oligopolistic markets as compared with the theoretically purely competitive markets. The amount of oligopolistic or monopolistic limitation required for a given price increase is less where the demand is very inelastic, though by the same token, unit for unit the curtailment hurts the buyer more.

It has been pointed out above that lack of price competition in itself does not operate to restrain, but to a degree promotes, what many feel to be the most valuable competition of the industry, namely product competition. The product competition may be of much more significance to the individual buyer and user of drugs, although this is not to say that prices are not also significant to buyers and users. It is, however, necessary to balance the need for product improvement and innovation against the economic requirements of our society with the hope of achieving as much progress in both areas as possible. Lower profits and

prices in the industry might be bought at too high a cost if they led to decreased technological competition. The rivalry in the drug industry has resulted in the development of new products, some of which are quite literally life-saving in their effects. The human benefits are beyond calculation. The drug industry is dynamic and it epitomizes Schumpeter's concepts of innovation and "creative destruction" which he calls the really great and important competition.

There are certain aspects of the drug industry which it has not been feasible to explore in this study, given the self-imposed limits of the investigation, but which would be significant areas for future studies. It might well be enlightening, for instance, to undertake comparisons of the American drug industries with some of those abroad, as to licensing and patenting arrangements, prices and profits, and the degree of innovation associated with certain types of patent agreements. It would perhaps be fruitful to investigate such factors as quality control and inspection of drugs in this country with reference to the role of the Food and Drug Administration. There would conceivably be some advantage in exploring possible methods of distinguishing between productive and therapeutically useful innovation and less valuable innovation, with a view to diminishing the latter and, consequently, effecting lower prices in the industry.

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