

AN ANALYSIS OF RESEARCH AND DEVELOPMENT
PRACTICES AND PROSPECTS IN THE
PHARMACEUTICAL INDUSTRY

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This is to certify that the
thesis entitled
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ABSTRACT

AN ANALYSIS OF RESEARCH AND DEVELOPMENT PRACTICES AND PROSPECTS IN THE PHARMACEUTICAL INDUSTRY

by Stephen Stewart Castle

This investigation delineates the nature and role of research and development in the ethical and proprietary segments of the domestic pharmaceutical industry in the United States. Additionally, the study indicates the probable direction of drug R and D programs within the environment imposed upon the industry by its economic characteristics and legal requirements.

Methodologically, the study is based upon an extensive review of the literature concerned with pharmaceutical economics, federal regulation, and research and development. A heuristic model of the R and D process in the drug industry is presented. This model serves to introduce thirteen confidential interviews with managerial personnel from as many major pharmaceutical firms.

The study broadly concludes that the major innovative area in pharmaceutical research and development is --and likely will remain--increased emphasis on marketing research techniques. Specifically, it is thought that research and development in proprietary firms is of only passing academic interest, and that this group is amply regulated under existing laws. Accordingly, the paper's

Stephen Stewart Castle

ultimate major concern is with ethical drug manufacturers. Because of virtually absolute demand inelasticity at the consumer level, a need for new products with which to support intensive and extensive sales promotion efforts, a profit orientation inappropriate to so vital an area of social concern, and the risks inherent in the very nature of research itself, substantial changes are indicated as immediate necessities for this important portion of the drug industry.

Since present federal legislation controls ethical drug manufacturers with respect to product quality, safety, and efficacy, it is concluded that two additional legal requirements--price and profit control--must be instituted. It is suggested that ethical pharmaceutical firms be restructured as public utilities, with product monopoly and relative freedom from research and development risks assured. Similarly, prices must be stringently controlled at all distributive transaction points, particularly retail pharmacies.

Compliance with these recommendations may be expected to result in new, useful products; more orderly marketing programs; halted consumer exploitation; and profits adequate to justify the existence of competent firms at the manufacturing, wholesale, and retail levels.

**AN ANALYSIS OF RESEARCH AND DEVELOPMENT
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PHARMACEUTICAL INDUSTRY**

By

Stephen Stewart Castle

A THESIS

**Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of**

DOCTOR OF PHILOSOPHY

**Department of Marketing and Transportation
Administration**

1964

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Stephen Stewart Castle

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Chiefly, I am indebted to the members of my dissertation committee who willingly agreed to undertake the guidance of the project in the face of a most serious handicap--a thesis written in absentia.

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No paragraph could adequately discharge my debt to Professor William J. E. Crissy, the chairman of the

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thesis committee. His interest in, and understanding of, the nature and direction of the project are perhaps best typified by his willingness to meet my needs at what must have been considerable inconvenience to himself. Neither he nor the other committee members are responsible for any errors of omission on my part. It should be clearly underlined, however, that such merit as the study may be thought to possess stems largely from their efforts.

To Professor Thomas A. Staudt, Head of the Department of Marketing and Transportation Administration, and my academic advisor, and through him, to the faculty and staff which he serves, go my thanks for, and appreciation of, the instruction which I received while in residence at Michigan State University. As those who know me will testify, I am a hopeless chauvinist with respect to that faculty and indeed to the College of Business Administration en toto, so capably directed by Dean Alfred L. Seelley.

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effort. The final manuscript was typed by Anne McCartney. The most notable distaff contribution was made, of course, by my wife, Dana Furth Castle. She has been a source of unfailing assistance and inspiration throughout my doctoral program.

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Finally, with all possible warmth, I inscribe the name of Professor William Roderick Sherman, who long ago started the chain of circumstances leading to this dissertation. It is dedicated to him as a mark of affection and respect.

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CHAPTER I

INTRODUCTION AND BACKGROUND

Pharmaceutical Research

"Research" may be defined in a number of ways, according to the purpose and intent of the person concerned. At this point, it is sufficient to observe that any definition of research must contain certain common denominators--observation, orderliness, purpose, and, above all, creativity. In this fourfold context, we may observe for ourselves that the first two are carried out. We may assume that the researcher paid by a profit oriented firm will either satisfy the third condition or be eliminated. It is the last which becomes most elusive, for "creativity" is an almost hopelessly entangled and complex element.¹

Far easier is the matter of accepting a convenient definition of research and then asking what end this

¹"There is today a veritable flood of written commentary on the subject of creativity in scientific research. Most of this commentary must be based upon common sense, speculation, or clairvoyance, for the fact of the matter is that little is conclusively known about creativity." John R. Hinrichs, Creativity in Industrial Scientific Research (New York: American Management Association, 1961), p. 31; and John A. Shubin, Managerial and Industrial Economics (New York: The Ronald Press Company, 1961), p. 31.

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nebulous entity serves. At any level of abstraction, research has become synonymous with two desirable socio-economic attributes, viz., growth and innovation.

In its broadest sense, the scope of the problem has been brilliantly stated by Silk:

. . . Growth via technological progress and innovation is, of course, nothing new; long before Schumpeter, the early eighteenth-century Canadian economist John Rae--Adam Smith's foremost critic--built a theory of growth based on technological change and industrial innovation. And, economic theory apart, technological progress has played a major role in propelling this economy, and other economies, forward, particularly since the middle of the eighteenth century.

But what is new in our time is the multiplication of innovations--and the widespread recognition and systematic application by industry of the notion that new products and new processes are the key to a company's growth, an industry's growth, a nation's growth--and the recognition that, through systematically planned and administered research, we can count on the continuous development of innovations to keep the economic system expanding.

We do not know precisely what our laboratories will discover in the years ahead. But we do know that if we sponsor an adequate research program, they will make discoveries that call for new investment and generate greater production. Knowing this, we can, in a real sense, make innovation a deliberate program rather than a chance development and thus ensure further growth.²

Now, if the foregoing quotation is adapted

²Leonard S. Silk, The Research Revolution (New York: McGraw-Hill Book Company, Inc., 1960), p. 59. This attitude is hardly new, of course. In a somewhat similar form, Phelps' classic study foreshadows the statement. See Dudley M. Phelps, Planning the Product (Chicago: Richard D. Irwin, Inc., 1947), p. 12. Also, Paul De Haen, "Trends in Product Development," Drug and Cosmetic Industry, XCII, No. 2 (August, 1961), 159. It is, however, difficult to envision a more thorough and (in view of the literature) a more succinct statement of the issues at hand than that of Silk's.

wholeheartedly with respect to the pharmaceutical industry, it is likely to be wrong with respect to many member firms of that industry. Silk implies affairs of great magnitude here, as was fully justified. On a firm-by-firm basis, however, "research" efforts for many may be quite modest. By no means all pharmaceutical firms are innovators. Indeed, most hardly engage at all in innovative research per se, except insofar as they reflect an unusual attribute of the pharmaceutical industry. (This stems from a broad definition of research which admits quality control and product testing into the research domain.) The federal food, drug, and cosmetic laws have required research in the broadest sense, and if all other things are equal, creativity may unfold an invention or, more normally, an innovation, though that may not have been a goal of the research.

A second facilitating device through which to appreciate the concept of research is to inquire as to the nature of the activity's output. In general, and in summary form, management may expect to garner such benefits as:

1. New products.
2. Maintenance of competitive . . . position.
3. Cutting of production costs.
4. Sales volume and net profits on new processes and products.
5. New and improved processes to increase production.
6. Informed assistance in long-range planning.³

³Maurice Holland et al., Management's Stake in Research (New York: Harper & Brothers, 1958), p. 7.

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All occur in the research processes of the pharmaceutical house, with particular social emphasis on the innovative functional area--new products.

Routine research (e.g., analysis of competitive products, journal searches, etc.) is inexpensive research, given capital equipment. The work, by its very routinization, can be so structured as to call for technicians rather than scientists for its implementation. Innovative research, on the other hand, is likely to require talents of a more scarce, expensive economic variety, as well as a lengthy period of sheer uncertainty as to the value of expected results.

The rewards of routine research are virtually self-evident, whether the prevailing commercial atmosphere is competitive or essentially non-competitive. The rewards of innovative research are highly speculative, whether under competitive or non-competitive conditions.

Thus, in essence, we may suggest certain apparent truisms with respect to research in the pharmaceutical industry:

1. Innovation and growth are concomitants within the industry, yet they may be found in diverse proportions and relationships within specific firms.
2. Routine research, implemented to comply with federal regulations, may be clearly perceived and appreciated; innovative research, based

essentially on an economic motive, is far more obscure in nature, content, and result.

3. Emphasis on inexpensive routine research may assure reasonable short-run stability of the firm as an entity, yet may prove fatally costly in the long run because of product displacement.
4. Emphasis on expensive innovative research may lead to extensive short-run fluctuations, and to even more amplified fluctuations in the long run, ranging from substantial success to bankruptcy.

All of these queries are based on the tacit assumption that some combination of research at some economic level is inherent in the firm's progress. Alternatively, it will be necessary to face the specific question of the extent to which something other than research will be a prime determinant of progress in the pharmaceutical industry. These concepts form the basis--the raison d'être--for the present inquiry.

The Problem

In its broadest sense, this investigation explores the role of research and development⁴ as presently found

⁴The differentiation between "research" and "development" will be clearly evident later. It is, however, a matter of degree rather than essential nature. The two are functionally identical.

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in the pharmaceutical industry, and seeks to determine the probable nature and direction of R and D practices in the future. To approach this ultimate goal it is necessary to deal with a series of confounding, often vexing, problems of smaller scope. While the segments of the over-all goal are of limited nature, their delineation is mandatory if the primary purpose of the study is to be attained.

Any widely sweeping study based on the pharmaceutical industry is, as a rule, unsatisfactory, particularly from the point of view of a marketing strategist. Procedures applicable to one or a few firms may be inappropriate in the case of others. The basis for this differentiation may be found in one or more of the several functional areas of business behavior--in finance, in management, in production, but most of all with respect to marketing.

This suggests that no adequate, general description of the pharmaceutical industry is available. Materials circulated to date are designed to supply intensive information concerning the philosophy of, but not the operations of, the member firms. Operational knowledge of business entities are little enhanced by the genealogical records of privately held firms. Corporate mottoes are of literary interest, but contribute nothing to insight into the marketing methods and philosophies of the firms in question.

Perhaps equally important, there are substantial

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misconceptions with respect to the nature of research and development as a corporate activity. When regarded as a unit of dynamic operations, R and D possesses certain important characteristics. A salient problem is the enumeration of the activities involved in R and D with the knowledge that an expansive investigation will demand certain simplifications which must be clearly denoted.⁵

As in the case of other industries, the components of and rationale behind reported costs are quite unclear, even for those firms which regularly report their annual R and D volumes. So far as is known, this element of obscurity has effectively discouraged attempts to account for results from the research and development process.

Tangentially, studies have been conducted and papers published based on the grand assumption that R and D is a non-fluid activity, one which when delineated is not subject to change, either over time, or from industry to industry, or from firm to firm. This unfortunate misinformation calls for extreme care in both the interpretation and the adaptation of the existing literature.

⁵An example of the perplexity occasioned by abstraction from the real world is this of Penrose's: "Extreme simplification of concepts may be justified for carefully specified purposes, but it may also lead to an analysis which conceals more than it reveals of the essential characteristics of those aspects of the world that it is designed to explain; insufficient simplification, on the other hand, will prevent the development of any general analysis at all." Edith T. Penrose, The Theory of the Growth of the Firm (New York: John Wiley & Sons, Inc., 1959), p. 198.

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Hence, any discussion of the several problem areas and any attempt to speak broadly for or against the subjects at hand require that the critic first delineate the characteristics of the industry, and then address the matter of research and development therein.

In the context of the emergence of research and development as a dynamic element in the American commercial scene, and continued societal and humanitarian interest in the products and thus progress of the pharmaceutical industry, it appears that a profitable opportunity exists to relate these matters. A dispassionate analysis, abstracted from emotionalism and political motivation, should prove useful not only to pharmaceutical manufacturers and research and development practitioners, but to marketing executives generally.

Research Methodology

The melding of research and development and the pharmaceutical industry stems from a literary base which is uneven in both quantity and quality. Generally, the attention to the issue of R and D has received more extensive and more uniform treatment over time. Books and journal articles (indeed, entire journals themselves) are devoted to the topic. It should be noted, however, that specific unrelated industrial settings play an important part in much of the available material. A conscious effort has been made to avoid improper adaptation of

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concepts developed in incompatible industries.

Pharmaceutical literature, on the other hand, is a less attractive prospect. Where information has been published, it tends to reflect the corporate "puff-story" --series of vignettes on the beneficial effects of free enterprise and the Alger-like success of particular entrepreneurs. Worse, alarming evidence suggests that direct corporate influence was exerted in certain nominally informative journals published over the pertinent time span. This introduces a problem of potential bias impossible to assess or to control.

Academic papers--doctoral dissertations and masters' theses, as well as their occasional published adaptations--have proved highly insightful. Too often overlooked, they frequently have been the source of data and operating procedures normally outside the public view. In many instances prepared by employees of pharmaceutical firms, they are thought to be no less reliable than materials available in the press.

In this study, the major source of printed information on the drug industry consists of the Congressional Hearings which report verbatim proceedings from recent inquiries into so-called "administered" pricing, passage of the most recent federal drug legislation, etc. These volumes are invaluable as a source of day-to-day corporate procedures, as well as being samples of the reactions of corporate practitioners.

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Because these Congressional Hearings purport to reveal materials otherwise clandestine, a policy statement regarding their use in this paper seems warranted. First, they are accepted (however tenuously) as the epitome of revelations, since to suggest that the Federal Government might elicit less than the absolute truth from its respondents violates all current tenets of corporate and social ethics. Thus, the materials offered by the companies which have testified, their industrial representatives, and their advocates in general have been abstracted with no thought to the degree of confidentiality inherent in them. This is done on the premise that any firm whose corporate strategy and tactics have been compromised by the need to testify openly will have subsequently changed its procedures.

To this literary background and its secondary data have been added a series of thirteen interviews with research practitioners and corporate officers active in as many pharmaceutical firms. Because of the confidential nature of the material under discussion, every effort has been made to conceal the identity of specific sources. Accordingly, the primary observations gathered should be regarded as indicative of informed opinion rather than conclusive evidence of the policies and procedures of any given firm.

The interviews were based on a structured, open-end questionnaire, attached as Appendix A. While this

technique was used to provide continuity in the field work, it did not prevent the discussion of allied, germane topics when these arose in the course of the visit.

Structurally, this report delineates the environmental nature of the pharmaceutical industry in Chapters II and III, which are concerned with economic and legal considerations, respectively. These are assumed to be the major structuring parameters which outline the environment of the firms involved in the analysis. Historical perspective is employed where required in order to reflect significant shifts in intra-industry emphasis. In the interest of a complete record of industry growth and progress, some attention is devoted to earlier years, particularly where notable economic or legal activities or both have wrought marked changes in the nature and direction of the industry.

Primary attention to pharmaceutical research is the subject of Chapter IV, and the basic nature of research and development is reviewed. The section is based upon a simple model of the research and development process as it might be structured from a priori reasoning which combines R and D characteristics and the economic and legal nature of the drug industry.

In Chapter V, the simplified model of drug R and D is critically examined in terms of reported industry practice. Chapter VI, the summary segment of the paper, is devoted to a recapitulation of the highlights of the

study, and to those recommendations which the research directs.

Limitations of the Study

Perhaps the single most important limitation of this study stems from the dynamic nature of the pharmaceutical industry itself. While firms' product lines have been arbitrarily classified according to major product composition, in reality most are either involved in cross-categorical operations or are likely to be contemplating such a move.

The degree to which corporate income is derived from non-primary sources, coupled with an industry propensity to lump all income together, leads to the necessity of making industry estimates--often of a crude nature. Moreover, when a published "average" figure is applied to known data (as when estimating firms' research and development expenditures as a percent of known sales), the result tends to be neat but statistically meaningless graphs, all tending toward the average and showing a high, but spurious, correlation.⁶

With conglomerate data on the one hand, and partial data on the other, one must stress the confidential nature of that which may be developed within the firms themselves. There is a marked degree of reluctance

⁶U.S., Congress, Senate, Committee on the Judiciary, Administered Prices in the Drug Industry, Part 24, 86th Cong., 2d Sess., 1960, pp. 13722 et passim.

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on the part of operating personnel to provide dollar facts. If this is overcome by appealing to corporate officers willing to reveal the data on, say, a disguised basis, familiarity with the operational dynamics of research are often sacrificed.

Further, the nature of the industry suggests that product composition may shift suddenly, which, in certain cases, it does. Thus, if any group of firms is selected as "typical" for analytic purposes on any currently defensible grounds, it is unlikely to remain so for long. That is to say, on an individual firm basis, even total information would run the risk of rapid obsolescence.

The prosaic matter of time inserts still another limitation. For example, for maximum effectiveness, a ten-year study such as this one ideally should be pertinent ten years hence. Industrial dynamics and legal activity preclude the likelihood of such broad, enduring applicability.

In short, the limitations speak for themselves, not only in this general sense, but in the more detailed portions of the paper. Every effort has been made to underline verbally specific cases of limited confidence as they appear. The findings of this study, however, should be regarded broadly. No specific inference to a single firm is justified beyond the boundaries indicated.

The limitations, though displeasing to the writer, do not destroy the usefulness of the study so long as the

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reader is aware that they exist. The data are no more fragmentary than those employed for planning purposes under actual competitive conditions. By virtue of extensive literary resources, they are felt to be in some respects superior. So long as the pharmaceutical industry remains a semi-competitive one, there is every likelihood that the "n" firms treated herein will be restructured to "m" firms in the future. More importantly, from a macro-analytic point of view, the findings may well remain essentially the same--even though the nominal composition of the industry changes, as we shall suggest it should.

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CHAPTER II

THE ECONOMIC STRUCTURE OF THE PHARMACEUTICAL INDUSTRY

Introduction and Definitions

In the business environment, operating entities which produce similar products or which engage in similar economic service activities or both are usually regarded as belonging to the same industry.¹ In the pharmaceutical industry, this general definition is true enough in the broad sense--the products are designed for consumption rather than being primarily prepared for further processing involving radical changes in form. However, the essential nature of the companies operating within the industry's confines makes such a broad, generalized definition all but useless.

An examination of the component firms will be of value in circumscribing subcategories of the industry which may then be treated as "groups." The definition of a firm, in every instance, implies the usual aggregate of human talents, capital equipment, and inanimate resources

¹"The term 'industry' customarily denotes all firms and plants devoted to the output of a single product or a closely related group of products." Shubin, op. cit., pp. 73, 75.

combined to produce products and services.² Since the service output observed in the drug industry may be more properly regarded as sales promotion activities, major emphasis in this examination is placed upon product rather than service activities.

The most useful way to segment the pharmaceutical industry for analytical purposes is to refer to the predominant product classes of the several firms. Particularly for marketing purposes, the existence of these product classes contains the essence of the structure of the groups involved.

A prescription drug firm is one which manufactures chemical, biological, and antibiotic products available to the ultimate consumer only at the direction of a licensed practitioner--a physician, a dentist, and in the case of certain product lines, a veterinarian. Retail outlets for these so-called "ethical" products are primarily registered pharmacies. A further distinguishing feature of prescription drugs is that traditionally they have been promoted to the prescribers and purveyors, but not to the general public.

By contrast, a proprietary drug firm produces substances and compounds which are promoted and advertised

²For example, see Kenneth E. Boulding, Economic Analysis (3rd ed.; New York: Harper & Brothers, 1955), pp. 491-503; or Richard H. Leftwich, The Price System and Resource Allocation (rev. ed.; New York: Holt, Rinehart and Winston, 1960), pp. 12, 95-105.

extensively to the consumer himself. Less likely to be toxic when used as directed, proprietaries require no prescription. Although stocked by the pharmacies which control sales of their ethical counterparts, proprietaries are also widely available at many convenience goods outlets--foodstores, department stores, discount houses, gas stations, etc.

Essentially, ethical and proprietary products form the two broad divisions of the total industry.³ Other significant offerings which deviate in form, usage conditions, and sales location, or combinations of these, include over-the-counter products (usually ethical drugs found over time to be extraordinarily safe, thereafter available without a prescription but advertised and promoted to those competent to deal in ethical products), appliances (trusses, mechanical contraceptives, etc.), and hospital supplies (bandages, pads, etc.). Other product categories sometimes encountered in the industry include personal hygiene items of every description, cosmetics, heavy industrial chemicals, and other miscellaneous products. Rather than dealing with clear-cut entities, the investigator in the pharmaceutical industry often is faced with heterogeneous firms which market conglomerate product lines. In an effort to minimize the analytic

³Additional background may be found in Administered Prices in the Drug Industry, Part 19, pp. 10721 et passim.

disorder which results, arbitrary classification of firms into "Chamberlin groups" provides a sensible first approximation.⁴ In so doing, it must be noted that the goal of such a separation is simply to facilitate perception of textural similarities. No pretense is made of seeking or of finding meaningful equilibrium solutions, at least in the Chamberlin sense.

Firms are thus grouped according to their major product interests. We shall deal with a prescription group, and a proprietary group, and we shall have to refer to a number of firms which can only be regarded as a conglomerate group. In using this approach, it must be recognized that most prescription (or ethical) firms have, or are acquiring, substantial proprietary branches. A number of proprietary firms have adopted at least limited specialty lines in prescription drugs. Omitted altogether are the contract or toll manufacturers which produce only for others' labels,⁵ as well as foreign-owned firms. The former are numerous but economically unimportant; the latter offer no data to the analyst.

⁴The concept of the "group" is discussed in Edward H. Chamberlin's The Theory of Monopolistic Competition (7th ed.; Cambridge, Mass.: Harvard University Press, 1960), pp. 81 et passim. Usage of the term here includes the conditions that each producer in a given group is a monopolist, but that his market is interwoven with those of other firms bracketed with his, and he is not strictly isolated from other similar firms in his environment.

⁵Administered Prices in the Drug Industry, Part 16, p. 9382.

The term "monopoly," when used in this paper, refers to a single seller of a given product in a given market at a specific point in time. Moreover, it is used to reflect the fact that a buyer has no choice of size, type, grade, or number in the purchase of the pertinent commodity, i.e., the prescription drug. In any event, monopoly, as found in this paper, describes a state of being in the marketplace. It is employed only as a useful descriptive term, and no economic aspersion per se is intended.

In the remainder of this section, as throughout the entire paper, subordinate definitions arise. To provide continuity, these are outlined as they occur.

Industry Size and Composition

The American domestic pharmaceutical industry is one of moderate size. With 1962 total manufacturers' shipments approximating \$4.55 billion,⁶ all firms' sales were less than those of General Motors (\$14.6 billion), Standard Oil of New Jersey (\$9.5 billion), or Ford Motor Company, whose 1962 sales, including Philco, are reported to have been nearly \$8.1 billion.⁷ By product class, and hence by groups, ethical shipments approximated \$3.19

⁶Standard & Poor's Industry Surveys--Drugs, Cosmetics: Current Analysis and Outlook, Section 3 (New York: Standard & Poor's Corporation, December 26, 1963), p. 1.

⁷See "The Fortune Directory" (New York: Fortune Magazine, August, 1963).

billion. Proprietary sales were about \$1.36 billion.⁸

The industry estimate of \$4.55 billion is a complex sales figure. It includes not only domestic drug sales but consolidated sales by foreign subsidiaries of U.S. companies and American exports as well. While so little information is available on proprietary shipments that the \$1.36 billion estimate must stand unrefined, it is possible to reduce the ethical sales estimate to a more meaningful array. In so doing, it is necessary to compare data for adjoining years, but it is premised that ethical sales by product types remain fairly stable from year to year.

In 1961, the 141 member firms of the Pharmaceutical Manufacturers Association indicated the following prescription sales, as shown in Table 1:

1. Sales to the private and government sectors accounted for 76 percent of total output.
2. The remainder, 24 percent, occurred in foreign commerce.
3. Of total sales, 93 percent were for human ethical use, primarily (87 percent) in dosage form.
4. Veterinary products contributed but 7 percent to total output.

⁸Standard & Poor's Industry Surveys--Drugs, Cosmetics: Basic Analysis, Section 2 (New York: Standard & Poor's Corporation, December 13, 1962), p. 8.

TABLE 1.--PMA member firms--ethical pharmaceutical net sales, domestic and foreign, 1961 (millions of dollars)

	<u>Totals</u>		<u>U.S. Sales-- Private and Government</u>		<u>Foreign-- Subsidiary Sales and U.S. Exports</u>	
	(\$)	(%)	(\$)	(%)	(\$)	(%)
All Types	\$2,992	100%	\$2,259	76%	\$733	24%
Human Ethical:	2,771	93	2,081	70	690	23
Dosage Form	2,582	87	1,954	66	628	21
Bulk Form	189	6	127	4	62	2
Veterinary:	221	7	178	6	43	1
Dosage Form	103	3	85	3	18	a
Bulk Form	118	4	93	3	25	a

^aLess than 1 percent of total sales.

Source: Adapted from Prescription Drug Industry--Fact Book (Washington: Pharmaceutical Manufacturers Association, June 15, 1962), p. 2.

Applying these percentages to estimated 1962 ethical sales of \$3.19 billion, the volume derivatives obtained are presented in Table 2.

TABLE 2.--Estimated 1962 net sales of domestic ethical pharmaceutical firms by destination of output (billions of dollars)

	Total Sales		Domestic Sales		Foreign Sales	
	(\$)	(%)	(\$)	(%)	(\$)	(%)
All Types	<u>\$3.19</u>	<u>100%</u>	<u>\$2.42</u>	<u>76%</u>	<u>\$.77</u>	<u>24%</u>
Human Ethical	2.97	93	2.23	70	.74	23
Veterinary	.22	7	.19	6	.03	1

Source: Calculated from Table 1, p. 21 supra.

Further refinements are possible, although recourse must again be made to 1961 data for estimating purposes. Moreover, it must be noted that while the projection factors used refer to all ethical sales, they are applied here to total sales, domestic sales, and foreign sales as though there were no differences among them. The results are shown in Table 3.

At this point, it is possible to make three observations with respect to the nature of the ethical industry. Although far from dogmatic certainty by virtue of the degree to which tenuous estimates are required to derive data, most ethical pharmaceutical sales may be traced to products designed for human end usage. While domestic sales form a substantial part of the total (about 76

TABLE 3.--Estimated 1962 net sales of domestic ethical pharmaceutical firms by type of firm (billions of dollars)

	Total Sales		Domestic Sales		Foreign Sales	
	(\$)	(%)	(\$)	(%)	(\$)	(%)
All Firms	<u>\$3.19</u>	<u>100%</u>	<u>\$2.42</u>	<u>100%</u>	<u>\$.77</u>	<u>100%</u>
15 Largest U.S. Companies	1.44	45	1.09	45	.35	45
Ethical Divisions of Proprietary Firms	.70	22	.53	22	.17	22
Ethical Divisions of Primarily Non-Drug Companies	.38	12	.29	12	.09	12
Swiss-Owned Firms	.22	7	.17	7	.05	7
All Other Firms (Toll Manufacturers, Bulk Processors, etc.)	.45	14	.34	14	.11	14

Source: Adapted from Standard & Poor's Industry Surveys--Drugs, Cosmetics: Basic Analysis, Section 2 (New York: Standard & Poor's Corporation, December 13, 1962), p. 8.

percent in 1962), a creditable portion of the country's output is accounted for in foreign markets. Finally, substantial economic concentration exists, inasmuch as the number of firms producing the bulk of the nation's ethicals is relatively small. The first two contentions are reasonably obvious. The third merits additional development.

Table 3, page 23, indicates that "All other firms" account for 14 percent of the industry's ethical sales. Estimates of the number of firms included in this category range from approximately 700 U.S. manufacturers,⁹ cited by the Pharmaceutical Manufacturers Association, to a high of 1,359 establishments manufacturing drugs as reported by the 1958 Census of Manufacturers.¹⁰ The latter figure, frequently encountered in the literature, does not, of course, indicate the number of firms (some multi-plant affairs) that are operating in the economy at a given time. Thus, not only does the 700-firm estimate represent a more conservative figure upon which to base observations concerning concentration; it is probably much more realistic in terms of competitive corporate interaction.

It will be instructive to postulate the composition of the ethical group from the point of view of the concentration categories used in Table 3. The fifteen

⁹Prescription Drug Industry--Fact Book, pp. 1-2.

¹⁰Ibid., pp. 3-7.

largest U.S. companies regarded as having about 45 percent of 1962 ethical sales would include:

Abbott Laboratories
 Baxter Laboratories
 Cutter Laboratories
 Eli Lilly and Company
 Mallinckrodt Chemical Works
 Mead Johnson & Company
 Merck & Company
 Parke, Davis & Company
 Charles Pfizer and Company
 William H. Rorer, Inc.
 Schering Corporation
 G. D. Searle & Company
 Smith, Kline & French Laboratories
 U.S. Vitamin & Pharmaceutical Corporation
 Upjohn Company

Proprietary firms with important ethical divisions would include:

American Home Products Corporation
 Bristol Meyers Company
 Carter Products, Incorporated
 Richardson-Merrell, Inc.
 Sterling Drug, Inc.
 Warner-Lambert Pharmaceutical Company

Primarily non-drug companies in which ethical drug products contribute heavily to the parents' progress are typified by:

American Cyanamid Company (Lederle Laboratories Division)
 Dow Chemical Company (Allied Laboratories Division)
 Olin Mathieson Chemical Corporation (Squibb Division)

The Swiss-owned firms are four in number:

CIBA Pharmaceutical Company
 Geigy Chemical Corporation
 Hoffman-LaRoche, Inc.
 Sandoz, Inc.

Thus, from a base of 700 firms, twenty-seven firms

may be identified as being likely to account for some 86 percent of ethical pharmaceutical sales. Indeed, it has been observed that: "In 1957, the 29 largest drug companies accounted for 89.8% of total industry sales, as measured by joint studies by the Federal Trade Commission and the Securities and Exchange Commission; in 1961, they accounted for 90.1%."¹¹ Whether or not it is adequate to suggest that the addition of two firms would account for the four percentage points difference between our present calculations and the Standard & Poor estimate is of no particular importance. The desired impression is that if there are indeed 700 firms in the ethical industry, about 673 of them must divide a \$450 million market, or an average yearly sales volume of some \$670 thousand each.

Alternatively, one may follow the suggested definition of "all other firms" found in the Standard & Poor discussion.¹² This leads to the average sales possibility of about \$375 thousand each, based on 1,200 small firms.¹³

The non-ethical group reveals a similar pattern of concentration. Paraphrasing the Standard & Poor report, "the proprietary field is dominated by 14 companies that

¹¹Standard & Poor's Industry Surveys--Drugs, Cosmetics: Basic Analysis, p. 9.

¹²Ibid., p. 8.

¹³The names of over 200 of these small firms, together with approximate annual volumes of business for each, are noted in Administered Prices in the Drug Industry, Part 22, pp. 12141-44.

accounted for about 90% of total [1962] sales of [\$1.36] billion."¹⁴ "The remainder came from about 200 [sic] smaller firms."¹⁵ "However, no single company accounts for as much as 10% of total drug sales, and relative standings of the largest firms change frequently."¹⁶ Once again, the domination of the group by relatively few firms is quite obvious.

In the case of the prescription group, the manifest tendency toward concentration has more notable effects than is true of the proprietary group. The extent to which these effects are perceived will be the topic of the next several sections.

Concluding, then, ethical sales of \$3.19 billion in 1962 indicates that this industry's sales were exceeded by seven non-drug firms in other U.S. industries. Proprietary sales of \$1.36 billion were exceeded by twenty-nine non-drug firms' sales in the same year.¹⁷ The bulk of the

¹⁴Any array of the fourteen firms involved would include American Home Products, Bristol Meyers, Carter Products, Miles Laboratories, Norwich Pharmacal, Plough, Inc., Richardson-Merrell, Sterling Drug, and Warner Lambert. Ethical houses with important proprietary subsidiaries should also be considered.

¹⁵Given the nature of proprietary products, a more seemly figure for the number of competitors would approximate 2,000.

¹⁶Standard & Poor's Industry Surveys--Drugs, Cosmetics: Basic Analysis, p. 8. For a less flexible appraisal, see "The Bayer Facts," Forbes Magazine, XCII, No. 9 (November 1, 1963), 28.

¹⁷"Fortune Directory," op. cit., p. 2.

industry's sales was accounted for by a handful of its firms.

In this, as in many other instances, interindustry dollar volume comparisons are useful primarily as benchmarks--means by which to achieve a sense of perspective. As Shubin notes, ". . . many smaller industries (pharmaceuticals, for example) make a notable contribution to economic and social progress."¹⁸

Industry Growth

An important measure of corporate performance in any segment of the economy is the extent to which an industry "grows," or expands its volume of trade. This is particularly true during the current era when a generally expanding national economy has given evidence of over-all progress. The securities markets and influential mass media have combined to enhance the image of the so-called "growth" stocks, and of their first cousins, the "glamour" stocks. With the possible exception of certain defense-oriented firms (particularly those involved in space exploration) and the electronics innovators, few industries have attracted growth stock investors as have pharmaceutical securities. Pre-World War II performance offered little evidence of the subsequent economic explosion in this field.

In 1939, some 1,000 companies then in the ethical

¹⁸Shubin, op. cit., p. 80.

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pharmaceutical industry were said to have attained a sales volume of about \$150 million.¹⁹ Proprietary sales the same year were about \$152 million. By 1946, ethical sales had grown to \$428 million,²⁰ and with the addition of only some 200 new companies, passed the \$1 billion mark by 1957.²¹

It is almost certain that by 1958 ethical sales approximated \$2 billion, and proprietary sales had reached about \$700 million,²² a thirteenfold growth for prescription sales, and nearly a fivefold expansion for proprietary products, both based on the modest prewar reports. Moreover, it is important to single out the relative importance of ethical volumes as opposed to proprietary ones, and to recall that the latest figures quoted indicate that 70 percent of all pharmaceutical product sales are presently in ethical form. This shift in product emphasis has a number of speculative implications which will be discussed subsequently.

¹⁹Tom Mahoney, The Merchants of Life (New York: Harper & Brothers, 1959), p. 4; and Administered Prices in the Drug Industry, Part 19, p. 10721.

²⁰Charles Hampton, "Ethical Drugs," Chemical Week, XCI, No. 20 (November 17, 1962), 138.

²¹Mahoney, loc. cit. It appears that this is an extremely conservative estimate, since the PMA offers the suggestion that the \$1 billion mark was reached as early as 1950, and that, by 1957, ethical sales had reached \$1.7 billion. See Prescription Drug Industry--Fact Book, p. 3.

²²Administered Prices in the Drug Industry, Part 19, p. 10721.

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Although a fractional tabulation, sales progress during the past decade is indicated in Table 4. The most notable impression to be gained from this consistent array is the fact that, as a group, total sales for both ethical and proprietary products have shown an absolute increase over the previous years' sales throughout the decade--i.e., continuous growth, as it is normally reckoned.

With the same ten ethical and eight proprietary firms as a basis from which to generalize, we may observe a second set of accountants' bench marks by which firms' performances are normally judged, viz., the amount of profit, or the excess of income per year after deducting operating costs, depreciation and amortization, and taxes applicable to that same year.

In Table 5, two atypical years (1958 and 1960) are entered for the ethical firms represented. Otherwise, the remaining years for ethicals and proprietaries indicate in post-tax profits the same increases which have characterized corporate sales.²³ In general, annual post-tax profits within the ethical group nearly trebled during the decade. Proprietary net profits were nearly four times the 1953 volume as of the end of 1962.

²³It is recognized that absolute profits in 1961 had not yet attained the level of 1959. No particular importance is attached to this at present, largely because profits in 1961 did exceed those of 1960. Explanations of the ethical profit declines are complex, including the probable effect of the congressional investigations.

TABLE 4.--Pharmaceutical industry sales performance
by major groups (millions of dollars)

Year	Ethical Sales ^a	Percent Increase Over Year Previous	Proprietary Sales ^b	Percent Increase Over Year Previous
1962	\$1,545.6	9.3%	\$1,607.0	14.5%
1961	1,395.1	6.9	1,403.6	6.7
1960	1,305.0	3.0	1,315.4	8.6
1959	1,266.7	7.9	1,214.4	10.8
1958	1,173.5	3.6	1,101.9	7.5
1957	1,131.5	15.9	1,024.8	15.7
1956	976.1	12.9	885.8	22.8
1955	864.1	16.4	729.5	9.6
1954	743.9	1.7	660.6	5.4
1953	731.4	-	622.9	-

^aIndustry group composed of:

Abbott Laboratories
Baxter Laboratories
Eli Lilly and Company
Merck & Company
Parke, Davis & Company
Charles Pfizer and Company
Schering Corporation
G. D. Searle & Company
Smith, Kline & French Laboratories
U.S. Vitamin & Pharmaceutical Corporation

^bIndustry group composed of:

American Home Products Corporation
Bristol-Meyers Company
Miles Laboratories, Inc.
Norwich Pharmacal Company
Plough, Inc.
Richardson-Merrell, Inc.
Sterling Drug, Inc.
Warner-Lambert Pharmaceutical Company

Source: Moody's Industrial Manual (New York: Moody's
Investors Service, Inc., 1963), pp. a15, a17.

TAB

Year

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1961
1960
1959
1958
1957
1956
1955
1954
1953

Source

TABLE 5.--Pharmaceutical industry net profit performance
by major groups (millions of dollars)

Year	Ethical Net Post-Tax Profits ^a	Percent Increase Over Year Previous	Proprietary Net Post- Tax Profits ^b	Percent Increase Over Year Previous
1962	\$183.6	10.3%	\$155.3	14.6%
1961	166.4	4.2	135.9	8.4
1960	159.7	(5.2) ^c	125.4	7.4
1959	168.5	7.1	116.8	12.7
1958	157.4	(3.1) ^c	104.1	9.3
1957	162.5	23.2	95.3	24.2
1956	132.0	31.9	78.4	27.9
1955	100.5	37.6	61.4	26.1
1954	73.0	11.8	48.7	22.8
1953	65.3	-	39.7	-

^aSee footnote a, p. 31 supra.

^bSee footnote b, p. 31 supra.

^cDecrease over previous year.

Source: Moody's Industrial Manual (New York: Moody's
Investors Service, Inc., 1963), pp. a15, a17.

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These representative firms have appeared to have satisfied certain criteria of growth: Sales have increased regularly, and net profits have been positive. Moreover, by far the majority of the measures used to indicate changes over time reveal positive, only slightly erratic, annual increases both in sales and in net post-tax profits.

Industry Profitability

Except in the most unusual circumstances, the matter of growth treated in the previous section is dependent on profitable operation over time. That is to say, when regarded as a stock concept, the strategic mobility of a firm (i.e., the ability to shift resources in response to competitors' moves) is enhanced when, at the end of a given period, the firm's income has exceeded its costs. The residual following such an achievement permits the firm to increase its capital plant, to increase or maintain its pool of funds with which to conduct interim transactions, and to distribute some portion to its owners.

Too, as a measure of industrial efficiency, profitability is a useful criterion. Clearly, in an inefficient firm, unnecessary (often nearly unknown) costs are piled one on another until at year's end, these costs have approached, if not exceeded, revenues. The converse is obviously true. Moreover, the ease of stating that profitability is a reflection of efficiency is to tell only a half-truth. It is quite possible that highly

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efficient, cost-conscious firms are observed from time to time to react in a most unprofitable manner simply because effective demand does not materialize for their products.

Resorting again to the consistent tabulations offered by Moody's Industrial Manual, Table 6 suggests that pharmaceutical firms tend to be extremely profitable, both on a year-to-year basis and over the reported decade as well. The point to be made is simply that both groups --ethical and proprietary drugs--have maintained profit margins from annual sales which are adequate from a strategic point of view and which are attractive to investors. It appears likely that the component firms are sufficiently successful to permit capital expansion when desired. But (and this is quite vital) they may also undertake long-run programs, particularly of research and development, the financial outcome of which may not occur in the following period, or the following n periods, if ever.²⁴

Hesitancy to assess the level of pharmaceutical profits stems from the fact that it is not clear that the industry is maximizing its potential profitability. Yet in this industry, as in nearly every other, it is reasonable to assume that, in their operations over-all, the firms strive toward profit maximization. If they fall short of this goal, it may be by a greater or lesser

²⁴An extensive discussion of drug firms' costs and profits may be found in Seymour E. Harris', The Economics of American Medicine (New York: The Macmillan Company, 1964), pp. 77-85 et passim.

Year

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1960
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Source

TABLE 6.--Pharmaceutical industry profitability
index by major groups

Year	Ethical Net Profits as a Percent of Sales ^a	Proprietary Net Profits as a Percent of Sales ^b
1962	11.9%	9.7%
1961	11.9	9.7
1960	12.2	9.5
1959	13.3	9.6
1958	13.4	9.4
1957	14.4	9.3
1956	13.5	8.9
1955	11.6	8.4
1954	9.8	7.4
1953	8.9	6.4

^aSee footnote a, p. 31 supra.

^bSee footnote b, p. 31 supra.

Source: Moody's Industrial Manual (New York: Moody's
Investors Service, Inc., 1963), pp. a15, a17.

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degree, the magnitude of which we may never logically measure in any meaningful sense. A useful alternative conceptualization is that of Professor Griffin, who indicated:

The profit motive is not simply a desire for maximizing profits. The profit prospect, which leads to action, is a complex of a number of specific desires and aims. One consideration that will determine action is the size of the profit that is envisaged as a possible reward. The larger that prospective profit, other things being equal, the more likely action is to be taken. But another consideration is the assurance or the degree of probability of obtaining the profit. Another is apparently the prospect of regularity or irregularity of profits secured from a prospective line of endeavor. A fourth consideration is the prospect of loss of the principal itself. This last is a different consideration from the uncertainty of profit, which merely involves the earning of more or less, and is a positive incentive; the prospect of loss of principal is always a negative incentive and deterrent.²⁵

For individual firms, each of the components of Griffin's "profit prospect" may be quantified. Our major concern, however, is with the fourth point--indulgence in a corporate activity which is likely to involve a total loss of inputs. In essence, research and development is a singular example of this sort of process, and, from the point of view of a drug firm, the prospective loss of principal appears to be especially important.

Anticipating an important line of attack, we will be contented for the present to suggest two possible alternatives to hedge the danger of such losses. First, a firm may concentrate on carefully screened product lines

²⁵Clare E. Griffin, Enterprise in a Free Society (Chicago: Richard D. Irwin, Inc., 1949), p. 68.

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which will be likely to offer the greatest chance of ultimate profitability. Second, and perhaps polar, a firm whose product line is given may strive to enhance research payoff by means of marketing and promoting products whose intrinsic nature is suspect on any of a variety of grounds. This is no place to entertain discussion of the propriety of either alternative--rather, the alternatives are introduced on the premises that: (a) the research process, if structurable, will vary in component nature according to the path chosen; and (b) if there is factual substance to the second alternative, research, as we have come to regard it, will take on a much different nature with respect to rigor and respectability.

As will be seen, there is substantial product displacement in the pharmaceutical industry. Hence, a profit-oriented firm must innovate in order to gain the maximum possible competitive advantage. Moreover, as Griffin observes,

. . . profits are to be made not merely by being better than your competitor. A concern may discover a new product, a new way of making things, or a new principle of management; or it may merely use existing methods more effectively and thereby lift itself above the level of its competition and make profits. But if this concern rests on its oars, it will find that other companies will have copied these improvements; and when most of the competitors have done so, the improvement will cease to be profit yielding. The conclusion evidently is that continuous profits can only be made, assuming effective competition, by continued progress.²⁶

²⁶Ibid., p. 126.

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The degree to which effective competition exists in the ethical drug industry is a subject of much debate, all of it based on special definitions. Certainly the existence of patent laws gives rise to some measure of firm protection.²⁷ However, although it appears that patent protection is adequate for recovery of pharmaceutical research costs, it does not follow that such is always the case. In the event that a highly protected product finds no favor in the marketplace, its research costs may never be recovered. At the same time, a highly successful and adequately "protected" product is inevitably susceptible to innovations of other firms. No copying, in the Griffin sense, has occurred. Severe displacement has, and the rest of the analysis is accomplished.

We further recognize that it is highly likely that a general profit orientation, together with the possibility of product displacement by other manufacturers, combine to impel pharmaceutical manufacturers toward short-run profit maximization. In temporal terms, this may take years, since it is customary to regard the short run as a period during which no adjustment is made in the fixed factors employed in producing an item.²⁸ Following

²⁷This highly complex subject is discussed at length in U.S., Congress, Senate, Hearings on S. 1552 (Patent Provisions), Part 3, 87th Cong., 1st Sess., 1961, passim. See also Harris, op. cit., pp. 93-96.

²⁸For example, see Boulding, op. cit., p. 570. Boulding cleverly discusses "the indefinite morass of the 'short period.'"

Fellner, we observe a peculiarity of the ethical drug industry:

There is no reason to assume that firms try to maximize their profits in the short run, unless the policies accomplishing this end happen to be those which also maximize long-run profits. Whatever the other qualifications to profit maximization may be, we should realize that the profit incentive is not typically a short-run incentive.²⁹

But, by maximizing short-run profits, it so happens that the ethical drug group provides its best chance of maximization of possible long-run profit since product life within the industry is said to be essentially short run.³⁰ Hence, it may be said to be atypical in this respect, a fact that will bear on the total research process.

While the competitive environment for proprietary products is substantially different, there is no reason to assume a priori that profit maximization tendencies for those firms are markedly different from those of their ethical counterparts. Many of the products of this group are directly competitive and functionally interchangeable. Such legal protection as they may enjoy depends on securing the rights to a product name, rather than a product formula.³¹ Brand loyalty, occasioned by aggressive

²⁹William Fellner, Competition Among the Few (New York: Augustus M. Kelley, 1960), p. 158.

³⁰See pp. 57 to 58 infra.

³¹Hence, the term "patent medicine," which is synonymous with "proprietary drug," has caused some confusion. Ingredients may change--the name remains the same. Given consumer brand acceptance, this is obviously a powerful promotional tool.

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programs of advertising and sales promotion, has for many years lent inelasticity of demand to certain proprietary products (e.g., Bayer Aspirin, Anacin, Alka-Seltzer, etc.). Viewed during this period, it might have seemed that the responsible firms were concerned with long-run profit maximization. With the recent introduction of such innovations as Bufferin and Excederin, together with the ambitious introductory and aggressive preferential advertising campaigns surrounding the new entries, established firms are seen to react almost desperately in an effort to hold their current markets or to minimize market share losses. The extent to which this violent controversy will disrupt earlier orderly markets cannot be foreseen. However, the immediate realities of the competitive struggle suggest that it would be very difficult to construct an argument on behalf of current long-run pricing orientation for the proprietary group's firms.

Note 1 to Industry Profitability

The Kefauver Committee found that for four patented ethical drug products, the gross margin (i.e., the difference between unit production costs and the manufacturer's price to his customers) ranged from 88 to 92 percent.³² Since drug firms justify such margins as necessary to

³²Administered Prices in the Drug Industry, Part 14, p. 8042; ibid., Part 16, p. 9157; ibid., Part 20, p. 11045; and U.S., Congress, Senate, Study of Administered Prices in the Drug Industry (Washington: U.S. Government Printing Office, 1961), p. 24.

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insure continued research programs, it is important to note that the array presented in Table 7 includes all products in a given firm's line--the highly profitable, the moderately profitable, and the unprofitable alike.

Table 7.--Cost of goods sold and gross margin as percentages of sales for fifteen drug companies in 1959

Company	Cost of Goods Sold	Gross Margin
Norwich Pharmacal Co.	21.6	78.4
Schering Corporation	21.7	78.3
Bristol-Meyers Co.	25.5	74.5
The Upjohn Co.	25.6	74.4
Smith Kline & French Laboratories	27.4	72.6
Carter Products, Inc.	27.8	72.2
G. D. Searle & Co.	31.3	68.7
U.S. Vitamin & Pharmaceutical Corp.	34.3	65.7
Sterling Drug, Inc.	36.4	63.6
Warner-Lambert Pharmaceutical Co.	36.6	63.4
Parke, Davis & Co.	36.8	63.2
American Home Products Corp.	37.3	62.7
Abbott Laboratories	40.1	59.9
Merck & Co., Inc.	41.1	58.9
Mead Johnson & Co.	41.4	58.6

Source: U.S., Congress, Senate, Study of Administered Prices in the Drug Industry (Washington: U.S. Government Printing Office, 1961), p. 27.

The committee report concludes:

The drug companies are a case apart. . . . [Here comparisons are made with 50 non-drug companies, each a leader in its industry and among the 500 largest U.S. firms as shown in the Fortune report.] . . . Not one of these companies has a gross margin above production costs as high as the lowest gross margin shown among the 15 drug companies, i.e., 59 per cent. Among the 50 nondrug industries, in only one case, soft drinks, does the margin of the firm shown, Coca-Cola Co., approach this figure. In 6 of the 15 drug companies listed, the gross margin is more than 70 per cent of sales, while in 41 of the 50 nondrug companies

the margin is below 35 per cent. Indeed, two-thirds (33) of the nondrug companies have margins which are less than half of the lowest margin reported for any of the 15 drug companies.

No unique characteristic inherent in the economics of the drug industry suggests itself as a logical explanation for this startling difference in the breakdown of the sales dollar of the drug producers as contrasted with large firms in other industries. It should be noted that the nondrug list contains a number of firms which are generally considered to rely very heavily on advertising and other promotional and selling expenses to create sales volume--e.g., General Motors, General Electric, Colgate-Palmolive, R. J. Reynolds, General Foods. The expectation . . . would be that because the basic demand for drugs, namely the incidence of illness, cannot be significantly increased by advertising and selling expenditures, selling costs would be relatively smaller in drugs than in other industries. Moreover, because of the unique importance of the product to the public health, management might be expected to be content with lower profit margins. These expectations, it appears, find little support in the actual showings.³³

The Implications of Industry Supply and Demand Characteristics

Ultimate consumers of ethical pharmaceutical products are supplied through a distribution system which includes drug wholesalers, retail pharmacists, hospitals, and medical doctors. Nationally, it has been estimated that the institutional magnitudes involved in the trade are those shown in Table 8.

As an indication of market delineation for a single firm, it may be further noted that "a full-line

³³Study of Administered Prices in the Drug Industry, pp. 28-29. See also p. 30, which states that "only one of the 22 companies in 1958, Searle, devoted as much as half the amount to research that it reported for selling expense, while 11 of them spent from 5 to 11 times as much in advertising, promotional and selling expense as they did for research."

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drughouse in 1958 divided its U.S. market: 156,454 physicians and surgeons, 53,000 retail pharmacies, 6,966 hospitals, 392 drug wholesalers, and 10,347 veterinarians."³⁴

TABLE 8.--Distribution outlets for human ethical pharmaceuticals^a (total United States)

	Approximate Number in United States
Physicians with an M.D.	170,000
Osteopathic Physicians	12,000
Hospitals (including osteopathic)	9,000
Retail Pharmacies	53,000
Pharmacists	110,000
Drug Wholesalers	2,800

^aAdapted from Administered Prices in the Drug Industry, Part 19, p. 10728. Other product outlets include veterinarians and their hospitals, military procurement agencies, etc.

In addition to their function as transaction points, most of these same outlets are the promotional targets of the firms involved. This is an important finding. It implies strongly that concentrated promotion efforts may be employed by ethical drug manufacturers. Unlike many consumer goods firms whose promotions must be directed broadly and uncertainly, this opportunity to limit strictly the potential market to relatively few individuals and institutions has at least two advantages, namely, less waste in communication, and greater efficiency in product promotion planning. Both suggest the

³⁴Mahoney, op. cit., p. 27.

possibility of greater control over marketing costs than might be found outside the ethical pharmaceutical industry.

During 1958, approximately 655 million prescriptions were filled in the nation's 53 thousand retail pharmacies. Data for 1959 indicate that this figure had risen to about 712 million.³⁵ In 1959, the Pharmaceutical Extension Service of the College of Pharmacy of Rutgers University disclosed that of prescriptions written in 1958, 94.5 percent were dispensed as manufactured, i.e., no compounding was required.³⁶ This, too, is a highly significant finding, since it clearly illustrates the disfunction of the retail pharmacy, by tradition and outdated law a fixture in the pharmaceutical marketing channel. It is thought that a major source of criticism of the ethical drug industry stems from costs added and prices charged by retail pharmacists, despite the fact that their major function is that of transferring the contents of one package to another.

In 1962, total civilian spending for prescription drugs amounted to nearly \$2.5 billion, 98 percent of which took place in the nation's drugstores. Of these drugstores, 90 percent were independently owned, and 10 percent were chain stores of four or more units. For both

³⁵Administered Prices in the Drug Industry, Part 19, p. 107²⁸.

³⁶Details of this study are presented in Administered Prices in the Drug Industry, Part 15, p. 87⁷⁶.

types of pharmacies, new and refilled prescriptions each accounted for about half of total prescription sales. In chain stores, prescription sales were but about 12 percent of total chain sales. In the independents, on the other hand, prescription sales amounted to approximately 33 percent of total store sales, and prescription spending in independent stores was 89 percent of all prescription sales.³⁷

In the actual physical movement of goods, there is probably no "average" way to market pharmaceuticals. One firm may utilize wholesalers exclusively; another may sell directly to physicians or to hospitals. According to size, preference, or perhaps distributive resources, some firms market regionally, while others are engaged in national sales efforts.

Proprietary products are distributed through a wide variety of service organizations (food brokers, wholesalers, rack jobbers, etc.) and they are retailed in many non-drug outlets. At the same time, proprietary manufacturers make use of ethical drug distribution channels. As a serviceable approximation it is suggested that proprietary firms attempt to stimulate demand through direct promotion to consumers, thus pulling their products through the channels of distribution.

³⁷Drug Trade News--Special Section (New York: Topics Publishing Company, July 22, 1963), pp. S-4, S-30, and S-35.

Regardless of how conditioned he may have become through various promotional efforts, in the final analysis, the customer for a proprietary product is the ultimate decision-maker as to the product he selects. For the consumer armed with a prescription from his family doctor, the purchase of an ethical drug is a vastly different matter. He simply has no choice in the transaction. This, then, has resulted in the widespread objection to the effect that ethical pharmaceutical manufacturers are monopolists, a charge which must be examined carefully.

One industry critic voiced his dissatisfaction in this way:

The fact is that marketing the ethical product differs very little from the over-the-counter proprietary product. Both require extensive research, formulation, controls, huge advertising and promotional budgets--which may or may not be necessary in your or my estimation.

We can see that the only relative difference between the two markets is that the ethical market operates as a monopoly, because the consumer is a captive, whereas the proprietary product only has a psychological hold on the customer due to advertising.³⁸

Assuming that no distinction need be made between "over-the-counter" and "proprietary," part of the statement is true. Although proprietary products can be said to have substantial promotional cost elements related to their presence in the marketplace, this is true for many other consumer goods. Moreover, the choice of a

³⁸Administered Prices in the Drug Industry, Part 14, pp. 8207-8208.

proprietary retail outlet depends on a variety of factors --convenience, store layout, friendliness of the store's personnel, etc. Finally, aside from the attractiveness of packaging, power of advertising, and a host of similarly promoted differences, aspirin of Brand A is legally equal to that of Brand B, liniment X approximates liniment Y in essential respects, and most appetite tonics contain about the same amount of alcohol by weight. Though perhaps unmeasurable, it may be stated that, as a rule, cross elasticity of demand for proprietaries is high at least insofar as intrinsic product differences are concerned. The decision to purchase one brand as opposed to another is conceptually independent with respect to the embodiment of effective demand, the exceptions being two in number: (1) psychological habit induced by advertising, and (2) out-of-stock at the point of purchase. Regardless of the extent to which these operate, no agent outside the consumer forces him to purchase a given proprietary product.

The opposite is true for prescription products, a condition which manufacturers appear improperly to deprecate. Demand for the major products of most large ethical pharmaceutical houses is perfectly inelastic at two critical junctures, namely, the retail pharmacy and the final transaction from retailer to consumer.

In perhaps the most significant sense, demand for an ethical drug is generated by the physician to whom the bulk of the ethical group's promotional efforts is

directed. Given a new ethical product, the pharmacist may ultimately find himself faced with prescriptions from one or more physicians calling for the product by brand name. Product properties, quality control, and content consistency aside, the point is that the pharmacist must have access to inventories of the product in order to fill the prescriptions generated by corporate sales promotion whether he secures these outright, or on consignment, or through special order from a convenient wholesaler.

Moreover, the bearer of the prescription--the consumer with whom we associate effective demand--has no choice but to accept the product specified by the physician.

The consumer of drugs, the patient, has no free choice whatsoever as to whether or not he will purchase the drugs that have been prescribed for him by the physician. He can decide not to buy the prescribed drugs, but then he is not following advice that he is paying for.

The law usually requires that the specific prescribed drug be the one sold by the pharmacist. As a result, we cannot apply the same logic nor rules of the marketplace when we talk of drugs as we can when we talk of refrigerators.³⁹

The summation of purchases by all patients who do, in fact, purchase the named drug constitutes a perfectly inelastic demand curve for that product over the relevant economic range.

It must be emphasized that this analysis represents the viewpoint that product monopoly can and does

³⁹Administered Prices in the Drug Industry, Part 18, p. 10247.

exist in the pharmaceutical industry, and that given the retail pharmacist as the primary transaction outlet for the industry's products, together with the industry's refusal to support generic prescription practices, the condition is likely to be a permanent one. The reiteration is necessary because of the anti-social connotation with which the term "monopoly" has been endowed. To date, the most general relaxation of non-acceptance of a monopolistic position in the industry has been recognition of a patent monopolistic position.⁴⁰ Within the present analysis, this is an adequate, but neither a necessary nor a sufficient condition to complete understanding of the role of monopoly in the ethical group.

For the sake of clarity, the following statement may be regarded as reasonably typical of the anti-monopoly defenses abounding in the industry:

The manufacturers in the drug trade who spend large amounts for general sampling and for advertising and other forms of sales promotion are in continuous and aggressive competition with each other. New makers appear regularly and others drop out. There is no such thing as monopoly in the drug trade.⁴¹ (Italics added.)

This is a paradox. There is no question but that ethical pharmaceutical firms compete for the attention and favor of prescribing physicians. However, prescribing

⁴⁰See Administered Prices in the Drug Industry, Part 24, p. 13653.

⁴¹Paul C. Olsen, Marketing Drug Products (rev. ed.; New Brunswick, N. J.: Rutgers University Press, 1955), p. 253.

physicians do not pay for drugs--consumers do. Since the consumer is incapable of legally changing the prescription, even if he were sufficiently well informed to do so, he must purchase the product of a single seller, and therefore of a monopolist. That this may be a socially uncomfortable position for the drug manufacturer does not alter the situation. In terms of the producer-patient relationship, the paradox resolves itself, and Olsen's position is untenable.

A further device employed to remove chance stigma from the industry is the frequent practice of licensing competitors to produce (under a unique brand name) a product on which one holds a patent. That this technique is simply an extension of monopoly power is of minor importance to the present argument.⁴² The fact remains that the consumer--at the time that money is exchanged for the product--is involved in a situation wherein he represents perfectly inelastic demand in the marketplace. Further, as a rule there is no opportunity to refuse the transfer of money for the good. Whatever the moral,

⁴²Compare the Fellner thesis--tacit oligopolistic collusion (Fellner, op. cit., pp. 158 et passim)--with Alderson's contention that "to co-operate in the vertical direction and collude horizontally at the same time would create impossible conflicts for marketing policy." (See Wroe Alderson, Marketing Behavior and the Executive Action [Homewood, Ill.: Richard D. Irwin, Inc., 1957], p. 128.) Ethical pharmaceutical sales support Fellner. Manufacturer's prices are stable. Insofar as the prime seller controls the industry supply of the drug, market shares are likely to be determinant to the extent that "competitors" can sell no more of the product than the prime source releases under terms of the license.

ethical, and social implications of the transaction, the fact that the product is sold under conditions of monopoly, reinforced by the physician and the pharmacist, places the manufacturing firm in an extraordinary position. Since the pharmacist must stock the product, and the consumer must purchase it under his doctor's orders, the implications for the firm are clear--it enjoys product monopoly.

The major market target for manufacturers of ethical pharmaceuticals consists of some 182 thousand physicians in the United States. Unless and until the prescription habits of these practitioners are changed, it is not reasonable to assume that there will be marked changes in product sales volumes in the market period--if, indeed, in the short run. Industry spokesmen attempt to reduce the market protection implicit in such circumstances. For example:

If, as could happen tomorrow, a drug with qualities superior to M_____ should be marketed by a competitor and receive the favor of physicians, M_____ sales would probably decline, and a price reduction would have little influence in persuading the physicians to continue to prescribe M_____ if they regarded the new drug as more efficacious.⁴³

Carefully reviewed, this statement which purports to explain competition at some high level in the ethical industry actually accomplishes the opposite effect. First, it implies perfect knowledge on the part of physicians--some instantaneous form of communication between

⁴³Administered Prices in the Drug Industry, Part 16, p. 9111.

producer and prescriber--an unlikely state of affairs. Second, this statement serves as evidence of the degree to which products of this nature are price inelastic and price inelasticity is a common characteristic, not of competition, but rather of monopoly. Third, it suggests that physicians are not subject to habit. In so doing, it far understates the problem of the new product producer, that of persuading the physicians to stop prescribing M _____ in favor of X _____, whatever the relative efficacy of the two products.

In summary, it is suggested that in the case of ethical drugs there is evidence of product protection adequate to encourage high prices in the market. From this it is deduced that an ample margin may also exist with which to recover production costs and to recover preliminary costs of research and development. Hence, it is expected that under these circumstances, adequate financing will permit more or less elaborate research and development programs, but that more elaborate ones could easily be supported.

To a lesser extent, proprietary products may obtain a measure of shelter from promotional activities, but they lack the built-in monopoly of their ethical counterparts. Subject to the availability of close substitutes, their cost recovery outlooks are accordingly less certain.

Some Elements of Firm Composition
and Product Life

The propensity of its firms to attain and maintain substantial operating profits leads to a type of instability in the pharmaceutical industry. Basic economic analysis generally postulates the prolific entry and exit of new firms in response to excess profits and their subsequent diminution. However, the instability encountered in the present-day pharmaceutical industry⁴⁴ is of a different nature, since the rigors of regulation and the expense of establishing a sales force discourage firm proliferation. Within the framework of a relatively narrow number of firms, we observe that excess profits appear to lead to product diversification. The process of enlarging the main product mix of a pharmaceutical firm is common. For example:

Several of the largest pharmaceutical manufacturers have purchased established products and added them to their lines. Diversification and greater stability is thus provided in a business which seems to have more than its share of risks and uncertainties.⁴⁵

⁴⁴See Shubin, op. cit., p. 74. Following his lead, the pharmaceutical industry is so defined on the basis of similar technology and homogeneous production--i.e., with respect to supply conditions rather than substitutability of products.

⁴⁵Olsen, op. cit., p. 234. It is interesting to note that the paragraph cited concludes: "Such sales are often advantageous to the seller because they transfer his investment from a big share in a small enterprise to a small share in a big enterprise. Should the seller or his heirs wish to liquidate, the share in the big enterprise is sure to be much more readily marketable than complete ownership or a controlling interest in a small enterprise."

If smaller ethical firms were acquired by larger ones, or if proprietary firms of any size merged with other proprietary firms, there would be no particular reason to inspect diversification practices. The issues would be relatively clear-cut, with size the major variable of concern.

However, there is no assurance that simplicity of corporate structure will rule in the industry. Neither, for that matter, is there assurance that extensions of, or additions to, product lines will emerge through the amalgamation of one existing firm with another. It is always possible (however infrequently) that a firm of a given composition may extend its productive activities through the creation of new operating divisions, designed specifically to produce and market new classes of products.

The degree to which substantial product diversity exists has been documented in a number of instances.⁴⁶ Any attempt to identify areas of consistency--operational or philosophic-- in an industry hinges inherently on the degree of similarity of products and product lines. The heterogeneity of firms within the pharmaceutical industry leads to an important question: Will it be possible to define areas of likeness with respect to corporate procedures? If an affirmative answer is forthcoming in one

⁴⁶For example, see Administered Prices in the Drug Industry, Part 16, p. 9240; ibid., Part 19, p. 10993; ibid., Part 24, p. 13958; Mahoney, op. cit., pp. 37, 40; and Olsen, op. cit., p. 236.

form or another, a second question arises: When a firm has specialized over time in a single area (e.g., ethical drugs), will its modus operandi carry over when, through diversification, merger, or whatever, it assumes the economic responsibility of producing a new set of products (e.g., proprietaries)?

Above all, the conglomerate nature of the industry poses a third broad question: Assuming levels of likeness within industry groups, differing between groups, which approach to corporate structure will wield the greatest operational influence?

Stated another way, the economic structure of the industry appears to dictate differences between broad groups in that industry. Since the end products are different (and in some instances, quite different), it is likely that corporate practices will tend toward group goals where differences are least marked. A firm, then, which produces products of natures which gravitate toward different goals must experience internal conflict. Which goal is most influential in terms of the total corporation, and what, if any, difference does it make to the world external to the firm?

Specifically, we are concerned with the research and development implications of expanded or "foreign" products in established product lines. In the remainder of this section, attention is directed to why a constant expansion of new products is observed. Two causes--firm

momentum and product life cycles--form the core of the essential argument for product proliferation in the drug industry.

Firm "momentum" is a phrase coined to express the writer's belief that a business entity, in order to achieve long-term commercial success (i.e., profitability, standing in the industrial community, favorable credit terms, etc.) must display annual improvement in profits and in new products generated. It must, in order to avoid the pressures inherent in defensive maneuvering, project a corporate image of financial buoyancy, social and community service, and dynamism in terms of new product progress. Generally true of all successful businesses, this appears to be particularly true in the pharmaceutical industry.

In the drug industry, this mandatory concept of ongoing growth may be a result of size of the firm, together with the aspirations of the policy making executives involved. Size alone, however, is enough to indicate clearly the need for new products. The reason is simply this: The major outlet for sales orders is stimulated by focusing promotional and sales efforts on the nation's physicians. Because of the enormous volume of advertising and promotional materials, and the frequency of the visits of detail men, it is not unreasonable to propose that physicians, being human, react most favorably to the unique, the unusual, or the new. There

is no reason to suppose that a physician, having experienced gratifying results with Firm A's Product X, will change haphazardly to Firm B's Product Y. However, if B is able to introduce a new, or improved, Product Z, there is the possibility that the doctor will be attracted to its use through curiosity alone. There may be, as well, a tendency to think in terms of B's product line generally, and thus to heighten the possibility of a "prescription propensity" away from A's X to B's Y as well.⁴⁷

But this is only half the matter. Detail men for pharmaceutical firms are usually highly trained specialists, more or less sensitive to the social superiority of their customers, real or imagined. Thus, a salesman's firm which does not introduce a new product (or, better yet, several new products) during the year deprives the salesman of a powerful motivational and sales tool. Generally speaking, the larger the firm, the more detail men. In the absence of new products as generators of salesman enthusiasm, the laggard company may be forced, for morale's sake, to substitute money for new products. Thus it increases costs and reduces both profits and ultimately the pool of funds available for future product development. Additionally, the firm risks a probable loss of current sales to more aggressive innovators.

Hence, company size, as reflected in the sales

⁴⁷So far as is known, no empirical work has been done in this area.

force, operates to generate an almost desperate need for new products. But what of these new products? What if they remain useful, effective medicinal agents? If the drug manufacturer agrees to the notion of habitual prescription, why will he encounter short-run sales declines for his products? The answer, simply stated here, is that the life cycle of pharmaceutical products (particularly ethical ones) tends to be very short.⁴⁸ Accordingly, a firm which does not attend systematically to the development of new products may ultimately face the prospect of having a worthless product line, no matter what the firm's attitude toward employee motivation. It is a dismal economic prospect, indeed.

It appears highly likely that the pressure for new products intensified the research and development efforts of ethical drug manufacturers during the last decade. By virtue of the rush of new discoveries--i.e., those drugs which yielded first to scientists and marketers--firms grew and prospered as we have seen them do. Presently, however, the composite secrets remaining require greater and greater dollar inputs for each sales dollar returned. To maintain the new product image, then, has been the prime motivation for diversification.

⁴⁸For example, see Administered Prices in the Drug Industry, Part 24, pp. 13627-28, 13634-39, 13833-34. These discussions, together with others throughout the hearings, suggest that a five-year life cycle is a reasonable rule-of-thumb estimate for ethical drugs. See also Hearings on S. 1552, Part 4, pp. 2516-33.

Ethical firms are thought to have adopted proprietary branches for reasons of profitability, less rigorous research requirements, and at least partially comparable marketing mix experience. Proprietary firms may well have followed the same reasoning content, substituting an enhanced corporate image as an offsetting factor to the increased research costs incurred.⁴⁹ Regardless of the precise motives for diversification, the fact remains that there are some important implications of this activity for the research and development process.

The Economic Rationale of Research and Development

Having sketched the operational environment of the pharmaceutical industry, we next examine specific reasons why its corporations might wish to devote funds to research and development rather than to alternative uses. It will be convenient to attack this problem area not from a production stance but from one which first involves the marketing (or distribution) of products.

Marketing includes all the factors involved in selling a product. All selling activity begins with a product (or service). To do marketing, something must be offered for sale.

Unfortunately, the "birth" of most products does not take place as part of a marketing process. Inventors and businessmen develop new products that interest them, and they assume or hope that the new product

⁴⁹See Herbert D. Strauss, "How to Fail in Proprietaries Because of Not Really Trying," Drug and Cosmetic Industry, XC, No. 3 (March, 1962), 284. He presents a sharp argument for ethical attention to proprietaries.

will sell. Their hope in too many cases stems from their own interest and not from an aroused or latent interest on the part of the customers.⁵⁰

Given the present state of the art of marketing, this statement stands in sharp contrast to the usual recommendations found in the literature. On the other hand, it represents a legitimate point of view which must be examined if pharmaceutical research and development are to be treated thoroughly.

The reasons for its importance are clear. If there is truth in the notion that new products are developed at the whim of businessmen, rather than in accordance with the interests of consumers, no amount of self-righteous publicity can justify pharmaceutical research and development expenditures, per se. The possibility that products are profit makers first and medicines second is far more serious a charge than a statement that the opposite is true, for if the commercial offerings of the firms under scrutiny primarily are useful in the healing arts, the fact that they may be profitable enhances the likelihood that others will be perfected.

Now, it is true that "unless [it] is an exceptional company, the product came first. The company was formed to make the product and then to sell it."⁵¹ But this is

⁵⁰Harry W. Hepner, Modern Marketing (New York: McGraw-Hill Book Company, Inc., 1955), p. 153.

⁵¹Robert M. Oliver, "The Marketing Concept in Developing Products for Profit," in Control of Non-Manufacturing Costs (New York: American Management Association, 1957), p. 81.

essentially ancient history of almost no importance to the present-day leaders in the pharmaceutical industry. They deal not in a product, but in hundreds--even thousands--of products. The existence of the company may be taken for granted, and the present line of inquiry may be confined to products emerging from on-going firms.

As a point of departure, it should be noted that the total market for, say, domestic consumer goods generally does not necessarily reflect the problems encountered in the marketing of drug products. Yet, the latter takes place within the former, and considering the macroworld of marketing, Clarence Walton has observed:

Perhaps on close examination there may be seen in the market a magnificently intricate and symmetrical mechanism which keeps customers supplied with need, businessmen excited by profits, and the total society satisfied with its merits.⁵²

This exciting prospect, the more so by having been enunciated by one of the towering intellects of our time, may not satisfy the critic of the pharmaceutical industry. While it is a brilliant statement of the national effect of an economic philosophy, customers for drug products (particularly prescription products) are supplied with need from a source (human illness) quite impervious to the marketing process with its implications of occasional artificial demand creation. Indeed, it is only when the

⁵²Steven F. Shaw and C. McFerron Gittinger, Marketing in Business Management (New York: The Macmillan Company, 1963), p. 436.

significant point of drug demand is held to be the practicing physician that the marketing processes of the industry fit within the Walton construct. Effective demand, we have shown, is established when the consumer exchanges money for the good and it appears that this negates Walton's premise so far as consumers of ethical drugs are concerned.

We have become accustomed, in recent years, to regard "The Marketing Concept" as a desirable state of affairs for any firm in the economy. The antithesis of Hepner's contention, it is held that ". . . the marketing concept . . . requires that the activities of the entire business be directed toward the satisfaction of consumer needs at a profit."⁵³

Still concerned with the possible unpleasant implications of the Hepner effect (i.e., that drug products may be developed through essentially selfish, shortsighted motives), we are reminded that the very nature of the marketing concept, with its profit

⁵³E. Jerome McCarthy, Basic Marketing (Homewood, Ill.: Richard D. Irwin, Inc., 1960), p. 680. A more extensive version is that of Robert King, found in Shaw and Gittinger, op. cit., p. 36: ". . . 'The marketing concept' is defined as a managerial philosophy concerned with the mobilization, utilization, and control of total corporate effort for the purpose of helping customers solve selected problems in ways compatible with planned enhancement of the profit position of the firm." The less elegant formulation must suffice here, since customers (i.e., effective demanders) for ethical drugs do not "solve problems." They follow orders. King's definition is, of course, quite appropriate for the proprietary group.

implication, impinges on product development. For example:

The time to begin to develop product for profit is before conception, and the place is the market in which it will be born and progress through demanding infancy to lusty adolescence and healthy maturity. Call it "planned parenthood," and in two words you will have the essence of the marketing concept in developing products for profit.⁵⁴

There may be merit in the unusual phrase, "planned parenthood," for the drug firm which makes a practice of offering a limited line of products may well be expected to devote its research talents and resources to products in which it enjoys traditional expertise.⁵⁵ Moreover, the impact of pertinent federal laws may be seen to lend this measure of consumer security: the products must, in one sense, be quite safe for use as directed.⁵⁶ Regardless of uncertainty over demand conditions in the industry, the ultimate consumer is generally assured of obtaining products which, from the manufacturer's point of view, are well designed and well made. The fact that they may have been

⁵⁴Oliver, op. cit., pp. 80-81.

⁵⁵See Penrose, op. cit., p. 113. Regarding the firm, she observes that ". . . its opportunities are largely determined by its existing resources. Its entrepreneurial and managerial personnel work within the framework provided by these resources and their interests and abilities are conditioned by them. Except in those instances where firms are dominated by entrepreneurs of the roving 'empire-building' sort, there is a strong tendency for each firm . . . to concentrate on the profitable development of what it has."

⁵⁶NB. This is not the same thing as saying that it will never arise. See Administered Prices in the Drug Industry, Part 22, p. 12115.

investigated first in accordance with a marketing orientation does not prove that they are undesirable in use. It does suggest that we may expect drug firms which are profit oriented and which adhere to the marketing concept to concentrate their research efforts on potentially profitable, readily marketable products to the exclusion of areas which may be no less socially desirable.

While regarded as a vital means of encouraging research, a marketing orientation is not the only factor involved, nor should the marketing concept's consumer orientation obscure the fact that competitive commercial success is ultimately determined in terms of economic profitability. The matter is strongly expressed by one author, who asks:

What sort of people are the industrialists? What do they want? In particular, what do they think of research, and why? The first, most fundamental thing about industrialists is the reason why they are in industry at all. . . . Men do not become industrialists for their health, nor to confer benefits upon humanity, but to do business at a profit, preferably at a very good profit. If an industrial concern cannot produce and sell at a profit, it must cease to exist unless it is nationally owned. . . . Naturally, not all men who become industrialists have the capacity to make profits, but those who do not have that capacity soon cease to be industrialists.⁵⁷

It is interesting to reread the preceding quotation, substituting "researcher" for Freedman's "industrialist." This is more than an idle exercise in

⁵⁷Paul Freedman, The Principles of Scientific Research (2d ed.; New York: Pergamon Press, 1960), pp. 199-200.

literary speculation, for it reveals possible arenas of agreement and disagreement between two contestants--the entrepreneur and the scientist.

The areas of possible disagreement are vital ones. It may be that many researchers enter the vocation because it is more healthful than, say, coal mining. And it may well be that an important motivation (at the conscious level, at least) for undertaking a career in research is to confer benefits upon humanity. By and large, however, the entrepreneur (or industrialist) is profit oriented from the firm's point; the researcher is profit oriented from his own point of view (i.e., from the financial reward which he can obtain). Both, obviously, stand to benefit from mutual satisfaction of conceptually divergent profit motives which, in operation, become one and the same. Both, logically, must turn from highly speculative research in fields of questionable profit potential since both stand to lose--the entrepreneur his standing as a profit maker, and the researcher his task as a profit contributor. So long as each, in a sense, successfully tends his Candidian garden, the other prospers, but the speculative possibilities of the untapped research areas may be minimized.

Yet another economic factor in the extensive utilization of research and development is simply firm size.⁵⁸

⁵⁸"The emergence of large corporations made it commercially feasible to allocate immense funds for research and development." Noted in Shubin, op. cit., p. 31.

Industry estimates suggest that some basic size--some critical mass--must be attained before significant research inputs are observed. As recently as 1962, it is reported that the twenty-three largest drug companies accounted for all but 15 percent of the industry's total research personnel. The ten largest commanded nearly two-thirds of all researchers, including over half of the industry's research scientists.⁵⁹ No data exist by which to confirm the possibility that, for the thousand-plus small ethical firms, profits will not support research, with the result that they must be imitators or toll manufacturers. By the same criterion, there is no evidence to confirm the possibility that the small firms are highly profitable without research expenditures, and within the scale of operations deemed adequate by their owners.

One final observation should be made at this point. Generally, we tend to regard "progress" as a desirable social and economic trait for men and businesses. By progress in commerce we regard new products as a favorable bench mark. Even more so, we regard profitable new products as the most favorable sign of progress of all. Combining this with the matter of size of firm, Carl Kaysen poses a series of unsettling questions in the format which follows:

⁵⁹"Drug Industry Research Manpower is Rising Sharply," Oil Paint and Drug Reporter, CLXXXII (October 29, 1962), 4.

When we come to test the economic decisions of the large firm against the standard of progressiveness, we find that we can say little that is unequivocal. That large firms spend heavily on research and development is clear. That some industries in which the application of improved techniques and growth of output of new products is spectacular are industries--such as chemicals, oil, electronics--dominated by large firms is also clear. But when we try to look deeper, obscurity replaces clarity. Is the present degree of dominance of large firms a necessary condition of the amount of progress experienced, or even a sufficient condition? Are larger firms more effective, per dollar of expenditures, in producing new ideas and new methods than smaller ones are, and over what size range is this true? Should corporations spend on research and development much more or much less than they now spend? Should the incentives of the market be allowed more or less control than they now have of the whole chain of sequential and interrelated processes from the first observation of a new natural phenomenon or the first conception of a new scientific idea to the introduction into the market of a new product or the application on the production line of a new technology? These are all questions to which well-informed and competent students do not give the same answer, if indeed they give any.⁶⁰

When applied to the pharmaceutical industry, these questions are particularly important. In point of fact, they form the core of the present discussion. But with specific reference to his last insightful observation, it is true that the best-informed and most competent student may never "answer" these queries completely. In our dynamic world, complete answers might obtain as much by chance as by design, for, among other reasons, the drug industry of yesterday is not the drug industry of today, nor, probably, that of tomorrow.

⁶⁰See Edward S. Mason (ed.), The Corporation in Modern Society (Cambridge, Mass.: Harvard University Press, 1959), p. 95.

Industry Economics--Summary

The development at length of the perceived economic characteristics of the pharmaceutical industry represents an attempt to uncover the significant interrelationships likely to affect research and development. It will have been noted that at no time was the argument directed as an attack on, or an apology for, the states of affairs of the pharmaceutical groups. The intent, and hopefully the achievement, represent an essentially normative discussion, although it is admitted that "norms" for such a heterogeneous industry are difficult to define and defend.⁶¹

To review, the pharmaceutical industry--ethical and proprietary--has been classified as one of moderate total size, composed of several thousand firms of which only a fraction may be considered economically significant. The industry's substantial growth and concurrent outstanding profitability have been discussed.

Marketing channels have been shown to be well defined, rigidly bound, and not subject to change with any degree of rapidity. This highly structured distribution system has been credited with importance in determining

⁶¹In this regard, six staff members of Arthur D. Little, Inc. prepared a paper with the self-explanatory title, "A Report on the Social and Economic Benefits of the Pharmaceutical Industry in the United States." Dated December 4, 1961, the paper is reprinted in Hearings on S. 1552, Part 4, pp. 2473-514. Its findings are of no use to this paper, but its contents are recommended to those seeking measures (however tenuous) of the humanitarian accomplishments of the ethical drug industry.

demand characteristics for the industry. Specifically, the perfect inelasticity of demand for prescription products has been compared with the less than perfect inelasticity of demand for proprietaries, the latter being dependent on advertising and promotional effectiveness to the ultimate consumer.

Next, it was suggested that substantial and sustained profitability was regarded by the industry as a necessary condition for the emergence of substantial research and development plans and expenditures. The implications of the presence and maintenance of high profit levels were examined. It was indicated that one significant effect was the enhancement of conditions conducive to product diversification and proliferation.

Finally, a discussion was centered around the problems of a marketing oriented industry and its research attitude toward the public. The evidence presented led to tentative agreement that in the case of pharmaceutical products the marketing concept probably has operated to consumer benefit; however, much uncertainty remains. It is toward the reduction of as much uncertainty as possible that the remainder of this paper is devoted. To this end, we must detour briefly to inspect the implications of federal legislation on the pharmaceutical industry and its research and development efforts.

CHAPTER III

LEGAL INFLUENCES IN THE ENVIRONMENT

Introduction

Social and cultural forces impinge upon the performance of an operating firm. The manner in which the external components of the environment affect a firm's production and marketing activities has been the topic of considerable learned debate. One description of the implications of outside forces to the firm's progress was elucidated by Boulding:

Within the market environment the business is reasonably autonomous; i.e., if it is successful in coping with the market environment there is nobody much to say what it should do or what policies it should espouse. The market environment is not, of course, the only one. It operates also in a legal environment of antitrust laws, labor laws, pure food and drug laws, tax laws, fair employment practice laws, and so on, to which it must conform in some degree, and it will shape its policies accordingly. The legal and political environment is felt as a rather abstract and impersonal matter, however, in a way not unlike the market environment, but much less important. The legal environment merely places certain restrictions on operations within the market environment--a sort of boundary within which the business is free to move, and a wide and elastic boundary at that.¹

Generally true for most businesses, Boulding's

¹See Kenneth E. Boulding, The Organizational Revolution (New York: Harper & Brothers, 1953), p. 174.

view is often inapplicable to the pharmaceutical industry as a whole. With respect to the ethical drug group, it is quite incorrect. As will be demonstrated in the remainder of this section, a certain degree of boundary elasticity in the industry existed before 1938. Over time, however, the impact of legal restrictions has become more and more rigorous until it may be observed that of the environmental forces which impinge upon the drug industry, legal ones now tend to be vastly more important than all others which might be postulated.

It should be noted that the passage of legislation is one thing--the enforcement of that legislation may be quite another. However, when legislative guidelines exist, it is possible to identify the adjustments which firms make to them. If, in isolated instances, certain firms choose to attempt to sidestep the letter of the law, it is thought that the resource energy expended in this strategic maneuver is as much attributable to the law's existence as though the firm were to adhere closely to legal requirements.

Developing the nature and force of legal restrictions bearing on the drug industry is best done from historical perspective. The rationale for progressively more stringent regulation becomes apparent as the narrative unfolds. The nature of the aforementioned adjustments may be made more evident. Where legal adjustment and some other corporate activity (for our purposes,

research and development) advance pari passu, historical emergence offers the opportunity to compare and contrast the two.

The broad brush treatment of this section should not be misleading.² Pharmaceutical legislation is a complex subject. On the other hand, to attempt more than is attempted here would only confuse the ultimate issue--to clarify further the role of research and development in the pharmaceutical firm.

Men, and hence corporations directed by men, resist change. Abandoning the comfort of industrial processes routinized through precedent and custom is a difficult task. To face the unfamiliar problems likely to emerge from a major directional change is disquieting to most of us. Thus it is not surprising to find the following plea for conservatism in the records of the Senate:

After many years of struggle the drug industry has found modes of operation which make it an amazing dynamic success for the good of all. I am gravely concerned that any tampering with it now will cripple or destroy all its present and future achievements.³ (Italics added.)

A contemporary petition, its equal was undoubtedly voiced

²For example, the legal scholar may wish to emphasize the sundry state laws, whereas only federal legislation is of importance to this paper. A pharmacist might wish to explore local and state laws affecting drug retailing, whereas only regulations affecting manufacturers have a place here.

³Administered Prices in the Drug Industry, Part 16, p. 9252.

in 1937, and in 1906 where the discussion properly begins.

The Federal Pure Food and
Drug Act of 1906

Insular industry protectivism appears to have inspired all federal pharmaceutical legislation during the nineteenth century.⁴ The public was protected only by such laws as the several states saw fit to enact; ultimately, however, the proliferation of practicing charlatans and quacks, and the flood of useless and often dangerous drugs attracted public attention.⁵ The Federal Food and Drug Act of 1906 (to be effective January 1, 1907) was enacted by Congress.⁶

The purpose of the basic act has been clearly

⁴See Olsen, op. cit., pp. 55-57; and Richard Mathison, The Eternal Search (New York: G. P. Putnam's Sons, 1958), passim. The latter work, while largely undocumented, contains interesting accounts of the development of medicines from the dawn of history to the present.

⁵Credit for agitation resulting in the first feeble legislation belongs to the outspoken group of reformers unkindly tagged "muckrakers" by President Theodore Roosevelt, who signed the first significant law to protect consumers at large.

⁶"The act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and for regulating traffic therein, and for other purposes . . . shall be known and referred to as the Federal food and drug acts." This quotation, together with the record of the several amendments to the act, may be found in Vincent A. Kleinfeld and Charles W. Dunn, Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record, III (Chicago: Commerce Clearing House, Inc., 1958), 429. The basic law is referred to as 34 Stat. 768.

stated by one drug industry proponent who noted that it "prohibited sale in interstate commerce of adulterated or misbranded products."⁷ The point to be made is this: in the federal legislative scheme beginning with the Pure Food and Drug Act of 1906, nothing can be cited which suggests that research and development evolved in any way from pressure occasioned by legal activity. On the other hand, the need for some sort of quality control is suggested, and we may presume that, in most instances, this requirement formed at least a nebulous basis for subsequent orderly investigation. But, for the most part, the vague beginnings of separate laboratory facilities had to be the result of internal inspiration rather than external direction.

Whatever the present tenor of public opinion toward the drug industry, it is sobering to recall that until slightly over a quarter of a century ago, there were no constituent requirements if a firm wished to market a new drug. So long as the product was free from adulteration and it was properly labeled, any substance reasonably safe for consumption could be offered.

Under the circumstances, it is not surprising that certain substances unsafe for consumption entered the marketplace. As a result, outraged and gradually intensified public opinion forced debate throughout the

⁷Mahoney, op. cit., p. 24.

mid-thirties on the problems of the pharmaceutical industry.⁸

The legislative outcome of the protracted and often desultory debate was more restrictive than it might otherwise have been. By the concatenation of circumstances to be repeated at a critical juncture some years later, a drug tragedy concerned with Elixir Sulfanilamide captured national attention and forced congressional action. As one authority describes it:

Now, it so happened that there was a drug called sulfanilamide, but it was difficult to place it in solution. A concern without any testing tried various solvents, and finally used diethylene glycol, which is a close relative of permanent antifreeze.

Using this as a solvent, the sulfanilamide went into solution, this was distributed throughout the United States [sic].

Now, the Food and Drug Administration had no knowledge of this until suddenly there was an epidemic of deaths throughout the country. It placed its investigators on the problem, and they found that there was one single common denominator, which was this Elixir Sulfanilamide.

As a result, Congress passed a new act in which there was a new drug section of the law.

Under this section of the act, it gave the requirements necessary to place a new drug on the market. Among other things full reports of all investigations which were made to determine the safety of the drug were required. This included the pharmacological and the clinical studies. Among the other requirements were those about what the drug contained, the methods of manufacture, controls, and so forth.⁹

⁸As at the turn of the century, social critics (Stuart Chase was perhaps the most notable) rose to demand government action. The shock value of certain flagrant abuses in product offerings aided their cause immensely.

⁹Administered Prices in the Drug Industry, Part 22, p. 12054.

The attention to new drugs, and the requirements for pharmacological and clinical studies, as well as the other requirements cited, were a unique combination under federal control. By fiat, from 1938 on, inventive and innovative pharmaceutical firms--of any size--were constrained to implement research and development procedures in their organizational structure.

The Federal Food, Drug, and
Cosmetic Act of 1938

The significant legislative period between 1938 and 1963, a span of twenty-five years, is of particular importance, since corporate performance measures used in this paper evolved under the aegis of the Federal Food, Drug, and Cosmetic Act of 1938 (52 Stat. 1046).¹⁰ The environmental implications of the law were, for practical purposes, immediately apparent. For example, at the time of its passage, it was observed that:

The bill will not discourage research for new remedies or new uses of old remedies since any valid claim can be substantiated by demonstrable scientific facts revealed by the research even though no substantial medical opinion on the subject has yet developed.¹¹

Thus the firm was permitted--even tacitly urged--to rely on its research facilities to further its own economic

¹⁰The act's precise operating implications for research and development procedures are detailed in the following section of this paper.

¹¹Charles W. Dunn, Federal Food, Drug and Cosmetic Act: A Statement of Its Legislative Record (New York: G. E. Stechert & Company, 1938), pp. 116-17.

interests, and the entire drug industry literally had thrust upon it the need to develop sound research techniques as a legal prerequisite to doing business.

Olsen regards restrictions on the marketing of new drugs as "the most important extension of coverage" in the Food, Drug, and Cosmetic Act.¹² Concern with new drugs was a novel concept in that, for the first time, the manufacturer was required to prove that his product was safe for prescribed use! Exempted from the "proof of safety" requirement were those substances which had been developed under the Pure Food and Drug Act of 1906, and others which were generally recognized as safe, even if relatively unused as drugs per se.¹³

Exemptions aside, drugs which were liable to proof of safety regulations and which were thus new drugs in fact covered a wide range of products and product components. Carriers, coatings, menstruums, and excipients, when not previously used in drugs, required clearance. Combinations of old (and hence acceptable) drugs, and proportions of ingredients not previously cleared might be regarded as new drugs. Even such adjustments as new dosage recommendations and all other possible changes in

¹²See his Marketing Drug Products, p. 58. There he also defines thoroughly the nature of new drugs. Adaptations of his presentation are used here.

¹³See Dunn, op. cit., pp. 1-22, esp. p. 3, paragraph (p). This "Grandfather Clause" will be seen to have been particularly important to proprietary research and development.

use could, and often did, require the manufacturer to submit proof of safety.

The Food and Drug Administration (FDA), the designated regulatory agency, called for a number of pieces of information to be used in determining the acceptability of a new drug. Those which do not materially affect this presentation include a complete enumeration of the drug's components; a full discussion of the drug's composition; and samples of the drug, its components, and the labeling proposed for use of the drug.

A full description of the methods, facilities, and controls used throughout the manufacturing process, together with processing and packing procedures were another area of concern. Here is continuing evidence that some elements of structured investigation were imperative in pharmaceutical product manufacturing. To the extent that control procedures are akin to the research process the nucleus of research formality is re-emphasized by this requirement of the Food, Drug, and Cosmetic Act of 1938.

The principal research catalyst, however, was the final requirement of the FDA. In new drug applications, manufacturers were required to file "full reports of all investigations that have been made to show whether or not the drug is safe for use."¹⁴ This involved basic chemical

¹⁴Administered Prices in the Drug Industry, Part 22, p. 12116. The present discussion centers around this source, where the concepts noted are arranged in a somewhat different form and order.

research, work with animals and human volunteers, clinical testing, and for each phase, the ever-present possibility that the Food and Drug Administration would require repeated investigation in one or more areas.

In the ethical group, firms desiring to market new pharmaceuticals became involved in research and development that was expensive, time consuming, and complicated. According to the Pharmaceutical Manufacturers Association, however, the more stringent requirements stemming from the 1938 legislation were far from inhibiting in terms of the emergence of new and useful remedies.¹⁵

A less vigorous case for research adjustment could be made for the proprietary group and its products. Since these drugs were regarded as safe enough for self-medication, and since the consumer was free to evidence product dissatisfaction by substituting others' brands, and since the components of proprietaries were unprotected by patent regulation,¹⁶ it was a rather more simple matter. By retaining combinations of drugs which had been sold during the 1906-1938 era, proprietary firms were able to concentrate their efforts on new brand and trade names. Thus, in effect, old proprietaries in new packages helped this

¹⁵See pp. 87-88 infra.

¹⁶Protection normally has been sought for packages, labels, and trade names. Drug contents could and did change frequently. Hence, the title "patent medicines" was not strictly correct, and the alternative "proprietary drugs" was probably more satisfactory.

group keep pace with the ethical group in the offensive marketing of new products. Research burdens on proprietary firms were accordingly less than those on ethical ones.

What were the sources of dissatisfaction that led to increased pressure for further rigorous control of the drug industry? Speaking only in terms of the Food, Drug, and Cosmetic Act of 1938, two suggestions appear to have merit: (1) the Food and Drug Administration was inadequately manned and financed to police the industry properly, and (2) the firms (especially the smaller ones) either were careless or took advantage of this inadequacy to circumvent the law.¹⁷ These problems, however, were essentially matters of inadequate quality control. There is little evidence that new drug introduction via the FDA route was especially difficult, despite its time consuming nature.¹⁸ Toxicity, either in single doses or in extended therapy, was the major determinant in the release of the new drug until the late 1950's.

Many of the new drugs emerging in the post-World War II era were increasingly powerful in their therapeutic

¹⁷The workload and resources of the Food and Drug Administration during the last years of operation under the 1938 statute are discussed in detail in Administered Prices in the Drug Industry, Part 22, pp. 12130-32. For extensive listings of regulatory violations during the period January 1, 1950, to June 3, 1960, see ibid., pp. 12137-65.

¹⁸See ibid., Part 18, p. 10427.

activity. Unlike their earlier counterparts which were safe for use in wide concentrations and in most humans, the powerhouse antibiotics, corticosteroids, tranquilizers, and oral antidiabetics were a different matter. Although of unquestioned over-all value in the treatment, control and cure of certain illnesses, their administration sometimes resulted in what are termed "side effects."

Assume that a person suffers from diseases A and B in combination, or that he has A, and B results as well. The physician administers product X, specifically designed to cure ailment A. Further assume that treatment with X cures A, as expected, but B, and all other facets of the patient's health remain the same. In the case of dual disease or disease with the complications B, no side effect would be cited. If, however, X cures A and B as well, X may be said to have had a positive side effect.¹⁹ Because of the potency of the new creations, however, it appeared that in many instances product X cured ailment A, but aggravated B, and perhaps introduced complication C. The grim old wives' tale that the cure was worse than the infirmity was revived. The side effects were often negative, and sometimes alarmingly so.

The medical and ethical implications of this turn

¹⁹It is highly unlikely that side effect claims would be based on a single case. The precise number of observations necessary to establish the fact would depend on the frequency of occurrence of the disease, the reputation of the physician in charge, the attitude of the person responsible for authenticating the claim, etc.

of events is a matter for physicians and pharmacologists to debate. The point to be made here is this: under economic pressure to introduce new products, serious flaws appeared, if not in pharmaceutical research and development procedures, at least in the reports of research findings. Data were falsified or omitted where their presence might have hindered the issuance of FDA approval. Claims were made for combinations of drugs which were, in fact, less useful than the claims implied. Journals of ostensibly sound medical nature became, instead, the hired sounding boards of corporate sales promotion departments.²⁰

The foregoing is by no means a blanket indictment of the entire industry. No attempt has been made to prove that the majority of the sound, reputable firms relaxed their long-established standards of excellent research and excellent products. But in terms of human interest, the pharmaceutical industry, and particularly the ethical group, is so vital to society's welfare that any marked deviation from perfection by one is to create suspicion directed toward all.²¹

It is quite possible that despite the unattractive situation noted, no legislative change would have occurred

²⁰Background material for these observations may be found in Study of Administered Prices in the Drug Industry, pp. 165-222. This summary report contains extensive references to the complete hearings cited frequently in this paper. Cf. pp. 134-46 infra.

²¹For the spirit of the 1938 legislation in this respect, see Dunn, op. cit., pp. 251 and 482.

had it not been for the Senate investigation of administered prices in the ethical industry, the proceedings of which form so important a part in the framework of this paper. Obviously, drug prices--their levels and durations--were of initial importance, enhanced by consumer complaints and government recognition of the political--if not the humane--matter of federal medical assistance for the aged and indigent.

Two factors are thought to have enabled the passage of legislation that followed the Senate hearings. First, the drug firms and the industry itself, through the Pharmaceutical Manufacturers Association, pointed to excessive research and development costs as a primary reason for alleged "high" prices, thus virtually inviting the subcommittee to question the nature of the R and D process as well as other operating practices. Second, the Elixir Sulfanilamide tragedy which prompted passage of the Food, Drug, and Cosmetic Act of 1938 was virtually repeated in the case of the product Thalidamide, the use of which by pregnant women led to occasional distressing defects in their infants.

The result was the passage of S. 1552 as amended (in lieu of H.R. 11581), signed into law by the President on October 10, 1962, becoming P.L. 781, 87th Congress, 2d Session. Known popularly as the Kefauver-Harris Amendment to the Federal Food, Drug, and Cosmetic Act of 1938, its adoption signaled the beginning of a separate era in drug

products. Among the new law's requirements was one which would enhance the role of pharmaceutical research and development. Products were required to be proven effective, as well as pure and safe.

The Kefauver-Harris Amendment to the
Food, Drug, and Cosmetic Act--1962

The nature and extent of firms' adjustments to the Kefauver Amendment's provisions may not be apparent for some time to come. By reviewing the substance of the legislation it will be possible to suggest likely trends for the future of the industry, provided that no further changes are implemented.

The principal addition to prior-existing regulation occurs in the area of new drugs and their introduction. Whereas the Food, Drug, and Cosmetic Act of 1938 required demonstrations of safety, the Kefauver Amendment (P.L. 781) adds efficacy, or effectiveness to the basic statute. Generally, this means that the FDA will require more extensive clinical evidence before releasing the drug for use by physicians. More data from pre-clinical and clinical research, together with adequate and appropriate background from the literature, are presently mandatory.

This requirement does not automatically signify marked intensification of research efforts for most firms. Presentation of an additional volume of product data may become as much a matter of clerical activity as of research, since the materials with which the FDA now

evaluates a drug are held to be no more "than is customarily acquired by any prudent drug manufacturer."²² The implication here is that, through adequate research, the better producers may have always satisfied themselves that their drugs were acceptable in the very spirit of the present law. Earlier FDA procedures would then simply require that less of the accumulated evidence be presented in support of the new drug application.

The grandfather clause of the Kefauver bill presents interesting possibilities for ultimate consumer protection as well as possibilities for R and D activity. At this writing, the Food and Drug Administration has proposed a new set of regulations under the enabling legislation. They will "require the makers of all drugs marketed in this country between 1938 and last June 20 [1963, when the latest regulations took effect] to prove to the FDA that they are not only safe but effective. . . . The ultimatum will cover more than 2,000 drugs placed on the market in the past 26 years."²³ If successfully implemented, this FDA activity may occasion widespread research and development efforts. Products offered in good faith under earlier regulations may require updated

²²See William W. Goodrich, "FDA's Regulations Under the Kefauver-Harris Drug Amendments of 1962," Food Drug Cosmetic Law Journal, XVIII, No. 10 (October, 1963), 566.

²³"U.S. Orders Drug 'War,'" Newark Evening News, February 28, 1964, p. 3.

evidence of effectiveness and safety. While there is no reason to assume that this will lead directly to a high rate of product withdrawal, it seems likely that the FDA will require current proof rather than to rely on R and D results as much as twenty-six years old. Thus, some portion of drug firms' research costs may be attributable to re-research, or the repeated testing of products once known to meet government standards.

Three additional points--quality control, advertising control, and packaging requirements--complete the essence of the new regulations. All drugs--new and old--must be prepared in proper facilities, with adequate equipment and all needed control procedures. Failure to meet these minimum standards results in adulteration charges. One authority notes the lack of industry controversy over this requirement, noting that its acceptance "may be a tribute to the fact that major manufacturers scrupulously meet or exceed these minimums, and marginal firms will be likely to disregard them anyway."²⁴ Nothing suggests that the control requirement will affect earlier practices of most reputable firms.

Advertising jurisdiction is transferred from the Federal Trade Commission to the Food and Drug Administration, and product labels must display the generic name of the product in addition to the corporate brand name.

²⁴Goodrich, op. cit., p. 562.

What effect has the Kefauver Amendment had upon the industry? It is too early to say, but it appears that progress so far represents the pattern which a social psychologist might have postulated--from fear and mistrust to adjustment to the change and the cultivation of an attitude of acceptability. Prior to passage of the amendment, one source noted tartly that "current thinking emphasizes that a drug must never harm a single individual."²⁵ Such an attitude could hardly have helped those firms which awaited the legislation with a real desire to conform to the expressed needs of society. There was no reason then (and there is none now) to assume that the FDA would bar a product which produced some side effects. Rather, the legislative intent may be thought to have been directed toward those products whose side effects overwhelmed the alleged curative effects, and toward those producers who, one way or another, distorted the clinically demonstrated incidence of non-specified side effect activity.

A better assessment of the situation was that suggested by Mackel, who said that objections to P.L. 781 ". . . are reminiscent of the early days after the enactment of the so-called 'new drug' section of the 1938 law. . . ." He astutely observes that, as a long-run process ". . . industry sources have, in recent years,

²⁵Manufacturing Chemist, XXXIII, No. 2 (February, 1962), 75. This excellent British journal regularly presents editorial material pertaining to the U.S. pharmaceutical industry.

characterized this law [the Food, Drug, and Cosmetic Act of 1938] as having been the most important influence in bringing about rational therapeutics."²⁶

Finally, in view of the stated purpose of this paper, the Kefauver Amendment may prove to have at least one of three possible influences on research and development in the pharmaceutical industry. For those firms which have observed meticulous research and development procedures in the past, no particular change in levels of research activity should be expected from the change in legal environment alone. Slipshod, careless firms, previously content with the most marginal research evidence, will now be faced with the necessity of improving their general research and development procedures, if only from an intensified clinical research need. Dishonest operators with no interest in adequate research and development--past, present, or future--stand a greater chance of being eliminated from the industry than under previous legislative provisions.

²⁶Michael F. Mackel, "Legal Considerations in Experimental Design in Testing New Drugs on Humans," Food Drug Cosmetic Law Journal, XVIII, No. 4 (April, 1963), 230. Long-run appreciation is quite different from short-run apprehension. For example, one researcher found wide divergence of opinion among ten drug firms as to likely field staff alterations following passage of the 1962 amendment. See Dana M. Beverly, "The Effects of Noneconomic Limitations Upon the Ethical Pharmaceutical Industry" (unpublished Master's thesis, Graduate School of Business Administration, New York University, 1963), pp. 12 et passim.

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Legislative Summary and Implications

For the producer and marketer, legal limitations are likely to impinge on three important product decision areas: product quality, product design, and product line additions.²⁷ As we have seen, the pharmaceutical industry (and especially the ethical group) constitutes an almost perfect example of this combination. Moreover, the evolutionary nature of the legal process in federal drug control serves to illuminate more clearly the implications of external regulations as they affect research and development activity.

The Federal Pure Food and Drug Act of 1906 outlined regulations designed to control product quality. The Federal Food, Drug, and Cosmetic Act of 1938 enlarged the dimensions of the control element to include product design (insofar as safety was concerned) and product line additions (with special reference to new drugs). Both were essentially attained through the intensified use of R and D procedures. The Kefauver-Harris Amendment of 1962 to the Food, Drug, and Cosmetic Act served to reinforce and expand government control in all three particulars. Accordingly, quality control procedures were followed by research and development requirements, and these corporate functions were substantially strengthened in the most recent legislative activity.

²⁷See John A. Howard, Marketing Management (Homewood, Ill.: Richard D. Irwin, Inc., 1957), p. 212.

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Two questions arise following such an array: first, are all observable corporate research reactions the result of legislation, and second, is it reasonable to assume that further federal legislation will impinge upon corporate research procedures?

The answer to the first question is generally negative. Certain firms appear to have anticipated later legislation, carefully controlling the quality of their products before the Act of 1906, and instituting research and development sections before the Act of 1938. Assuming only that these firms acted because of their own preferences, the names Lilly and Upjohn and a host of others exemplify best an important attribute of the American private enterprise economy: firms often have conducted their affairs with such social conscience that their public relations activities are virtually superfluous. Thus it is suggested that rather than being driven to conformity with legislative requirements, the better firms may experience only the most minor readjustment of R and D policies and procedures. Indeed, the commercial research activities of these better firms may well serve as models for laws designed to constrain their more erratic counterparts.

An answer to the second question ultimately may be positive. Discussing the appropriateness of public investigation of private industry, Walton points to the drug industry as one likely to "face the continued scrutiny of

Congressional committees and a drumfire of criticism calling for more direct regulation."²⁸ Based on the absence of bargaining opportunities between buyers and sellers, the former must depend on the intercession of political forces for an assessment of the relative fairness of corporate performance. As in the case of the Kefauver Committee hearings, public attention to one phase of business activity (the industry's price structure) can ultimately result in legislation which adjusts other facets of the firm (expanded clinical research requirement, for example).²⁹

The legislative hurdles to date erected within drug firms' marketing systems and operating through R and D sections may be said to have had both favorable and unfavorable effects on the firms' marketing activities.³⁰ Requirements for additional tests and the communication problems arising from bureaucratic inertia have delayed

²⁸Clarence Walton in Shaw and Gittinger, op. cit., p. 471.

²⁹Additionally, the requirements of the Kefauver-Harris Amendment could further stimulate R and D activity. If the current investigation of the effectiveness of old drugs (those introduced in the period 1938-1963) reveals many unacceptable ones, firms marketing substantial numbers of the old drugs are faced with two possibilities to counteract losses in their product lines. They may elect to refine the old product to the point of effectiveness or they may wish to concentrate on introducing new acceptable drugs. Both possibilities tend to increase the need for more alert, active research efforts.

³⁰See Ralph S. Alexander, James S. Cross, and Ross M. Cunningham, Industrial Marketing (rev. ed.; Homewood, Ill.: Richard D. Irwin, Inc., 1961), p. 154.

the introduction of new products. The needs of the Food and Drug Administration have directed clinical tests and the presentation of their results in ways which may have been at odds with the firm's needs. Final release of a product may have depended more on FDA budgets, workloads, personnel attitudes, etc., than on firms' marketing plans or the elements of seasonal demand so vital to industry sales.

On the positive side, however, a product release from an official government agency "goes far to assure users that the product will do what is claimed for it and thus eases the marketing task materially."³¹ As the release has been dependent first on safety and then on a combination of safety and effectiveness, this last point is so important that it has tended to lessen the impact of the several commercially unfavorable influences. On balance, it appears that legislative control in the pharmaceutical industry has been generally beneficial. Rather than seriously inhibiting the marketing activities of the firms, it is more likely to have encouraged, through requisite research and development, the multitude of useful drug products which society has come to expect as a matter of course.

The growing expertise in pharmaceutical marketing manipulation is suggested by the observation that

³¹Ibid.

throughout the 1950's "the traditional relationship between drug maker and doctor has been reversed. Instead of supplying the drugs he wants, the industry now tries to tell him what he should want. This is done by the same promotion methods that sell deodorants."³² Another interpretation of the stand suggests that such circumstances may not be totally critical. Rather, they might be thought to reflect the superior research accomplishments of the industry, together with advancing sophistication in marketing methodology by the industry's firms. Above all, they form important evidence that legislation has not stunted the mobility of pharmaceutical firms in their growth and progress in the economy, no matter how rigorously they may have influenced the technical composition of the firms.

Note 1 to Chapter III

The government agencies responsible over time for enforcement of pharmaceutical legislation are arranged in Table 9.

Detailed information concerning the judicial and administrative proceedings resulting from investigations, tests, and standards violations may be found in the series, Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record, published occasionally by the Commerce Clearing House.

³²Marion K. Sanders (ed.), The Crisis in American Medicine (New York: Harper & Brothers, 1961), p. 96.

TABLE 9.--Government agencies enforcing major
pharmaceutical legislation (1907-1964)

Dates	Senior Agency	Responsible Agency
1907-1927	U.S. Department of Agriculture	Bureau of Chemistry
1927-1930	U.S. Department of Agriculture	Food, Drug and Insecticide Administration
1930-1940	U.S. Department of Agriculture	Food and Drug Administration
1940-1953	Federal Security Agency	Food and Drug Administration
1953 to date	Department of Health, Education and Welfare	Food and Drug Administration

Sources: Food Law Institute Series, Federal Food, Drug, and Cosmetic Law: Administrative Reports--1907-1949 (Chicago: Commerce Clearing House, Inc., 1951), pp. 713 et passim; Vincent A. Kleinfeld and Alan H. Kaplan, Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record, V (Chicago: Commerce Clearing House, Inc., 1962), 301, fn. 1; and Miriam Offenberger, The Federal Investigators (Englewood Cliffs, N. J.: Prentice-Hall, Inc., 1962), pp. 169-190.

CHAPTER IV

RESEARCH AND DEVELOPMENT

Research Components in Research and Development

A broad discussion of research and development, or R and D, involves the use of an important abstraction. Viewed casually, it might appear that they are really one and the same, and that processes and procedures applicable in research are identical with those found in development. Since the literature is often aimed at the practicing specialist, rather than the uninformed investigator, neither the components nor the abstract entity tend to be defined. This is regrettable, since the concept of R and D is essentially a simple one, and much harm can arise through misunderstanding what is involved and what values can be derived through R and D application.

Research of any kind, in any discipline and at any time, has been defined as an organized, diligent investigation for the purpose of discovering facts.¹ Development, we may then suggest, involves organized,

¹L. W. Wallace, "Organizing the Research Team," in George P. Bush and Lowell H. Hattery (eds.), Teamwork in Research (Washington: The American University Press, 1953), p. 25.

diligent investigation of the means and methods of commercial exploitation of facts revealed through the original research. The point to be made is that development, in the sense that it is worth separating from the total research process, differs only in that it starts from a well-defined point (a researched fact) and proceeds toward an equally well-defined end (commercialization). Further examples will be useful in securing this point of view, as well as indicating the extent to which segmentation of R and D activities proves insightful.

Research is frequently divided into basic and applied areas.² Basic research is best represented as the activity which seeks to learn more about the nature, rather than the value, of things. Understanding for its own sake, rather than the usefulness of whatever may come to be understood, is the force which motivates the basic researcher.³ All of this is evident in the alternative titles for the basic research process, including such often encountered terms as "pure" research or "fundamental" research.

²See Shubin, op. cit., p. 28; Harley H. Bixler, The Manufacturing Research Function (New York: American Management Association, 1963), p. 12; and Dael Wolfle (ed.), Symposium on Basic Research (Washington: American Association for the Advancement of Science, 1959), p. 253, as well as other sources cited below.

³See Wolfle, op. cit., p. 254. There he notes that both types of research contribute to total knowledge, and he cautions that the differentiation is a matter of separation of responsibility; one type is not "better" or "higher" than the other.

Traditionally, basic research has not held a place of primary emphasis in American industry. It is suggested that there are two excellent reasons for this state, the first a matter of time, and the second a matter of organizational scope. Basic research is, by its nature, a function which is future-oriented. Any economic rewards likely to arise from basic research may be years away, not only because a firm may be inadequately staffed to exploit the finding, but because society itself may be unreceptive to the novel. Moreover, given a firm whose horizon includes stability of growth, as well as profitability, there may be a notable tendency to cultivate intensively an innovation over long periods of time rather than to proceed onward to new research points.⁴ Applied research, on the other hand, is far more important to the business community than basic research. What do we mean when we discuss "applied" research?

In the first place, applied research is a short-run, end-oriented activity, so that it may be said to fit well within the normal corporate structure where operating funds are released for tangible purposes. At its widest, however, it embraces the determination of ways and means of adapting to concrete problems the knowledge, materials, equipment, and processes made available by prior research

⁴In general, these attitudes are implied by Shubin, op. cit., p. 29, and by Wolfle, op. cit., pp. 127-28.

efforts, whatever their origin.⁵ Hence, under ordinary circumstances, we would be reasonably safe in regarding all significant commercial research efforts as simply being "applied" in one way or another, regardless of the particular title by which they are designated.⁶

Research and development becomes conceptually complicated only when it is subject to fractionalization at the hands of specialists seeking to illuminate the role of their particular specialties. This is not meant as a snide criticism of those who segment an abstract idea for the purpose of reflecting the minutiae contained therein--far from it! Rather, we have tried to indicate that the functional process can be highly complex, and hence that it may be unwise to think of R and D as being applicable across the board. From industry to industry and firm to

⁵Wallace, op. cit., pp. 24-25.

⁶Greater detail in terminology and specific practice may be found in a number of sources, including J. A. Leermakers' "The Selection and Screening of Projects," in M. J. Docher and Elizabeth Marting (eds.), Getting the Most From Product Research and Development (New York: American Management Association, 1955), pp. 81-82; Paul McVicker, "Meeting Company Objectives Through a Successful Technology Team," in Maintaining the Product Portfolio (New York: American Management Association, 1960), pp. 77-78; Social Science Research Council to the National Resources Planning Board, Research--A National Resource, Part III (Washington: U.S. Government Printing Office, 1941), p. 5; Dexter M. Keezer et al. in their "Appendix" to Silk's The Research Revolution, p. 213; Wallace, op. cit., pp. 23-25; and William F. Whyte, "Applying Behavioral Science Research to Management Problems," in Social Science Approaches to Business Behavior, George B. Strother (ed.) (Homewood, Ill.: The Dorsey Press, Inc., 1962), pp. 125-28.

firm, the components of an R and D system may change. R and D's contributions, too, may change as a result of more or less complexity.

Two additional points may be made with respect to the construction of corporate research programs. First, except insofar as highly complicated R and D formulations reveal the nature of specific corporate procedures, they should be avoided when discussing the research process itself, as well as its products. This is because, in part, it is virtually impossible to prove that discovery in any sense proceeds from the abstract to the applied. The notion that such a sequence exists has been cited as the core of the scientist's belief structure.⁷ When it becomes necessary to treat a highly segmented research process sequentially, it should be understood that its purpose is simply heuristic, rather than necessarily realistic.

Second, any normal research project may be accomplished according to the choice of the scientist involved. He is usually at liberty to proceed either in order or on a basis of random attack. Normally, the essence of the scientific method suggests that the problems of discussing research and development are minimized through order.

⁷Hilbert Schenck, Jr., writing in Science Digest (LIV, No. 6 [June, 1963], 46-47), observes that "this is the myth that equates science to art as a purely personal, creative endeavor, an activity responsive only to the genius of an individual mind." Cf. Whyte, op. cit., p. 128.

But, particularly if basic research reaches any importance at all, it will not be unusual to find, as Baker has suggested, ". . . that those having the ablest and most creative minds will prefer to use them in basic research by following up the undirected, uncontrolled, unspecified, unprogrammed, and certainly unknown courses revealed as the work itself goes ahead."⁸

It is quite possible that a firm's random research behavior could supply new products or adequately solve product deficiency problems. On the other hand, it is equally evident that a planned program of research and development could anticipate each problem area before the firm were forced to act. When a firm operates under intense social or competitive pressure or both, the confusion and waste likely to arise from random behavior can prove to be a substantial handicap. Alternatively, planned research programs can create within the firm an environmental atmosphere which will aid greatly the firm's ability to counter unusual economic forces.

The foregoing discussion was designed to illuminate the research and development process in the pharmaceutical industry. There (at least in the ethical group) the research process is a complex one--one which we shall be forced to compress in order to facilitate meaningful

⁸From W. O. Baker's "The Paradox of Choice," in Wolfle, op. cit., pp. 43-44.

interfirm comparisons.⁹ The Senate Hearings are particularly rich as a source of pharmaceutical research procedures. One such concise description has been selected as representative of normal operating procedures within the ethical group.¹⁰ The steps in the product development process may be identified as:

- | | |
|--------------------------|---|
| | 1. Emanation from a basic research project. |
| Basic Preparation | 2. Product produced in the laboratory. |
| | 3. Advanced to a pharmacology screen. |
| | 4. Toxicity study: probable dosages determined. |
| | 5. Animal testing. |
| Pre-clinical | 6. Experiments through a physician on a single human. |
| | |
| Clinical | 7. Internal clinical testing. |
| | 8. External clinical testing. |
| | |
| Post-research Procedures | 9. FDA clearance. |
| | 10. Marketing. |

We may assume that an active synthetic chemical or an organic substance has been detected in a firm's basic research facilities.¹¹ The new substance or compound is

⁹Again, it must be noted that the process of simplification conceals specific operating characteristics of individual firms. Support for the procedure may be found in John G. Kemeny, A Philosopher Looks at Science (Princeton, N. J.: D. Van Nostrand Company, Inc., 1959), pp. 250 et passim.

¹⁰The particular source described may be found in Administered Prices in the Drug Industry, Part 14, pp. 7967-68. This may be compared with ibid.: Part 16, pp. 9314-23; Part 19, pp. 10724-28; and Part 20, pp. 11104-12. The last cited is particularly complete in terms of a single product's progress.

¹¹This assumption is not particularly realistic, as we shall see. There are a number of sources for new product ideas. Use of a basic discovery as a point of departure happens to be the most convenient point.

prepared in laboratory facilities in quantities adequate for further testing.¹² Once these are available, the test product is advanced to a screening process, generally termed a pharmacology screen, where the amount and type of activity of the substance are determined.¹³ In most instances, the product will be returned for adjustments in activity, or toxicity levels. This we shall regard as basic research activity.

Once initially cleared by the pharmacologists as properly active, further toxicity studies are conducted in order to determine probable dosage levels. In general, this is a matter of testing which employs a variety of animal subjects, although at some point in the process, a human volunteer will be selected for participation in the project.¹⁴ Broadly speaking, the industry regards this

¹²In many cases, preparation of test quantities is so difficult that substantial expenditures in time and money are required to derive even minimum amounts of the substance.

¹³"Pharmacology is the study of the action of chemical agents on living material whether the living material is plant or animal in origin, and whether the action is good or bad for the living material. The field of pharmacology is related to toxicology, which is the study of the poisonous actions of chemicals on living things. Poisonous action of chemicals simply extends from ordinary action and is due to a larger dose." Quoted from Administered Prices in the Drug Industry, Part 18, p. 10435.

¹⁴This is a lengthy process in many cases. For example, the drug may appear to be extremely useful in each animal species tested--yet manifest quite a different reaction (ranging from no effect to a highly toxic effect) in humans.

as pre-clinical research. We shall include it hereafter in basic research on the premise that there is no assurance to the end of this stage that there will be any commercial usefulness in the proposed product.

Next, a two-phase clinical research approach unfolds. The first step is the administration of the drug by selected specialists to a limited number of human patients. These specialists are usually employed by the firm; their patients are carefully observed. Finally, the drug is subjected to "in-use" testing, i.e., it is distributed to independent physicians, whose administration of the drug and whose subsequent more-or-less objective appraisals are thought to reflect the normal patterns of use and abuse which would obtain in the regular employment of the product.

In the light of statistical analyses of the data obtained from this lengthy testing process, a judgment decision is made with respect to marketing the product. If the decision is an affirmative one, the materials supporting the value of the drug are submitted to the Food and Drug Administration and, upon its approval, the drug may be marketed and used "as directed."¹⁵ To attain this

¹⁵This procedure, related from experience under the Food, Drug, and Cosmetic Act of 1938, is not particularly different in substance under the more recent legislation described above. The major departure is that more data must now be forwarded to the FDA, and, presumably, the efficacy requirement would require more carefully prepared data than before.

commercial eminence will have required what we shall term developmental research.¹⁶

For purposes of constructing a visual model of the research process, we have now identified two broad areas which form the core of the pharmaceutical firm's R and D program, and we have arbitrarily titled them basic research and developmental research. In terms of time dimensions, it is technically unrealistic to hypothesize a smooth unidirectional flow in the pharmaceutical research and development process. A product may cross and recross boundaries a number of times before it is marketable. But it is convenient, obviously, to assume that most products emerge (or are discarded) in a progressive sense. It would appear that attempts to enhance this flow would save both time and money, since few firms are concerned with a single product over the development span, and any product returns may be thought to disrupt research manpower and funds in backtracking.

For a complete model, basic research and developmental research are too restrictive. The conflict occurs in the assumption that new products originate in basic research laboratories alone. The problem is well illustrated in the following observation from the ethical industry:

¹⁶An appreciation of developmental research may be found in C. Wesler Scull, "Pharmaceutical Research," in Drug and Cosmetic Industry (LXXXVI, No. 10 [April, 1960], 446).

Inspiration, or the idea for a new drug product, can come from any of a number of sources. There might be an obvious need for a specific new product with certain characteristics; the ideas may emanate from any of the research departments--biochemical, organic chemicals, viral, biological, clinical; or top management or sales representatives may come up with suggestions.¹⁷

Here we see a number of possibilities for new product suggestions, including two unlikely to occur through primary members of an organized research effort--top management (by courtesy privy to research progress) and the sales force.

These sources aside for the moment, a third broad possibility exists--market research. Parker continues:

Market research also plays a significant role in the initiation of research and development of new products; it supplies management with periodic surveys, giving information on the incidence of a disease, percentage of cases treated, suitability of existing treatment, dosage forms, and so forth--all of which may point to promising new research areas.¹⁸

(The use of marketing research as a source of new product entities has outstanding possibilities. For one thing, it decreases the range of uncertainty for a firm which seeks profitable new product classes for exploitation. Rather than wasting resources in a multiple attack on a product diversification problem, the firm alert to the potential offered by marketing research can concentrate its resources in a single, purposeful attack in a specific area, one /

¹⁷R. P. Parker, "Developing New Drugs," Drug and Cosmetic Industry, XCI, No. 6 (December, 1962), 698.

¹⁸Ibid. Hereafter we substitute marketing research for the more restricted "market" research.

which may even be defined as appropriate to the corporation's experience and desired product path.

Another strong argument in favor of including marketing research in a pharmaceutical research model is that, compared with alternative research components, its cost is virtually insignificant.¹⁹ Hence, if it is (or could be) a significant source of new product ideas, its use should be fairly widespread.

A difficulty arises when we attempt to establish the proper sequential location for marketing research. If it is the source of a new product idea, its function does not end there. Instead, marketing research--and particularly the syndicated data services--form a continuous ongoing program, analogous perhaps to a dredging operation, where facts are collected regularly. Accordingly, it is regarded here as of a parametric, rather than a self-contained, nature. Viewed this way, specific marketing research projects may be underlined whenever it is appropriate to do so.

Thus we may regard the world of pharmaceutical research as shown in Figure 1.

Far more complicated models could be advanced. For example, basic research itself could be dichotomized to represent pure and applied research. Similarly,

¹⁹The writer has been informed that, for most large pharmaceutical firms, the total annual cost of an entire program of marketing research (including market research) approximates 1 percent of the R and D budget.

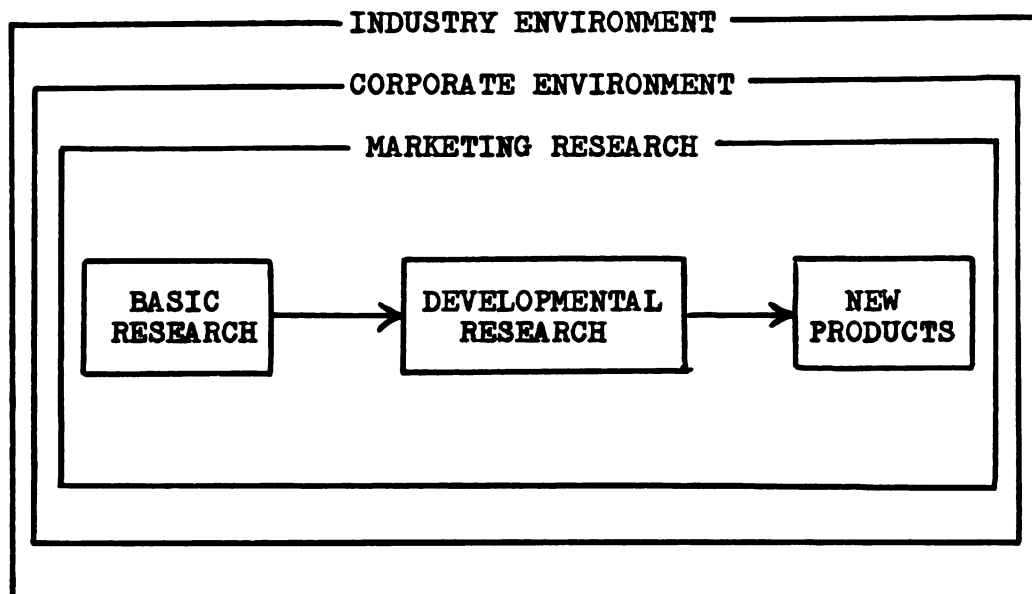


Figure 1.--A hypothetical model of the pharmaceutical research and development process.

developmental research could be expanded to form product development and product application groups. A firm, having access to its own records, might wish to analyze the research process in terms of each operating laboratory. However, the more inclusive components are adequate to serve our present purposes--to subject them to scrutiny in light of actual operating practices among selected pharmaceutical firms.

Note 1 to Research Components in Research and Development

No particular originality is claimed for the model introduced above, although the writer does not recall having encountered it in its present form. An early, more expanded form was developed by C. E. K. Mees and J. A. Leermakers.²⁰ Another author, D. H. Killeffer, described the problem through a series of case studies.²¹ Again, Kemeny's forceful argument for simplicity heavily affected the nature of the model.²² His appreciation of the needs of social science should be compared with Edward B. Roberts' extensive research.²³

²⁰The Organization of Industrial Scientific Research (2d ed.; New York: McGraw-Hill Book Company, Inc., 1950), p. 5.

²¹The Genius of Industrial Research (New York: Reinhold Publishing Corporation, 1948), passim.

²²See fn. 9, p. 101 supra.

²³"The Dynamics of Research and Development" (2 vols.; unpublished Ph.D. dissertation, Massachusetts Institute of Technology, 1962), 514 pp. (Mimeographed.)

Using defense industry R and D projects and a formidable combination of heuristic models and computer programming, Roberts reports that the outcome of R and D depends on three product-related factors: (1) the intrinsic job size, (2) the state of product technology, and (3) the intrinsic product value. He further cites three significant firm characteristics as important for R and D results: (1) the over-all quality of the firm, (2) the firm's willingness to undertake risk, and (3) the integrity of the firm. Unimportant firm attributes he found to be: (1) financial resource, and (2) previous job size experience. Hence, it appears that Roberts has amply supported the Kemeny thesis that social science problems (and in this instance, administrative science) tend to yield nebulous results when viewed through complex lenses.

Finally, all writers in the area of research and development--and particularly those proposing models of R and D activity--are deeply indebted to Professor James B. Quinn, whose competent book is, and is likely to remain, the definitive volume on the subject.²⁴ It was with mixed emotions that the writer departed from Quinn's models and terminology. On the one hand, there appeared to be a profitable opportunity to extend his analysis to a specific industry. In the final decision, however, it was thought that Quinn's attention to offensive and defensive

²⁴See his Yardsticks for Industrial Research (New York: The Ronald Press Company, 1959).

research, as well as his tacit assumption that R and D leads to profits, could more readily be handled by present methods.

Nevertheless, it is now difficult to separate Quinn's influence in this exposition. Thus, extensive citations from his original work, as well as several of his adaptations for the Harvard Business Review are replaced by this over-all expression of appreciation for a solid background in R and D administration.

Measuring the Growth of Research and Development Expenditures

Prior to 1935, most of the important drugs used in the United States were "foreign" ones, in that they did not originate in this country. It was not until the 1930's that Parke, Davis & Company; Merck & Company; Eli Lilly and Company; Abbott Laboratories; and E. R. Squibb and Sons instituted formal research activities.²⁵ Data for the formative years are unavailable, and it is not until 1948 that we are able to observe that the pharmaceutical industry spent \$30 million that year for research, although even here it must be admitted that the precise definition of research used is missing.²⁶ An early

²⁵See Max Tishler, "The Scientist's Stake in the Kefauver Hearings," Drug and Cosmetic Industry, LXXXVI, No. 11 (May, 1960), 609.

²⁶Estimate derived by Frederick T. Icken, "The Development of Marketing Research in the Ethical Pharmaceutical Industry" (unpublished Master's thesis, Farleigh Dickinson University, 1961), pp. 8-9.

investigation of pharmaceutical research and development expenditures yielded the startling observation that, in a ten-firm sample, 1958 research expenditures were almost 234 percent over the amount the same firms spent in 1948.²⁷ Adding two respondent firms for whom 1948 data were not available (and probably not significant), 1958 research expenditures for Hayes's total sample of twelve firms is reported as \$82 million, or approximately half the total estimated drug R and D outlay of \$170 million in that year.²⁸ Spokesmen for the industry claim about \$250 million as the 1962 expenditure for ethical drug research alone, or a level approximately 2 percent of that of the total United States research and development outlay.²⁹

Briefly, what do these dollar figures mean in terms of manpower requirements in the pharmaceutical industry? The New York Stock Exchange study indicates that its twelve respondent firms employed well in excess

²⁷Kenneth Hayes, "Research--The Key to a Healthier America," The Exchange (New York Stock Exchange), XX, No. 4 (April, 1959), 13.

²⁸Ibid.; the total estimate may also be found in Administered Prices in the Drug Industry, Part 2, p. 10958. Of the total, \$157 million were spent within fifty-nine PMA firms, \$13 million were used for outside research services from universities, hospitals, etc. Market development research is excluded from the R and D definition. Ibid., p. 10957.

²⁹Prescription Drug Industry--Fact Book, p. 18; also see Thomas Moranian, The Research and Development Engineer as Manager (New York: Holt, Rinehart and Winston, 1963), pp. 1-2.

of 5,000 researchers in 1958.³⁰ One giant in the industry points to 750 members in its research division, a second claims from 600 to 650 similarly situated.³¹ A smaller firm reports 328 employees engaged in research alone, compared with 265 production employees.³²

It has been claimed that "it takes about ten years to establish a research program, hire the people and establish your lines of research and really begin to do an effective job."³³ Also, as we shall have occasion to recall, a significant characteristic of the pharmaceutical industry is a high rate of product innovation and obsolescence.³⁴ Even allowing for the interruption of World War II, it might be expected that a generally high level of research and development, stimulated by the Federal Food, Drug, and Cosmetic Act of 1938, would result in an impressive list of new, useful products from all corners

³⁰Hayes, op. cit., p. 16. His sample was composed of:

Abbott Laboratories	Olin Mathieson
Allied Laboratories	(Squibb Division)
American Cyanamid	Parke, Davis & Company
(Lederle Laboratories)	Charles Pfizer & Company
Bristol-Meyers Company	Plough, Inc.
Chemway Corporation	Schering Corporation
Merck & Company	Smith, Kline & French
	Laboratories

³¹Administered Prices in the Drug Industry, Part 14, pp. 8305 and 8899.

³²Ibid., Part 16, p. 9391.

³³Ibid., Part 24, p. 13675.

³⁴See Howard, op. cit., pp. 250 et seq.

of the industry.

This has not especially been the case. In the decade from 1949 through 1958, the 417 completely new prescription drugs (i.e., new chemical entities distinguished from combination or duplicate products or new forms of existing products) were developed by 59 of the ethical industry's 1,371 companies! Moreover, 19 companies introduced about 313 of these, or 75 percent of the new products.³⁵ The same ten-year period saw the emergence of certain research organizations whose primary purpose is to guide pharmaceutical marketing efforts rather than product development efforts.³⁶

In light of the foregoing, whatever the growth in dollar expenditures, successful inventive pharmaceutical research and development has been restricted to relatively few firms. We must conclude here that whatever the scope of research activities within the pharmaceutical industry, for most firms it is a matter either of innovation or imitation. It is regrettable that such a conclusion obscures whatever research risks other firms may have underwritten to no profitable end. However, pharmaceutical firms--

³⁵Administered Prices in the Drug Industry, Part 16, p. 9385.

³⁶For a discussion of these interesting, sometimes ingenious groups, see Larry Ziment, "An Evaluation of Some Major Marketing Research Services Commercially Available to the Ethical Pharmaceutical Industry" (unpublished Master's thesis, Graduate School of Business Administration, New York University, 1961).

like firms in other industries--seldom discuss their research failures at length.

Measuring Research and Development Results

Frequent mention has been made in the literature and in this paper to problems of timing and their impact on the research and development process.³⁷ We have seen that to start a research program requires a period of years; to anticipate any concrete payoff from that program is a matter of a lengthy wait infused with uncertainty.

But we also know that new products have appeared in some profusion during recent years. Thus, despite the somewhat primitive planning conditions under which the pharmaceutical industry must operate, it does seem likely that R and D programs are proving successful, at least from a product introduction stance.³⁸ Accordingly, in this section we will examine available materials concerned with new product output--quantitative and qualitative assessments of the results of research and development activity. This approach will be of assistance in side-stepping the problems of time lags, although, obviously, it will not perfectly answer the predictive needs of future research efforts.

It is important to note initially that one

³⁷See p. 112 supra; and Administered Prices in the Drug Industry, Part 24, pp. 13831-32.

³⁸See Table 10, p. 117 infra.

authority has set the stage for just such an inquiry.

Silk has observed:

Capital investment represents consumption deferred in the interest of greater production later; and research and development carries the process one step further. It represents a charge against current production in the interests of greater investment--and greater productivity--later. This may be a qualitative change of the same order of importance as the development of the concept of capital itself.³⁹

All producing firms employ capital in one form or another, and with it they offer tangible products for sale. Not all producing firms employ research and development, however, and there is considerable confusion over whether or not those who do can claim unusual success as a result.

At least part of the increase in pharmaceutical R and D expenditures reflects the high return on a major new successfully salable drug.⁴⁰ Another portion of the increase may have reflected a tendency toward diminishing returns over time to the total industry effort, as compound after compound came to light. It is reported, for instance, that a single new chemical entry cost about \$830 thousand in research and development expenditures in 1948. By 1961, it had risen to \$5.54 million. During roughly the same period of cost growth, perhaps as many as one

³⁹See Silk, op. cit., p. 15.

⁴⁰While imperfectly documented, this return must border on the fantastic. One source sympathetic to the industry divulges that "fewer than 10 per cent of the drugs introduced will be novel and important enough to be large prescription sellers. Another 10 per cent will pay their way. The remainder will be unprofitable." (See Mahoney, op. cit., p. 27.)

million chemical compounds were screened as potential therapeutic agents. Only between four and five hundred of these became marketable medicines.⁴¹

The alternatives to totally new products form an interesting facet of the drug industry's operations in terms of costs, research and development, and marketing strategy. In reverse order, a progressive image for the pharmaceutical firm has demanded an annual series of product line additions. Given a single chemical entity, protected in many instances by patents, the manipulation and combination of the entity with other drugs reduced the R and D charges incurred in the pursuit of totally new products. By comparison, we may recall the previous level of R and D costs for new products as noted above, and learn that "the average cost per new product in 1948 was \$75,000, and in 1961, \$857,000."⁴² While substantial, the 1961 cost of a "new product" was far below the \$5.54 million cost of a "new chemical entity."⁴³

One competent authority provides the volumes shown in Table 10. Of all the marketed offerings of De Haen's sample firms, only about 10 percent represented, in one

⁴¹With some variations, these matters are discussed in C. M. Suter, "Drug Bill: \$5 Million," Oil Paint and Drug Reporter, CLXXXII (April 16, 1962), 7; Hampton, Chemical Week, XCI, No. 20, 142; and Administered Prices in the Drug Industry, Part 17, pp. 9951-52.

⁴²Hampton, loc. cit.

⁴³At this point, there is no intent to attempt a comparison of the merits of the two varieties of products.

TABLE 10.--Pharmaceutical products introduced nationally^a (1953-1962)

Year	Total New Products	New Single Chemicals	Duplicate Single Products	Com- pounded Products	New Dosage Forms
1953	353	48	79	226	97
1954	380	38	87	255	108
1955	403	31	90	282	96
1956	401	42	79	280	66
1957	400	51	88	261	96
1958	370	44	73	253	109
1959	315	63	49	203	104
1960	311	45	64	202	98
1961	265	41	33	191	106
1962	<u>255</u>	<u>28</u>	<u>47</u>	<u>180</u>	<u>84</u>
Sub- total	3,453	431	689	2,333	964
New Dosage Forms	<u>964</u>				
Grand Total	4,417				

^aData are derived from surveys in which the number of firms responding ranged from 101 to 127, and averaged 115. The source credits these firms with at least 90 percent of the total U.S. drug business.

Notes: New Single Chemicals--products developed by one manufacturer and not previously known.
Duplicate Single Products--generic drugs offered by several manufacturers.
Compounded Products--products with more than one active ingredient.
New Dosage Forms--changes in physical form for marketing (tablets to capsules, etc.).

Sources: Paul De Haen, "New Products Parade--1962," Drug and Cosmetic Industry, XCII, No. 7 (February, 1963), 151; U.S., Congress, Senate, Hearings on S. 1552 (Pharmaceutical Manufacturers Association), Part 4, 87th Cong., 1st Sess., 1962, p. 1656.

sense, the ideal culmination of the research and development process--the totally new discovery. The remaining 90 percent were refinements which, we may suppose, originated within the R and D system in that they benefited from earlier investigations.

It is important to stress that the De Haen compilation is deceptive with respect to new products. For proper clarification, we must turn to a simple, but highly dramatic, observation by an industry spokesman as recorded in Table 11.

TABLE 11.--Origin of 417 new ethical drugs introduced (1949-1958)

Number of Companies	Percent of Companies	Number of New Drugs Introduced
59 companies	4%	417
1,312 companies	96	-0-

Source: U.S., Congress, House, Committee on the Judiciary, Hearings on H.R. 6245, Drug Industry Antitrust Act, 87th Cong., 2d Sess., 1962, p. 623.

In the absence of any evidence that the 1949-1958 pattern varied significantly from that of 1953-1962, we must conclude that a very small group of firms have contributed virtually all of the ethical industry's truly new products. The remaining nine-tenths of the nation's ethical pharmaceutical firms are either innovators or imitators. It may be expected that the attitudes toward, perception of, and interest in research and development will differ between

the inventive minority and the majority remainder of the industry's firms.

Regardless of the desired end product of R and D--new entities or the adaptation of existing ones--it is not enough to regard product output as the sole measure of the effectiveness of the effort. A number of approaches have been suggested for this purpose. We may now examine a series of them, all designed to provide at least partial insight into the likely profitability of an investment in research and development. And lest the reader pursue this section with the expectation of a revelation, we may well start with the most recent attempt to evaluate R and D.

An impressive tabulation and analysis of the number of publications appearing under corporate imprimatur, resulting from research and development and appearing in learned journals, have been suggested as an appropriate approach to R and D assessment.⁴⁴ While this is indicative of the lengths to which investigators in their frustration will go to order a difficult area, it is no more than fair to suggest that the only certainty which attaches to the scheme is that it provides a count of journal articles.

At least three reasons may be offered to argue against the use of the plan. First, there is the problem

⁴⁴See Melville H. Hodge, Jr., "Rate Your Company's Research Productivity," Harvard Business Review, XLI, No. 6 (November-December, 1963), 109-22. This is an extension of an identical method advocated by J. C. Fisher in Hearings on S. 1552, Part 4, pp. 2565-73.

of corporate secrecy, arising from traditions engendered in days of poor communication. A firm may be willing to release its project results only so long as they do not appear likely to offer aid and comfort to potential competitors. Second, there is some question as to the willingness of a firm to release a substantial number of accounts of research failures. Such may prove the lot of a particularly unfortunate R and D department, and an enlightened discussion of its fruitless attempts should be counted as being as productive as the more grandiose announcements of stunning success. Third, no provision is made for articles offered for publication which are unacceptable to the journals themselves, whether from subject matter or literary style. In short, it is difficult to accept the suggestion that the output of learned papers is meaningfully correlated with the productivity of an R and D department. As a coup de grace, it might be suggested that a truly productive R and D department would be so busy consolidating its gains and breaking new ground that its members would have no time for the idle publications necessary to spell success for the journal count plan.

In an engineering setting, it is held that research planning can be facilitated through a graphic approach relating time and money expenditures.⁴⁵ Developed as a

⁴⁵For details of specific application, see David B. Hertz, The Theory and Practice of Industrial Research

means of appraising engineering phases of product development, the approach appears to have at least theoretical merit for pharmaceutical research planning. Assume that a firm regularly performs three broad types of research: basic, applied, and developmental. Further assume that it produces products of types A, B, and C, and that it has considerable experience in the development of several formulations of each type.

The essential piece of apparatus consists of the positive quadrant of a Cartesian coordinate, with the y axis calibrated to reflect the cumulative percent of research expenditures. The percent of total time to complete the project is cumulatively entered on the x axis. Then, utilizing its internally generated data, the firm analyst may enter the appropriate point loci on the respective axes and construct what we may call a "research progress curve," reflecting the approximate amount of effort required to complete the first project.

As an example, let us use the following hypothetical data, shown in Table 12, to construct the appropriate curves for two formulations of the type A product.

When entered in the graph outlined above, the results appear in Figure 2.

(New York: McGraw-Hill Book Company, Inc., 1950), pp. 156-57; and Gerard C. Gambs, "Representative Costs of Doing Research and Development," Research Management, II, No. 1 (Spring, 1959), 33-43.

TABLE 12.--Assumed time and expenditure data
for type A products

	First Formulation		Second Formulation	
	Total Time	Total Cost	Total Time	Total Cost
	(%)	(%)	(%)	(%)
Basic	25	20	8	10
Applied	25	30	17	30
Developmental	<u>50</u>	<u>50</u>	<u>75</u>	<u>60</u>
Totals	100%	100%	100%	100%

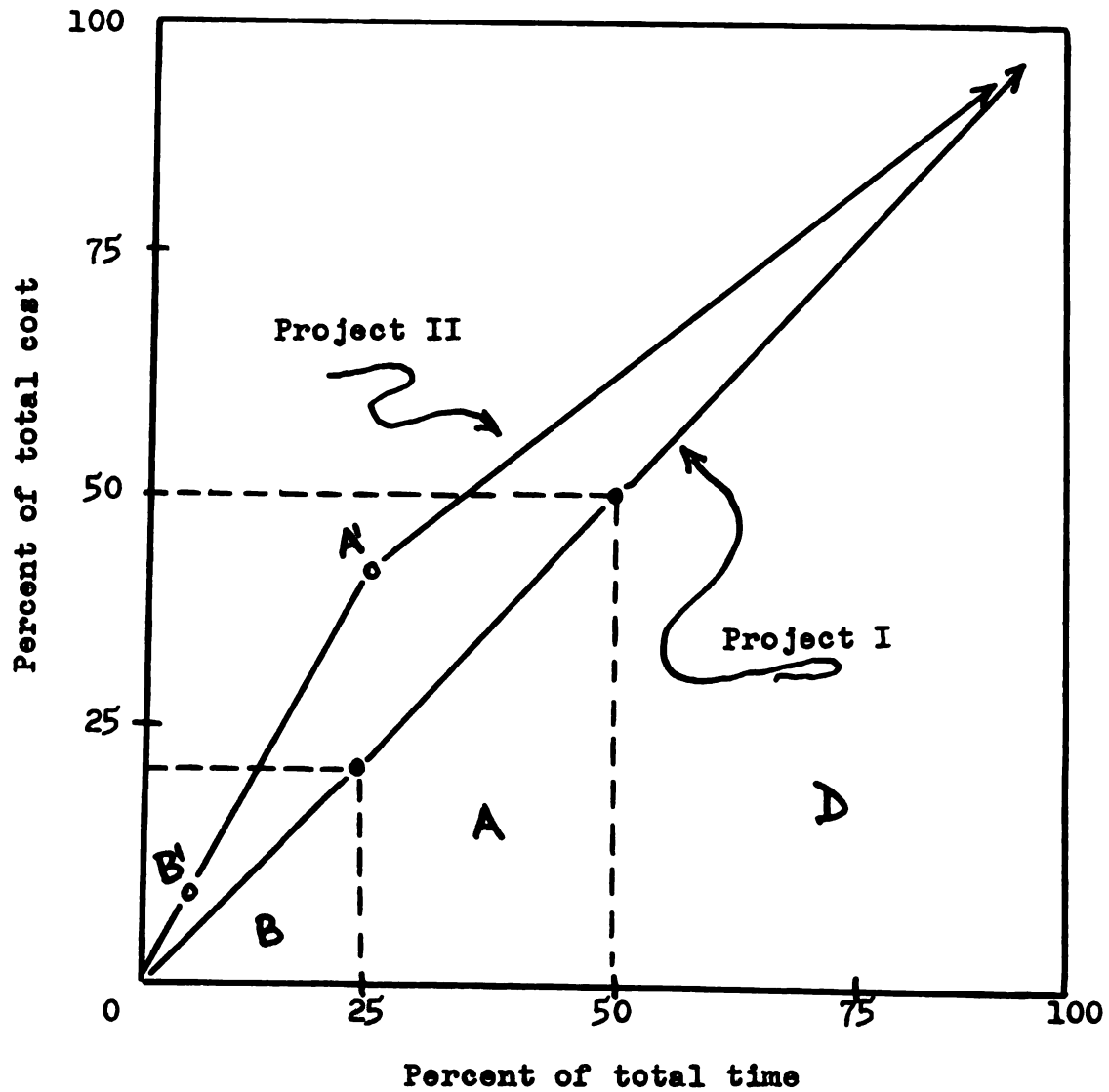


Figure 2.--Progressive research project estimates--
type A products.

For simplicity's sake, only the research components of the first formulation have been blocked out. But even from such a tentative outline, the possibilities in this approach are evident. Over time, a firm can accumulate a series of such curves which can then become the basis for more meticulous planning. Particularly when the data are more finely identified by a consistent means of cost accounting the curves become more complex, as well as more useful, since they will better reflect the problem of gray areas likely to exist in the present simple system.

What may we expect as a regular pattern of operation under actual conditions in the pharmaceutical industry? If the firm is an efficient one and makes good use of its experience in a product type, we would expect to find that the percent of time and money devoted to basic research would tend to decrease with each new formulation. Similarly, applied research would probably decline relative to the total research effort. If so, we would direct the firm analyst to look for a series of curves which shift up and to the left with each successive research project. Contrary behavior would require justification in the form of a separate analysis to detect exceptional circumstances. Finally, observation of a series of charts (for products A, B, and C) may disclose two areas whose research reaction is more stable and thus more predictable than the remaining one.

By now the reader will have detected the most

outstanding flaw in the approach. The use of percentages obscures an important point, namely, that each successive project may, through experience, cost progressively less in absolute terms! This is hidden by the use of a two-dimensional technique, and the analyst may wish to consider the merits of a three-dimensional configuration.⁴⁶

The graphic approach to estimating research and development effectiveness is strictly limited, both in terms of the number of variables which can be introduced and in the simple matter of visual complexity which can arise from the variables which are entered. An equation, on the other hand, can admit as many variables as the analyst feels are necessary to express the relationships he seeks to identify. Let us adapt one promising formula which was originally designed for a slightly different purpose.⁴⁷

To set the stage for the use of this particular approach, we must assume a firm which may be identical to

⁴⁶This technique is admirably employed by Professor Abba P. Lerner as a device for exposition in problems of economic theory.

⁴⁷The discussion which ensues is based on a project evaluation formula developed by James E. Young, and reported in Bixler, *op. cit.*, pp. 52-53. The original equation is concerned with cost saving; it is revised slightly here to reflect profit possibilities instead. Otherwise, the formula--and its method of presentation--follow the original exposition closely. Cf. Edward Hartshorne, "Research Cost Analysis and Project Evaluation," Costs, Budgeting, and Economics of Industrial Research, David B. Hertz (ed.) (New York: Kings Crown Press, 1951), p. 161.

the one put forward for the graphic analysis, i.e., an experienced firm with adequate internal data to provide a range of comparisons. We may then proceed to examine a research rating (RR) which is equal to the profit prospect (PP) times a constant (K) divided by estimated research costs (ERC) times research time required (RTR) times a risk factor (RF), or

$$RR = \frac{PP \times K}{ERC \times RTR \times RF}$$

The first step will be to determine the value of the constant to be used. This is done by estimating the value of a known marginal project, which, in turn, we define as a research project which has yielded a product of just-acceptable profit performance as perceived by the firm's management. Also, since the marginal project will serve as the evaluation base, the research rating is assigned a value of 1 so that the constant may be determined. Then, using data assumed to be known to the analyst, where 1 is

$$1 = \frac{\$50,000 \times K}{\$100,000 \times 24 \times 5}$$

an arbitrary assignment, \$50,000 the known profit in the first year, \$100,000 the cost for the research and development effort involved, and 24 the number of months required to complete the R and D. The 5 reflects, of course, risk. This is determined by measurement on a

scale of 1 to 10 in order of increasing risk, and 5 may be considered an average risk factor.⁴⁸ Solving the equation yields K equal to 240, which becomes the constant to be used for all subsequent calculations.⁴⁹

Paraphrasing Bixler, we may observe results of the use of the Young formula by supplying the following data:

- a. Estimated first year profit: \$100,000.
- b. Estimated research costs: \$50,000.
- c. Research time required: 12 months.
- d. Risk: below average (2).

We then have:

$$RR = \frac{\$100,000 \times 240 \text{ (constant)}}{50,000 \times 12 \text{ months} \times 2} = 20$$

It may be expected that a number of research ratings will range from less than 1 to, no doubt, more than the 20 which has been obtained from our assumed magnitudes. In any event, it is clear that a project which is evaluated on the basis of carefully estimated components and appears to be 20 times better than the marginal product shows high

⁴⁸Some firms, particularly in the proprietary drug group, might wish to employ a weighted risk factor to account for rapid product obsolescence. An even more refined approach might benefit from intrafirm "research" among responsible executives on the chance that functional group leaders would perceive different degrees of risk in the same project.

⁴⁹It is perhaps unnecessary to caution against the use of $K = 240$ for all possible calculations. If a firm's products A and B are markedly different, separate equations must be used for each product type.

commercial promise.

What are the weaknesses of such an approach to R and D evaluations? One is that, having gone to the trouble of calculating a series of research ratings, the responsible analyst might tend to disregard internal and external shifts which would change the rating equations mix. Another is the absence of a factor which reflects the possibility of whirlwind profits (or losses) in the event that the product attracts unsuspected attention during its introduction. But these are hardly damning shortcomings, since they are equally likely to occur in a company which is less formally structured in its attitude toward research and development.

No allowance is made for intervening competitive activity. While this is of marginal importance in the case of many ethical products, it is of primary concern to virtually all proprietary products. A competitive activity variable, moreover, cannot be a constant, and when it is introduced, it must be of such a nature that it affects the known components of the equation separately, for given a shift in competitive strategy, the known variables change--probably disproportionately.

The method offers little assistance to the firm which contemplates offering a new (to it) product class. Even the comfort of past internal data accumulations must give way to estimates based upon estimates, e.g., marketing research or other sources of corporate intelligence.

An even more limiting analytical problem is that the equation approach is a personal one--it is difficult to extend the logic of the approach beyond a firm, whether we wish to discuss the pharmaceutical industry or one of its subgroups. Any attempt to aggregate research ratings would involve comparisons of small, narrowline companies versus their large counterparts versus conglomerate firms who depend upon firm acquisition as a means of replenishing its new products larder. For the individual firm, however, the technique appears to be a good one, nor are its benefits confined to research and development evaluation alone.

On a basis of general corporate behavior, one source cites certain broad generalizations which may, in part, overcome some of the interfirm comparison problem. Specifically, four modest rules are noted:

- 1) Most organizations are aware of and probably use such simple rules as per cent of revenue as a guide to research and development allocations.
- 2) The pressure of [intrafirm] subunits for maintaining absolute dollar allocations, the logic of research appropriations, and the difficulties of forecasting revenues lead to considerable attempts to smooth allocations so that they vary less from year to year than do revenues.
- 3) Target allocations are substantially influenced by estimates of allocations (per cent of sales) in other "comparable" organizations.
- 4) Organizational failure on profit or sales goals leads to pressure to revise the allocation rules.⁵⁰

⁵⁰Richard M. Cyert and James G. March, A Behavioral Theory of the Firm (Englewood Cliffs, N. J.: Prentice-Hall, Inc., 1963), pp. 274-75.

In other words, R and D budgets tend to be allocated from a larger fund pool, are predictable over time, are influenced by the bench marks established by other departments and firms, and show change only under the stigma of failure. If we accept this arrangement as probable in the pharmaceutical industry, it will be of considerable value in overcoming the problems of diverse size and product characteristics.

A number of writers have expressed a preference for this essentially qualitative method of R and D evaluation, as opposed to strict reliance on quantitative appraisal.⁵¹ Perhaps the most stimulating of these is based on a series of questions designed to evaluate the progress of a new product.⁵² The assumption is made that the new product is an extension of research and development. While Parker's analysis is based on quantitative data derived from market studies, internal observations,

⁵¹For example, see Silk, op. cit., p. 160; Administered Prices in the Drug Industry, Part 1, p. 8023; Penrose, op. cit., p. 116, fn. 1 (with special reference to Manchester Joint Research Council, Industry and Science [Manchester: Manchester University Press, 1954], pp. 48-49); Hertz, The Theory and Practice of Industrial Research, p. 227; R. H. Boundy and L. C. Chamberlain, Jr., "Problems and Prospects of Industrial Research," Research Management, II, No. 2 (Summer, 1959), 81-96; and T. L. Wilson, "Budget and Cost Control in Research and Development," Research Management, IV, No. 2 (Summer, 1961), 95-105.

⁵²This article, "Developing New Drugs," by R. P. Parker, in Drug and Cosmetic Industry (XCI, No. 6, 698-700, 786, 793), is highly recommended as a thoughtful, well-expressed example of qualitative analysis.

and other sources of numerical expression, he includes such factors as the apparent extent to which the detail man's job is made easier with respect to the total product line, the likelihood that resulting publications will attract competent researchers to the laboratory, etc.

Since it has been suggested that an uncomplicated formula is an attractive proposition, why should one wish to insert qualitative factors into R and D assessment? Parker provides part of the answer:

Research cannot always be judged in the light of the immediate commercial results, for research that produces no product may also be considered a success. This reasoning can be applied to the case where the first concern is to protect an existing market position.⁵³

To complete the answer, we must again attempt to paraphrase a provocative analysis of dynamics in another facet of marketing.⁵⁴

Assume that a company in time t-1 is essentially homeostatic, and that at the very end of t-1 (or the very beginning of t), it introduces a new product. Now, when

⁵³Ibid., p. 793. Here it may be assumed that Parker refers to the introduction of a product for a use so rare that no profits will ever result from its sale, or to an imitated product of no particular commercial promise.

⁵⁴The following discussion is stimulated by Harry D. Wolfe et al., Pretesting Advertising (New York: National Industrial Conference Board, 1963), fn., p. 20. To avoid confusion, quotation marks have been omitted from the adaptation. In exchange, it may be noted that in discussing a new product, advertising may be subsumed, together with promotional programs, sales contest, etc. The original statement is too ingenious and insightful to be confined to one marketing function.

the new product is injected into the corporate mix, the new product effect is not simply additive; it changes the entire mix. Each element (e.g., physicians' attitudes, product quality, price, distribution, past advertising, and promotion) has a different importance or weight than it had before. Nor is this all. The elements of the mix all interact with one another and these interactions are changed when a new variable like a new product is blended into the mix. Thus the impact of the new product consists of: (1) the weight of the new product relative to the corporate mix as a whole, (2) the new relative weights of the other elements in the mix, and (3) the new interactions among the various elements caused by the introduction of the new product.⁵⁵

What does this imply for R and D evaluation (to say nothing of the evaluation of the remaining facets of the corporate mix)? So long as the firm has depended upon formulae of the type described on pages 126 and 127, supra, it means that since quantitative information will lag (i.e., if the product is truly new) it will be very difficult to estimate probable sales levels. This condition may exist into t+1 or longer. Similarly, previous estimates of risk factors become invalid for several important reasons. Substantial portions of other firms' product lines may become obsolete, heightening profit prospects

⁵⁵The paraphrasing noted above ends at this point.

for the new product firm for that product and for all others in its line! Conversely, should the inventive firm's own product line alone suffer from the introduction of the new product, its profit prospects are dampened in total and its risk factors increased accordingly.

In summary, the problems of R and D projection and evaluation--recognized in principle but obscure in origin --are thought to be directly traceable to the fact that consistent quantitative measurements appear to be preferable to qualitative measurements. Despite the danger of dogmatic reliance on the former, it is difficult to compare the latter approach between products and virtually impossible to provide useful firm comparisons.

Three schools of thought may then be identified: the first clings to quantitative data, the second prefers qualitative assessment, and the third professes to use both concurrently. All three are likely to experience dissatisfaction through failure to recognize that at a critical point in time, namely, the introductory phase of a new product's life, formerly tractable methods become dangerously invalid through the loss of comparable data, or experience, or both.

Given electronic data processing (EDP) equipment, the recomputation of research ratings for old, new, and projected projects is of only passing concern. But EDP will not supply the vital interim data. In order to overcome time lags, the data must be based on qualitative

estimates. The degree of "qualitativeness" may be expected to decline as the readjustments are made to the new competitive environment, and as new evidence is made available.

Controversial Aspects of Drug
Research and Development

Although favorably disposed toward the obvious achievements of the drug industry and neutral with respect to many of the current criticisms of the several firms, the present paper would be essentially empty if it were to ignore demonstrated and potential weaknesses in the administration of pharmaceutical research and development. The primary purpose of the discussion which follows is simply to centralize certain attributes of drug R and D which, when tolerated, damage the reputation of the industry and dilute the essential importance of the process under present study.

In the chemical industry, of which the pharmaceutical industry is a part, it has been suggested that potential new products face considerable resistance from the point of initial suggestion to the marketplace.⁵⁶ In terms of magnitudes, 540 ideas emerge from research. Of these, 448 are subsequently eliminated during new product conferences, a process apparently analogous to screening in the drug industry. The remaining 92 enter preliminary laboratory, or development, testing, of which eight show

⁵⁶See Alexander, Cross, and Cunningham, op. cit., p. 151.

sufficient promise for extensive development. In this phase, seven are dropped as potentially unsalable or unprofitable, and one is produced and marketed, an overall failure ratio of 540-1, and a post-screening ratio of 92-1.⁵⁷ By contrast, in one recent year, the drug industry is said to have tested 114,600 substances, of which 40 became marketable products, or a failure ratio of 2,865-1.⁵⁸ Moreover, the same source observes that such slim chances of success are further heightened by the possibility that, as a new product is marketed, another firm may "develop a different compound which makes your obsolete before it can get started."⁵⁹ Add to this the problems of timing with respect to FDA approval and new product introduction⁶⁰ and the pressures exerted upon firms in the industry (even those in the supposedly safe position of product monopolists) become apparent. Whether

⁵⁷This rate may be compared to the normally accepted bench mark for all industry of 40-1 at the post-screening stage. See Management of New Products (New York: Booz, Allen and Hamilton, 1960), pp. 14-15.

⁵⁸See J. E. McKeen, "Extracts from Industrial Research," Drug and Cosmetic Industry, XC, No. 3 (March, 1962), 281.

⁵⁹Ibid.

⁶⁰This point is discussed in James B. Quinn and James A. Mueller, "Transferring Research Results to Operations," Harvard Business Review, XLI, No. 1 (January-February, 1963), 64-65. The authors introduce distribution, advertising, and facilities planning problems. The process of planning and controlling technical projects toward commercialization is compared with devastating effectiveness to the card game, stud poker.

or not these pressures are greater in drug than in non-drug industries is a moot proposition. The point is that, from a research and development perspective, such pressures as do exist have had some outlandish effects.

Business and economic researchers have frequently paused in their labors to underline the problems which confront them. Data procured in one time period may suffer when compared with that obtained in another. Continuing panel studies are diluted over time as participants move away, decline to participate further, or simply die. Complicated samples are perfected for some particular task, only to have one city's questionnaires disappear in the mails, snowstorms hinder interviewers in another, and to find that in the selected test cities potential respondents are outraged over the recent pitch of encyclopedia salesmen posing as opinion researchers. In short, research controls in the true commercial world are difficult to obtain and to define. How many economic researchers long for the comfort and assurance of a nice laboratory experiment, or of, say, a clear-cut clinical test to evaluate a new drug? It is suspected that if not all, many of them do, and it is regrettable that the myth of the relative ease of research in the physical sciences has permeated much of the thinking and writing of the social scientists.

Consider pharmaceutical research and development, and a major problem of clinical evaluation therein. Assume that ten patients are treated with product X and

ten are treated with some other drug (or perhaps some other form of non-drug therapy), and that recovery rates of the two groups appear to favor the experimental group. The research is held to indicate the use of X as recommended therapy. This is wrong, for the medical researcher must contend with vis medicatrix naturae, or the healing power of nature, as it may be translated. Given the propensity of the human body to react in its own defense, the patients in the experimental group might have shown an identical recovery rate in the absence of the tested drug. Extending the argument, the identical recovery rate might have obtained when the drug in question was relatively inactive.

This interesting paradox in medical research serves to introduce the problem of experimental control, a problem no less critical in the physical sciences than in the social sciences. A method exists whereby chance cure can be controlled. This is termed a "double blind" test. In clinical use, neither the physician, the patient, nor the nurse knows which drug is being administered to which patients. At random, the test drug or a placebo (i.e., an inert substance) is given. At the conclusion of the experimental period, the researcher compares results in the two test groups and evaluates reported therapeutic and side effects.⁶¹

⁶¹The double blind technique is described in Administered Prices in the Drug Industry, Part 18,

But adequately controlled comparisons of the sort described above are held to be almost impossible to find.⁶² Cost and speed might conceivably affect a firm's decision to use a less convincing clinical technique, but there is no reason to believe that either the incremental cost or the time consumed in conducting the study would vary significantly if the double blind test were used. This is not to say that the best drug study designed would be foolproof--human errors in data collection are always possible--but we may all agree with one authority who has stated, "A drug trial which makes no allowance for placebo effect, and which fails to make accurate comparison with an untreated group is suspect, and the vast majority of reports on such studies are simply testimonials, not scientific evidence."⁶³

Journal articles are an important source of product information in the pharmaceutical industry. Assuming for the moment that they represent the sole available source of information for medical practitioners, what faith can be placed on the research results reported in them? We cannot say with respect to the United States, but turning to neighboring Canada, the chances for innocent

pp. 10420-21. An excellent discussion of the research process and its problems may be found in the same source, extending generally from p. 10417 to p. 10426.

⁶²Ibid., Part 14, p. 8139.

⁶³Ibid., Part 18, p. 10371.

misinformation appears to very high indeed. Commenting on an evaluation by a Canadian researcher of the methods and techniques of 103 studies published in the Canadian Medical Association Journal and the Canadian Journal of Public Health, Irving Ladimer notes the following results:

In 17.5 per cent of the articles, terms or system of classifications were not explicit; in 90 per cent, sampling was inadequate or inapplicable; as to controls, 35 per cent had none, 13 per cent were inadequate, 25 per cent were well controlled and 27 per cent were studies where controls were inapplicable; in respect to statistics and their use, over 57 per cent used inappropriate methods or required additional analysis; and, finally, in the derivation of conclusions, 42 per cent of the articles contained flaws of inference, particularly in assigning causal relationships.⁶⁴

This is hardly an impressive record, particularly since promotional mailings and the sales (or informative) visits of detail men to physicians are based primarily on information gleaned from just such studies.

Responsibility for poor research design rests with the medical profession, as well as with the pharmaceutical companies, a fact which Ladimer stresses. He points to five specific shortcomings in drug research.

The "scientific" paper is the first of these.

⁶⁴See Ladimer's "Quackery and the Consumer--Responsibility of the Medical Profession," Food Drug Cosmetic Law Journal, XVIII, No. 8 (August, 1963), 488. His data are taken from Robin F. Badgley, "An Assessment of Research Methods in 103 Scientific Articles from Two Canadian Medical Journals," Canadian Medical Association Journal, LXXXV (July, 1961), 246-50. Attention must be drawn to Administered Prices in the Drug Industry, Part 22, passim, for a lengthy examination of certain analogous practices in American medical journals.

This is a journal article which, by its terminology and publication locus, purports to be rigorously based, when in reality it is simply compiled by a firm's public relations or product promotion staff from inadequate data. The presence of a physician's byline renders it deceptively authoritative.

The "professional" investigator--a physician who regularly seeks to participate in clinical testing--is to be deplored, whether or not his primary purpose is to receive a fee for his cooperation. Repeated exposure to clinical testing is thought to violate the element of objectivity which is an indispensable condition for the usefulness of the technique. It is thought that, as in consumer product panels, participants tend over time to become either hypersensitive to testing conditions, or to adopt the posture of excessive dogmatism, or to become careless in the essential application of test procedures. Any or all of these are dangers which are enhanced when the physician participates regularly at his own request.

The existence of the "house" doctor--one employed by a firm and found willing to overlook or to obfuscate questionable test evidence--is similarly deplored. This is primarily a question of one man's moral fiber under the economic pressures generated within a business firm. It is difficult to imagine a pharmaceutical company operating without the services of competent medical advisors as members of the management team. Yet, it appears that

the opportunity exists for sins of omission as well as commission where physicians are employed by drug firms. When the opportunity is exploited, the onus rests upon the cooperative doctor as well as the firm.

Rigged research, i.e., studies so tailored as to yield predetermined results, are not unique to pharmaceutical manufacturers. Still, there is something particularly reprehensible about them when human health is involved, a notion heightened when the research is conducted by a physician.

Finally, incompetent research, whether stemming from poor educational preparation, or the pressure of other activities, or some other reason, is unhappily evident in certain cases. Primary responsibility for detecting, correcting, and eliminating this problem must rest with the medical profession, at least under present conditions.

The summation of the charges against some physician participation in drug testing is that imperfectly discharged responsibilities here can yield only testimonials akin to those of the days of the patent medicine circus. One vigorous critic of the industry and the healing arts holds that the foregoing weaknesses are not generally unknown:

Now, the true nature of these testimonials is well known to the industry and its own contempt for them is shown by its vernacular for sources from which they are easily obtained. These are called stables. Still it is an important function, usually of the medical

division, to send representatives with generous expense accounts to all parts of the country searching out these sources. The burlesque is compounded by calling the drug trials "scientific studies" and by supporting them with grants which are charged to research cost.⁶⁵

Charges to research cost must be next considered as a serious problem in an evaluation of pharmaceutical research and development. If the R and D account becomes a catch-all for non-research expenditures, and if no separate accounting is available, it is obvious that firms' R and D activities will be inflated substantially compared to their actual execution volume. One industry leader forcefully stated that "some" companies included in research and development such diverse charges as "quality control, materials analysis, costs of and for medical literature, and the expenses of operating a hospital."⁶⁶ Other things equal, it would be necessary to point out that in those instances where charges to R and D include items which might belong to other accounts (perhaps under other definitions of R and D) the industry output of new products would stem from smaller expenditures than it would appear. This might then be construed as calling for further felicitations for the industry's research personnel, since, on the surface, they have produced results with less financing than that indicated by

⁶⁵Administered Prices in the Drug Industry, Part 18, p. 10372.

⁶⁶Ibid., Part 24, pp. 13965-66. A more moderate position is voiced in Part 18, p. 10245.

corporate records. It so happens that irrespective of the nature and volume of R and D costs, it is difficult to determine the intrinsic extent of product progress in the industry.

The problem is less one of determining what should have gone into the R and D account than one of assessing what has come out of whatever funds were devoted to research and development. There are a number of discordant possibilities here, including "the molecule manipulation intended to bypass patents and other priority rights, and which has resulted in the flood of 'me-too' products."⁶⁷ Quoting further from the same source:

Many examples of such molecule manipulation are available. It must be granted, of course, that occasionally some slight improvement in a drug has been achieved, but most often the only improvement has been an increase in potency or "horsepower." The actual added benefit to the patient has been negligible, if any.

Another type of fruitless research has been the development of a multiplicity of drug combinations. Rarely has good medical rationale been the basis of these combinations. Indeed, such combinations can be detrimental to the patient because they lack flexibility and can compound the problems of dosage and toxicity. Despite advertising to the contrary, it is rarely possible to achieve an ideal drug regimen with a fixed combination of drugs.

Another type of activity which has been called research but which is even more remote has been the battle of the additives. . . . Fantastic amounts of effort and money have been expended in attempting to prove that the addition of certain additives . . . are of significant benefit to the patient. The proof has frequently been in the form of tortured statistics or vague clinical reports.

These expenditures and efforts are probably a legitimate business expense. However, in all fairness

⁶⁷Ibid., p. 10243.

to the public they should be considered not as research but as product development, process development, and promotion.⁶⁸

There is little to be added to the foregoing except to note that these problems are perhaps more a matter of social concern than of outright condemnation of an industry's product and marketing practices. The matter is stated moderately in this way: "Research is ordinarily a social waste if it seeks (a) to make a product worse or (b) to discover what is already known."⁶⁹ In the medical opinion noted at length above, there is evidence that both criteria for research as social waste are satisfied, and by extension of the argument, there appear to be grounds for charges of social waste in promotional expenditures as well as those for research. Perhaps, then, it does not really matter that it is difficult to separate the two in accounting for R and D. The matter becomes one of defining the nature of, and erecting a case against, social waste.

One final criticism must be discussed. It is perhaps the most sobering indictment of all. Relying again on medical opinion, we consider the following:

⁶⁸Ibid., p. 10244. Additional evidence may be found in ibid., pp. 10380 et passim, and Sanders, op. cit., pp. 99-105. That the problem is not unique today is evident in C. Rufus Rorem and Robert P. Fischelis, The Costs of Medicines (Chicago: University of Chicago Press, 1932), pp. 165-66.

⁶⁹Jacob Schmookler, "Technological Progress and the Modern American Corporation," in The Corporation in Modern Society, Edward S. Mason (ed.) (Cambridge, Mass.: Harvard University Press, 1959), p. 155.

While the pharmaceutical industry spokesmen would have us believe that all research is on wonder drugs or better medicinal products this is no more true than the euphemism of post-graduate medical education. They stress that there are many failures for each successful drug. This is true since it is the very essence of research. The problem arises out of the fact that they market so many of their failures. Between these failures which are presented as new drugs and the useless modifications of old drugs . . . most of the research results in a treadmill which moves at a rapid pace but goes nowhere. Since so much depends on novelty [,] drugs change like women's hemlines and rapid obsolescence is simply a sign of motion, not progress as the apologists would have us believe.⁷⁰ (Italics added.)

It would seem that the primary lesson to be learned from this is that any conclusions to be drawn from an examination of research and development expenditures in the pharmaceutical industry must be confined to the mechanical process of certain activities within firms. If the ultimate contribution of drug R and D is the proliferation of many failures for each significant advance, it would be meaningless to attempt to regard pharmaceutical research as more socially useful than, say, research in soaps, or paper, or gasoline.

In fairness to those firms who devote time and effort to the search on principle for effective curative substances, and to the industry's researchers who sincerely regard their work as a contribution to the welfare of mankind, it is regrettable that the facts of economic life cloud their efforts. However, it appears that the

⁷⁰Administered Prices in the Drug Industry, Part 18, p. 10372.

demonstrated weaknesses of pharmaceutical research and development practices are so structured as to remove the essence of the industry's protective cloak, i.e., that laissez-faire is necessary to insure socially desirable pharmaceutical products.

Summary

This investigation of research and development has concentrated on the intrinsic composition of the process as it occurs in the pharmaceutical industry. Additionally, it has been suggested that some drug firms have abused the essential meaning and character of research and development.

The section first examines the components of the total R and D process. Three segments--basic research, developmental research, and marketing research--are identified for use in the remainder of the present paper. They have been selected on the basis of end-product economic orientation, and each contains a number of sub-classifications which will be subsumed in the completion of the exposition.

Basic research is defined as organized investigation for the purpose of discovering new facts, regardless of the economic promise of those facts. Developmental research is defined as that product and clinical evaluation of economically promising commercial applications of new facts, irrespective of their origin.

Marketing research is considered as a totally economic-oriented activity which seeks to define the environment in which the new product will perform, and to suggest not only product adjustment to match the requirements of the market, but to suggest new product possibilities as well.

We have seen that R and D provides a critical link between science at a theoretical level and its technological offspring--products. The recency of the emergence of pharmaceutical R and D as a generally important business function has been emphasized through reference to informed literary sources. Tentative magnitudes of annual costs for drug research and development have been cited.

Apparent results of pharmaceutical R and D are next investigated. It is reaffirmed that new product output is confined to a few firms and that the majority of drug companies cannot be described as inventive in the sense that they have contributed totally new knowledge during the period under study. For those firms of an innovative or imitative nature, several alternative methods of ranking research projects on an intrafirm basis are discussed. All are attractive in one sense or another, but all are suggested to be lacking in effectiveness under stringent conditions of use. A time lag is cited as the major weakness in a firm's R and D effectiveness measurement.

Certain apparent shortcomings of pharmaceutical research and development practices and procedures are

discussed in the final section of this chapter. No useful purpose is served by singling out specific forms for condemnation, and it is assumed that dissatisfaction arises from the nature of the marketing process and the emergent nature of R and D in the industry. Accordingly, it is assumed further that all firms are liable to err in the same proportion and in the same direction. In that light, present R and D standards may be regarded as a function of profit orientation in the several firms, rather than strict adherence to a policy of research for the sake of research. This is unfortunate, since, while competition and the free play of market forces are adequate to adjust research in many non-drug fields, these are of inadequate help in the ethical pharmaceutical industry as it presently exists. Research and development per se offers no good reason why drug firm constraints should not be adjusted to meet the needs of society.

CHAPTER V

FIELD STUDY AND FINDINGS

Introduction to the Field Study

The simple graphic model described previously (p. 123 supra) mirrors a desirable trait of such instructive activity, namely, that the process outlined should be the most basic structure which can be conceived under the circumstances. It may be objected that the writer has already gone to some lengths to reveal pharmaceutical research and development as a complicated process quite unlike that of the suggested model. And so it is complicated, as long as we consider the individual steps--the search for new substances, pharmacology, toxicology, clinical testing, etc. At some future date, the presentation and manipulation of such a model might have substantial merit. Presently, two factors intervene to discourage this approach: first, data with which to judge adequately the form and nuance of the activities found in, say, the toxicologist's laboratory are unavailable; second, there is no reason to suppose that a complicated model of research and development would be meaningful within the context of the pharmaceutical industry as a

whole.¹

Fortunately, a solution to the quandary exists-- a solution represented by the reduction of the acknowledgedly complicated research functions to their economic denominators. Instead of a series of interrelated chemical analyses, we will treat three types of R and D, and since terminology departs slightly from ordinary usage, it will be appropriate again to define the concepts as they are used here.

Basic research is the term used to refer to R and D practice which is more or less speculative insofar as predictable economic benefit to the firm is concerned. It consists largely of preliminary examination of a number of substances which may be useful as drugs. In essence, it may be thought of as the ultimate in research (i.e., to deal in the unknown), and it includes a wide variety of professional techniques, most of them originating in the laboratories of physical scientists. Be that as it may, our sole concern with basic research is that it is deliberately undertaken with no clearly perceived economic end in sight.

Developmental research is segregated to allow for those procedures which have some sort of defined product or profit horizon, presumably in most cases the latter.

¹For example, it will be recalled that virtually nothing has been said concerning the R and D process in the proprietary division of the industry.

Although identified as sequential in nature in that it follows basic research, from the point of view of actual performance this is not precisely true. While developmental research involves pilot plant construction, preparation of materials for clinical testing, etc., it may be necessary at this stage to return to what are usually regarded as the domain of basic research for additional toxicity studies, animal testing, and the like. But always, in referring to developmental research, we are concerned with those activities which have progressed to a point where a recognized marketing potential for the product becomes part of the firm's concern.

/ Marketing research consists of the orthodox collection of investigative activities concerned with the delineation of markets, product adjustment, corporate brand impression studies, measurement of advertising, and promotion effectiveness--in short, the entire gamut of facilitating functions found in most manufacturing firms. Special attention is required when discussing marketing research in the pharmaceutical industry. To date, little evidence exists which pinpoints the place of marketing research here, and, accordingly, it has been assigned a parametric, as opposed to a sequential, role in the model.

By adopting an economic or productive attitude toward pharmaceutical R and D, we are able to reduce the number of components to be investigated to a finite, workable set of three. The essential rationale for this

simplification is that, broadly speaking, today's sales yield profits which may justify yesterday's, today's, and tomorrow's research effort, which, in turn, may be expected to contribute to tomorrow's sales, and so on. So far as is known, this view of the research world has not been explored adequately for the pharmaceutical industry, if at all.

If it appears, however tenuously, that the relative importance of the economic end-oriented research functions fluctuate in some consistent way or ways, it may be possible to advance certain very broad principles which underlie the industry. A notable lack of consistency will be equally meaningful.

Research Design and the Characteristics of the Sample

The primary purpose of the field study was to subject the economic model of the pharmaceutical research process to the scrutiny and criticism of research practitioners. An adjunct to this purpose was the opportunity to discuss allied topics in research and development activity, and to attempt to determine tentative corporate procedures in order to confirm suspected differences between firms and types of firms.

The cross-sectional study to be discussed was based on thirteen interviews in as many pharmaceutical companies. The interviews, which averaged about one hour each, were conducted during August and September, 1963. A purposive sample was utilized, based upon the writer's

need for specific points of information not treated in secondary sources. Accordingly, the sample is neither projectable to the industry as a whole, nor is it amenable to statistical testing. It should be noted, however, that even within the limitations imposed by the selected sampling procedure, seven fewer interviews were conducted than initially budgeted. The specific expressions of policy and procedures sought in the interviewing process rapidly became so standardized to warrant truncating the field survey in the interests of both time and money.²

Three types of firms were investigated and used in a quasi-stratified sense, both for purposes of interviewing and of analysis. These were ethical firms, proprietary firms, and conglomerate firms. They are defined as follows:

Ethical firms are those which concentrate on the manufacture and sale of prescription products. The study contains five of these.

Proprietary firms are those whose history reflects a background of non-prescription products, and which have tended to remain largely--if not entirely--proprietary-oriented during the decade under consideration. Three such firms are discussed.

Conglomerate firms are those which cannot clearly fit either of the preceding categories, because of non-drug diversification or other known characteristics which might

²Cf. Quinn, Yardsticks for Industrial Research, p. 208.

influence managerial attitudes and hence research practices. Data for five of these are treated separately.

Caution must be observed here in that, as suggested earlier, there appears to be a tendency toward intrafirm diversification. Ethical firms have adopted or expanded their proprietary divisions, probably as a hedge against future tightening of government restrictions on prescription products. Proprietary firms have activated or acquired ethical divisions to seek the high profits associated with successful prescription products. Conglomerate firms continue to introduce new non-drug products which conform to existing channels of distribution. Accordingly, a second, or follow-up, study might find the composition of the industry groups changed over the decade ahead, and substitution might be required to maintain the present balance among firm types.

In 1962, the thirteen sample firms reported total net income of just over two and a half billion dollars, of which about half is estimated to have consisted of ethical drugs, about one-quarter proprietaries, and the remainder represents income from other non-drug products and other sources. Of total sales, the ethical drug group accounted for 33 percent, proprietary firms, 19 percent, and the conglomerate firms about 48 percent.³

Also, in 1962, these firms indicated net profits

³See Total Net Income of Thirteen Sample Firms--
By Industry Group, attached as Appendix B, p. 215 infra.

of 276 million dollars, 39 percent to the ethical firms, 20 percent to proprietary firms, and 41 percent to conglomerate ones. It is not practical to segregate the percent of profit derived from each product type.⁴

During that same year, research and development expenditures are estimated to have been about 126 million dollars. Over half, or 52 percent, were accounted for by the ethical firms in the sample. Fourteen percent were found in proprietaries, and 34 percent in conglomerates.⁵

During the decade in question, research and development as a percent of income fluctuated for ethical firms, increased slightly for proprietary firms, and remained stable for conglomerate firms.⁶

Survey respondents included four corporate officers, three marketing managers, five research managers, and one assistant research director. Inasmuch as duties and responsibilities may vary through firm size, organization, corporate age, mergers, etc., no attempt was made to specify a particular executive level when seeking respondents. Rather, a description of the problem area

⁴See Total Net (Post-Tax Profits of Thirteen Sample Firms--By Industry Group, attached as Appendix C, p. 217 infra.

⁵See Estimated Research and Development Costs of Thirteen Sample Firms--By Industry Group, attached as Appendix D, p. 219 infra.

⁶See Research and Development Costs as a Percent of Net Sales for Thirteen Sample Firms--By Industry Group, attached as Appendix E, p. 221 infra.

was adequate to secure direction to the appropriate sources. These men were found to be well informed and cooperative during the course of the interviews.

Basic Guides to the Field Study

Pharmaceutical literature sources as well as those concerned with research and development were inadequate to illuminate certain important facets of the total problem. Recourse was made to the field investigation, which sought to supply the missing insights. In the absence of adequately detailed parameters against which to measure the precision of the information obtained, the discussions centered around six fundamental questions. These questions stand in lieu of statements more formally termed hypotheses, although it is suggested that future studies in this area might profitably use these as bases for more rigorous tests.

Given the economic model as the introductory construct, the interviewing process sought to answer the six queries which, together with explanations of their perceived importance, are outlined below:

The first question--Is the model a realistic economic description?--arose from the general lack of previous discussions of the economics of pharmaceutical research and development. While the writer felt secure in his grasp of the institutional procedures involved, there was no certainty but that some more refined economic

presentation might be required. The original model was not considered inviolable; if necessary, it might be changed.

The second question--Does the model have comparative dimensions?--sought to establish the relative importance of one type of R and D activity with respect to another. Since there was fragmentary evidence as to the complexity of each phase subsumed, for example, in the segment "basic research," if basic research was perceived as more important than, say, developmental research, it was thought that detailed research costs might be tentatively derived.

The third question--What time elements attach to the model?--was thought to be particularly important in light of the a priori argument that, for most firms, the research and development process could not and should not be subject to annual budget cycles. Short-run programs were thus defined as those which occupied a year or less, and long-run programs, those which would occupy over a year in the research cycle.

The fourth question--How are funds allocated for research?--represented another attack on the preceding area. It was premised that if, for example, most research was perceived as long run, and if funds for that research were allocated annually, this could suggest that human resources were being diverted from research to budget justification. The implications of this possibility were

thought to be important in comparison with question five.

The fifth question--How is the research effort evaluated?--was aimed toward appraising the extent to which the sample firms employed more or less complicated evaluation techniques for their R and D programs.

The sixth and final question--What revisions in research policies and procedures appear likely in the near future?--was a highly speculative query. As has been explained, the industry, at the time of the interviews, was experiencing its first adjustments to the Kefauver amendments to the Federal Food, Drug, and Cosmetic Act. It was hoped that question six might serve to detect shifts in research emphasis should those be appropriate under the circumstances. It was not expected that respondents were in any way clairvoyant with respect to the future of the industry.

Findings and Analysis of the Field Study

In presenting the findings of the field study, the first step will be to report the results of the interviewing process by industry groups--ethical, proprietary, and conglomerate. Then, the evidence will be summarized for the sample as a whole, with particular reference to similarities and differences from group to group. Throughout, adequate development of each topic will include the essence of the respondents' comments.

1. Is the model a realistic economic description?

Respondents in the five ethical firms indicated that the term "basic research," when used to delimit non-economic oriented projects, was a generally acceptable concept for the industry at large. However, two of the firms noted that basic research in an economic sense was not an important consideration in their operations. In both instances, the respondents cited specialization in limited drug lines as a reason for avoiding speculative research. Before a research project was authorized, evidence had to be offered which would assure management that the product area was of potential profitability. Since this initial evidence--from whatever source--cannot guarantee ultimate research profitability, these instances of disagreement do not destroy the concept of non-economic research in an ex post sense, although they indicate potential areas of weakness in using the concept in an ex ante sense.

There was general agreement that the "developmental research" is a useful way of regarding the toxicity studies and clinical tests which follow. Additionally, one executive of a large ethical firm cited two further refinements for inclusion here. The first was process design, or the selection of the best way to produce the product in terms of efficiency, equipment, costs, etc. The second was pilot plant design--either through simulation or actual construction. These are somewhat outside the intended

scope of the term research, but they do not appear to be generally bulky in the industry. Two other firms underlined the occasional use of university facilities for the clinical test procedures.

With respect to marketing research, only one of the respondents expressed indifference to marketing research as a corporate tool in ethical products. A second executive indicated that marketing research played no part in the two previously discussed research stages, although it was being used in an attempt to separate detailing versus media effects. The remaining three respondents expressed considerable enthusiasm for marketing research in terms of the total research process. The greatest flexibility in the use of marketing research was found in one large firm which used the process before, during, and after the basic and developmental phases. At the other end of the spectrum, a small ethical firm utilized two of the syndicated data services, together with mail surveys, to obtain what were termed "crude market trend analyses." Product properties and physician's acceptability of products were of importance to the third firm. For two of the three extensive users, it is interesting to note that both relied on the reports of their detail men for market information leading to new product possibilities, but that the larger firm followed these leads with marketing research staff interviews, while the smaller firm relied on the detail men for such market

feedback as they sought aside from that obtained from the reporting services.

In the proprietary group, basic research appeared to be of negligible concern, inasmuch as these firms were predominantly marketing oriented, and made no special point of discovering totally new products. Generally speaking, an adequate statement of the research process would begin with marketing research in one form or another, the results of which would signal a profitable opportunity for preparing a product entry for an existing product classification. Most proprietary R and D costs are found in the development phase as we have described it.

Since the ingredients of many proprietary products are more or less standard, primary attention is devoted to product differentiation through external manipulation as opposed to adjustments in the intrinsic nature of the product. A reflection of the last contention is the use of the term "technical" research to describe what we refer to as "developmental" research. The trade usage appears to be an appropriate one.

The importance of marketing research in the proprietary group suggests that, when referring to the research process for these firms, the use of a model will require substitution of a marketing research segment in the place of a broader basic research component.

At this point, we have observed that the premised model holds promise for the ethical group and is totally

inadequate for the proprietary group. The reactions of the respondents in the conglomerate group may be expected to reinforce these two extremes, since when these firms possess important ethical or proprietary divisions, or both, attention to research procedures may be expected to mirror attitudes similar to those which would be found if the firms were members of a single group.

Two of the five conglomerate firms report no interest in the basic research area as it pertains to their operations. In one large organization, no work of this type is done; the firm depends upon old, well-established products for the bulk of its sales. Diversification moves have been in non-drug areas. In another organization--this one small--centralized research facilities were only at an emergent stage. Laboratory facilities and personnel were greatly overburdened with routine testing and no plans were indicated for increased attention to basic research.

Respondents in the remaining three firms acknowledged interests in and agreement with the concept of basic research as part of the economic model. However, their attitudes were somewhat diverse. According to one executive, basic research was of less importance to his firm than in many similar ones. The reasoning was not that the firm was unappreciative of the role of basic research, but rather that during the decade in question, the firm's basic research had accrued accomplished, as it were, through the

acquisition of a number of other firms. The remaining two respondents agreed that the process did apply to ethical products, as well as to other technical products in their lines, but not to proprietaries.

In developmental research for conglomerate firms, four of the five respondents felt certain that this activity was of major importance to their firms. The dissenter (who earlier expressed disinterest in basic research) referred again to stability of the major products in his line. The other respondents cited such accomplishments of developmental research as innovation in their well-established product lines, and the clinical testing for new proprietary products. This latter item was of particular interest, since we had regarded such activity as mere routine--the constituents of the "new" product were known, as were their likely effects singly and in combination. However, more than conformity with any applicable legislation was the need for product claims with which to illuminate advertising campaigns!

With respect to marketing research, respondents' answers were quite diverse, although all five firms made use of the process in one way or another. The smallest firm used its advertising agencies as exclusive sources of marketing research reports. A much larger firm maintained only a skeleton staff for the purpose of selecting outside marketing consulting firms competent to conduct its occasional studies. A respondent from a comparably large,

diversified company stressed that he was concerned with a large number of products of a specific type, namely, pills. These, he observed, presented no particular problems of color, texture, taste, etc., which could be of importance to a firm with many different product types. Hence, other than in the areas of package research, the establishment of advertising claims, and sales analysis, his firm made little innovative use of marketing research. Another firm conducted broad continuing market studies for their proprietary products, and viewed marketing research for ethical reasons as almost non-existent. The final firm in the group, after far more than a decade of operation, was only beginning to exploit the potential offered by marketing research techniques. At the time of the interview, it was preparing its first major study to determine consumer usage of the firm's products.

2. Does the model have comparative dimensions?

It is impossible to evaluate fully the answers to this question. Initially, it was presumed that dollar volume estimates of basic, developmental, and marketing research as a percent of the firms' 1962 R and D budget would provide the necessary insight. Since R and D budgets for that year were known with reasonable accuracy, it was thought that at least nine important measurements would result--those for three types of research and for three types of firms. Two serious errors are at once obvious--

first, that respondents would be able to estimate closely the desired relationships between types of research which had been defined outside the normal data reporting patterns used in their firms; second, that dollar data, when viewed alone, would be in any sense indicative of anything other than research costs. Both assumptions were wrong ones.

Among problems with the first error is the likelihood that most respondents might be expected to be closely conversant with operating dollar magnitudes only in their own areas of specialization. This could be of particular importance in firms which, for one reason or another, contain a number of semi-autonomous divisions. Also, there would be no way of identifying the degree to which costs of specific research procedures (toxicology, for example) were incurred for basic, as opposed to developmental, research. This refinement would be a laborious matter of checks and re-checks.

With reference to costs, it may be seen that such variables as the number of product lines, the number of products within lines, manpower requirements, wages and salaries, and supplies and raw materials--to name a few--could result in not one but several dimensional variations of the basic model. Moreover, the data required to construct relative dimension models are not readily available to outsiders even if prepared regularly for member firms.

Thus, although more sophistication was desired and expected, we must be contented with a model which describes

a flow process, rather than comparative cross-sectional models. This is by no means a total loss, so long as we accept the idea of perceived changes in the R and D process during the decade 1953-1962 as intrinsically important regardless of the size of the base from which they stem.

In response to questioning as to changes in research orientation during the decade, two respondents who had observed such changes in their ethical firms remarked that marketing research had increased in importance. For one firm, this change represented a way of finding new product possibilities more efficiently. For the other, it was a matter of the availability of better personnel trained in marketing research techniques, together with the improved syndicated data services available to the industry.

All three respondents from the proprietary group cited the emergence of marketing research as the most important change of the decade. One research director observed that his important marketing research group was designated as such as late as 1958. Another executive noted that even seven years earlier (i.e., 1957) drug firms conducted little marketing research. "Many still don't," he observed, adding that at the close of the decade, developmental research had supplanted basic research as the scene of greatest activity.

Similarly, all five respondents in the conglomerate

group observed changes in the total research effort. Three named the now familiar marketing research as the significant occurrence. An officer of a small firm observed that, as late as mid-1961, marketing research had not been used as a matter of company-wide policy. New executives joining his firm from research-oriented companies had demanded--and were receiving and using--marketing research data. Another executive whose firm's marketing research experience pre-dates 1953 claimed the unusual distinction of having watched expenditures for this activity decline as a percent of the total research budget. At the same time, he was pleased to note that, in his opinion, his firm's experience had made this possible, since the total marketing research effort now eliminated all duplicate effort within the firm.

Two other broad comments should be reported. One firm in the conglomerate group underwent a change in corporate posture during the ten-year span under consideration. From the conduct of nearly all of its own service activities, it shifted to a vertical orientation and the use of outsiders, including developmental and marketing research suppliers. Another large firm was said to have increased its marketing research efforts particularly in proprietaries on the basis that it was growing rapidly, found it simple to duplicate successful proprietary products, but found that adjustment to its environment was difficult in the absence of the facts which marketing research alone could provide.

3. What time elements attach to the model?

Four of five ethical firm respondents agreed that, generally, basic research was a long-run proposition, occupying over a year in execution in new ethical product work. They likewise agreed that developmental research for ethical products required long-term planning. Three of the four regarded marketing research as a short-run matter, most such research being completed on a year-to-year basis. The single exception preferred to consider marketing research as long run in nature, since marketing research "followed" the product throughout its life cycle. It is thought that this latter attitude mirrors a defect in the questioning procedure which did not adequately specify the type of research project at issue--i.e., initial research or subsequent progress measurement. Since this respondent earlier mentioned marketing research as useful throughout the product's progress, little importance is attached to this variation.

The single non-respondent's reluctance to commit himself deserves elucidation. Given a specific drug and certain physical characteristics (e.g., its state of development, knowledge of its role as the ith from an original substance, etc.) he would have been willing to hazard a reply. But even under those circumstances, he felt that most research is probably long run because of what he styled "the problem of terminating the research project." He perceived two parts to his interesting problem. The

first was human preference for the project one was working on to the exclusion of all others. A typical such biased overt response would be, "If I go on, I may find the total medical answer next week." In reality, the answer may be a year away or it may never be found. The second part supports the first. Here the respondent assumed a researcher engaged in an on-going project. If he is required to undertake a new project, he may become involved in a long search to find the appropriate new test method. As he searches for the technique and time passes, the blunt question arises from management, "Is this guy any good?" Hence, the researcher would prefer to stand pat for the sake of his own reputation, and thus the research process would be lengthened irrespective of the absolute merit of the project.

Among respondents from proprietary firms, two felt that research at each level was a short-run process (recalling that little basic research is done in these firms) unless for some reason a new drug application was required. Then it was expected that developmental research would undoubtedly become long term. The third executive felt that long-run considerations were unavoidable in basic and developmental research for his company's products. So convinced of this was he that he cited the role of marketing research (short run) which he used to pressure other research efforts away from refining products and techniques into non-profitability.

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Within the conglomerate group, four of the five respondents concurred that research in the basic sense (when it infrequently occurred) and developmental programs were short run for their proprietary products. The dissenter held for long-run programs for derivations of products in which his firm specialized. Marketing research was also regarded as short run in four of the five cases, although the previous dissenter and two other respondents noted that marketing research followed the product throughout its life following introduction. Thus, again it was implied that marketing research performed a dual role in the context of the hypothetical model.

4. How are funds allocated for research?

Three of the five ethical firms are said to prepare annual budgets for all three types of research on a product-by-product basis. Estimates of probable costs in these--as well as in the remaining two firms--depend heavily on prior experience with products and techniques. Two other executives noted that budgets were handed down with no attention to individual projects, as opposed to the process outlined previously. Again, however, the year previous was regarded as the standard for budget projection.

Two of three proprietary firms reported product-by-product research estimates, in one instance in conjunction with product brand managers. The third respondent

observed that all budgets were prepared at a divisional level by divisional R and D committees. Presumably in all three cases the same preceding year reliance would be primarily important in determining budget levels.

One executive of a conglomerate firm declined to discuss his firm's budgeting procedures. The remaining four did so, however, and only one indicated that research budgets for his firm were prepared on a product-by-product basis. In his firm, this building process led to the establishment of divisional research budgets. The other three companies had previously held that their research activities were limited, largely because of relatively stable product lines and little dependence on innovation as a source of revenue. Their budgets for research (or perhaps more accurately, their managerial sources for project funding) are based on sales presentations, much in the same way that outside research organizations sell their services.

The issue of budget flexibility, or the ability of researchers to get clearance to pursue unexpected turns of events, was highly standardized in all firms. Of the twelve firms responding to questioning in this area, ten firms, including the five ethical firms, the three proprietary ones, and three of the five conglomerate ones observed that established budgets were reasonably flexible. Management appeared to be receptive to research projects which gave justifiable evidence of interest to the firm.

This is thought to be highly significant, since the restrictive potential of annual budgets in a functional area which is essentially long range, at least by implication, does not seem to be overwhelmingly important here. The firm claiming research budget inflexibility was a small one which was concerned with tight finances in areas in addition to that of research.

5. How is the research effort evaluated?

One respondent from an ethical firm felt that his company had established a research effectiveness criterion. He mentioned the rule, derived through experience, that his narrow-line firm had to obtain three income units per product for each research unit per product in order to stay competitively stable. A second respondent, whose firm had a much broader line of products, used two criteria in evaluating his firm's research. A target-oriented criterion was based on, say, the decision to screen 10,000 substances or combinations of substances to find ten marketable drugs. If mid-point evaluation of the 5,000 tests indicated five products in market, the research procedures are considered appropriate.⁷ This crude process is backed by further target goals consisting of dollar volumes attained from previously defined shares of market.

⁷The obvious weakness of such a plan is the possibility that potential products will not appear regularly. All ten may be located in the last 5,000 substances, or all ten may be found in the first 5,000.

Both criteria are qualified by the nature of prior research, which implies that if earlier efforts have been productive, those following will tend to be more certain in their performance.

The remaining three ethical firms were not particularly interested in accounting for research efforts. One cited the impact of the latest FDA regulations which destroyed any bases for even estimating research and development practices. Another expressed the problem of determining at what point to start measuring progress and how long a firm should continue to measure it. The third felt that adequate research was not an important issue compared with the need for better educational liaison between his company and physicians who used its products.

Two proprietary respondents expressed indifference to research evaluation per se, one invoking management faith in the research personnel, and the other stating that since the company was heavily marketing-oriented, it was bound to include research in its corporate mix anyway. The third respondent simply equated research evaluation with the profitability (ex post) of individual products, and the estimated profitability (ex ante) of products being researched established on a pure judgment basis.

Only one concrete example of research evaluation was encountered among the five conglomerate firms, and this was a somewhat negative procedure. As related to the interviewer, it was assumed that the company had

planned a twelve-month expenditure of \$8 million for the introduction of a new product. If, at the end of six months, marketing research showed that the product was selling at an annual rate of \$2 million, the product should be removed from the market. Under the assumption that the firm had spent \$4 million on introduction and \$8 thousand on the marketing research, the respondent felt that he had "saved" \$3.2 million by directing truncation of the project. Aside from one observation that target success of new products and sales of old ultimately justify research of any type and quantity, two mentions of such variables as timing, advertising efforts, psychological reactions to new products, etc., and two mentions of research as guidelines establishers, little else of weight was uncovered in the area of research evaluation.

6. What revisions in research policies and procedures appear likely in the near future?

Within the ethical group expected changes in research practices were roughly of two kinds--first, those occasioned externally, and second, those reflecting internal growth and maturation of the firms themselves. One respondent cited the so-called "new era" of pharmaceutical research, concentration on "the unmet needs in medicine." This, he felt, had emerged from his firm's role as a supplier of specialty items, and from a general lack of profitable opportunities in existing drugs. In essence, this point of view was echoed by a second firm's

representative, who added that new FDA rulings had narrowed the opportunity for new product introduction. That respondent saw an increasing role for marketing research as the source of more profitable market opportunities, as well as better ways of exploiting existing markets. The third respondent looked forward to research competence of his proprietary and industrial chemicals staffs equal to that of his splendid ethical research group. The fourth discussant felt that centralization of his research activity under one over-all authority would work changes in then-current procedures, but he hesitated to specify particular changes. The fifth and last respondent from the ethical group thought that volume growth would be the only perceptible change in the near future. His small company based its limited R and D budget on sales performance for the year previous, and since he assumed that sales were likely to grow, it followed that absolute research expenditures would likewise grow.

All three proprietary firm respondents predicted research procedure revisions in the years just ahead. Two representatives specifically felt that increased reliance on marketing research, including greater use of the several syndicated audit services, would be the most important development. Recalling that proprietary firms do little basic research, one respondent added that the increased use of marketing research would reduce the amount of "hunch" or executive judgment, presently found as his

firm's source of new product ideas. The third party, noting the importance of new products from his own research resources and from acquisitions and mergers, expected that centralized responsibility for product development and the use of marketing research for new marketing ventures would be of significant importance to his firm.

Three respondents from conglomerate firms cited changes in emphasis on marketing research as the most important research adjustments ahead. Two of these men expected to use more of this activity, one because of growth through merger, and the other because of the probability of instituting long-range (i.e., five year) planning for his product lines. The third who expected change thought that less, rather than more, research would be done, since experience had clearly defined the markets in which his firm wished to compete. The two remaining conglomerate firm representatives expected no change in research activity, based on general indifference in the one case, and satisfaction with the results of present research arrangements on the other.

Recapitulation--A Summary of the Findings

Ethical pharmaceutical firms tend generally to view the research process in the same manner as that which has been heuristically described in this study. Because of differences in corporate policy, structure, or size, however, the degree of emphasis on each research phase

varies from firm to firm, and it is nearly impossible to assign meaningful size-of-effort dimensions to the research process. Despite this problem, it appears likely that there has been some tendency to upgrade the role of marketing research in terms of importance relative to the total research mix.

With respect to the length of time necessary to complete a research cycle, ethical firm respondents tended to regard basic and developmental research as long-run (i.e., over one year) activities. Similarly, they generally regarded marketing research as a much less time consuming proposition, and assign to it a short-run (i.e., one year or less) role. Although all types of research can be viewed as best utilized within a complementary framework, the almost casual acceptance of the inevitable annual budget review does not seem to indicate conflict between types of research in the ethical group. Coupled with the apparent ready availability of contingency funds, we can cite no evidence to suggest that administrative regulations excessively inhibits researchers or their projects.

Among ethical firms, research evaluation is thought to be primarily a matter of the evaluation of the end products of that research rather than of the individual processes themselves. Thus, some years may pass before the contribution of, say, a basic research project is assessed, if it can properly be said to have been

assessed at all. This has an interesting implication, namely, that the key to research effectiveness may lie not in the area of evaluation of research procedures but in the areas of personnel selection, remuneration, length of service, etc. If such a study were conducted, it might prove useful in the years ahead, since, one way or another, it appears that the nature and extent of ethical research will change, becoming more rigorous under regulatory pressure and limited new product opportunities, as well as the changing outlook of the firms themselves as they abandon their traditional roles as suppliers of prescription substances and enter an era of product diversification.

Proprietary pharmaceutical firms require a different expression of the heuristic model to reflect their modest needs for basic research. One such adjustment might be to replace the basic research component with an innovative marketing research one. Another plausible revision might include a segmented initial block reflecting such project sources as successful competitors' entries, product committee recommendations, managerial suggestions, and all of the other sources of new product ideas. As in the ethical case, dimensions of the model are indistinct, although it appears that the decade with which we essentially are concerned witnessed a growth of the use and importance of marketing research in several specific applications.

For the most part, proprietary product research

has been characterized as short-run activity. Fairly modest budgetary requirements and an absence of research evaluation techniques are thought to be a reflection of an over-all more casual attitude toward the research process than that evidenced by ethical firms. This should not be construed as derision of proprietary research. To the contrary, the competitive nature of this group's market requires care in the formulation and presentation of new offerings. On the other hand, proprietary products are by nature relatively safe over a wide range of conditions of use. Whether or not this will permit in the future concentration of research efforts in areas expressly devoted to the marketing of proprietary products remains to be seen.

Conglomerate pharmaceutical firms appear to reflect for the most part the attributes of their major drug products, whether ethical or proprietary. Little further need be added except to observe that should product diversification continue among those firms heretofore predominantly ethical or proprietary, it will be important to observe the extent to which these emergent conglomerate entities cling to their "traditional" modes of research and development.

CHAPTER VI

CONCLUSIONS

Summary

In the foregoing discussion of research and development practices and procedures in the domestic pharmaceutical industry, two particular types of products have been considered--ethical or prescription ones and proprietary ones. Additionally, three types of firms have been identified--those concentrating in ethicals, those in proprietaries, and those which produce both types of drugs as well as substantial lines of semi- or non-drug products.

The industry comprised of these groups of firms has been found to be one of moderate size. While its constituents number in the low thousands, it is dominated by less than fifty major producers. During the decade under scrutiny, industry sales grew absolutely, as did post-tax profits and research and development costs.

By comparison with other industries in the economy, profit levels for pharmaceuticals were seen to be substantially higher over time. It appeared that these profit levels stemmed from established distribution systems, low manufacturing costs, and unregulated pricing practices. Additionally, demand for proprietary products was found

to be relatively inelastic as a result of extensive advertising and sales promotion efforts of the firms. Demand for ethical products was seen to be perfectly inelastic through combined physician's direction and retail outlet regulation. As a result, these profit-enhancing factors, together with alleged short product life for ethicals and the need for competitive proprietary products, tended to stimulate research and development programs.

Further, pharmaceutical firms were found to operate in an environment noted for its legal regulations, particularly those governing the introduction of new products. These regulations grew sporadically but progressively binding to the point where the R and D function was concerned not only with new products per se but with the justification for their marketability as well. While this was of concern to proprietary firms only in extreme cases, it was of constant concern to most prescription manufacturers. Generally, it was held that legislative rules had re-enforced the economic stimulus to research and development in the pharmaceutical industry.

An extensive discussion of research and development indicated that these activities were expanding throughout industry. This suggests the possibility that some unmeasurable portion of increased pharmaceutical R and D may have resulted from emulation of industry generally.

Several alternatives by which to measure the progress and results of pharmaceutical research and

development were examined. Again, whether mechanical or calculated, evaluation systems were seen to contain conceptual weaknesses. Moreover, diverse and complex factors intervened between the embryo product and the successful performer in a firm's product line. It was concluded that pharmaceutical research and development evaluation in and of itself was generally impractical at an industry or group level. Firms themselves may do so, but it is questionable whether or not their attempts measure R and D or the summation of all corporate economic activities including research and development.

The components of pharmaceutical research and development activities were seen to be complicated and obscure when viewed functionally. In an attempt to reduce this range of uncertainty, the functions were regrouped according to their perceived economic characteristics. A trichotomized model resulted, encompassing basic, developmental, and marketing research. The aforementioned legal restrictions and the institutional posture of the firm were regarded as parameters of the first and second order. The model was used as the basis of a field study.

Having identified the perceived limitations of the primary data collection process, the field study procedures were outlined. The nature of the sample was discussed to the extent consistent with the need to protect respondents' identities. The results of the

interviews were discussed by industry groups with the following informative patterns noted.

Ethical Firms

The model of pharmaceutical R and D was well suited to those firms which manufacture prescription products. While an attempt to estimate proportions of R and D effort devoted to each component failed through the wide diversity among products, it was felt that certain shifts in emphasis were made evident. The most notable change was toward the increased use of marketing research techniques as a means of pinpointing potentially profitable areas for product development as well as to follow more closely the progress of those products in market. This did not eliminate the need for either basic or developmental research, of course, but it did suggest that less time and factor waste might be expected in the future.

Proprietary Firms

Because of the nature of the products manufactured by this group, little reliance, if any, was placed on basic research as a source of new products. It appeared that marketing research supplanted the basic research component of the ethical firm model in all but the most unusual cases. In each component instance, the time required for product completion was thought to be substantially less than that required for most ethical products.

Conglomerate Firms

The degree to which these companies find the R and D model applicable appears to depend upon the relative importance of either ethical or proprietary items in their total product mix. As a group, they neither disavow the model completely nor do they accept it wholeheartedly. In the light of the evidence presented in this section, it must be concluded that they tend toward the research informality which marks the proprietary group.

All Firms

As indicated previously, it appears that the increased use of sophisticated marketing research techniques typifies, as much as anything else, the major direction for pharmaceutical research and development. In the face of increased legislative pressure, as well as an apparent exhaustion of readily available new product sources, pharmaceutical firms seem to be adopting an attitude of specific cultivation of specialty areas. This is an appropriate course of action so long as their short-run goals consist of sustaining complex production personnel groups, research and development personnel and facilities, and skilled salesmen operating within a rigid distribution system, all through and for profits derived from the sale of highly protected necessities.

It must be observed, however, that these goals, previously regarded as appropriate, must henceforth be

held to be socially unacceptable, and that a major and immediate reorganization of the pharmaceutical industry is of the utmost importance.

Conclusions and Implications

The ethical pharmaceutical industry has attained a peculiar position in the economy. It may be justifiably proud of its contribution to the level of living in the United States, the highest the world has ever known. Conversely, it has been the target of increasing public mistrust and dissatisfaction which only powerful political influence has abated in any way.

Without question, the industry has been brought to its present heights by a strong market-centered outlook based upon extensive sales forces, liberal promotional expenditures, and a host of product introductions. However, the unavoidable conclusion of this investigation is that a strict profit orientation is ill-suited to the ethical pharmaceutical industry, and to its research and development efforts.

The results of the drug struggle include high consumer costs for indispensable prescription products. They include consumer exploitation of the worst sort, since the burden of high cost drug therapy has fallen on those least able to pay for it--the ill, the aged, the chronically infirm. They include the reasonable assumption that research efforts have been directed often toward profitable

products rather than desirable products. The summation of the shortcomings spells wasted resources--human, material, and financial--for manufacturers, retailers, and consumers.

Because of the appalling economic and social illiteracy of some of the industry's proponents, it must be emphasized that these criticisms do not represent an attack upon either the personnel or the institutions which have brought the American pharmaceutical industry to its present state.¹ Rather, it must be recognized that, having achieved a certain plateau of economic evolution, further adjustments must be made in the methods of operation of the industry's firms. Above all, it must be clearly understood that these adjustments are required not only for the sake of society, but for the sake of the firms themselves, presently enmeshed as they are in a heated world of partial competition in an essentially non-competitive real world.

¹The industry argument runs in this vein:

"At this point, I would like . . . to remark that I believe that pharmaceutical companies exist for two reasons:

"The first being that they want to develop, make, and market products which are essential for the protection and maintenance of national health and welfare; and, secondly, because many thousand people have put their hard cash into the support of these companies with a full expectation of a decent appreciation of and return from their investment, management does its best to make a profit.

"Those research people, or doctors, who look down their noses at profits are, in my opinion, either ivory-tower recluses or people who deep in their hearts have a desire to destroy, if they could come to power, one of the major facets of the American way of life; namely, our competitive system, of free enterprise for a profit."

From Administered Prices in the Drug Industry,
Part 24, p. 13765.

The adjustments discussed below do not inhibit free enterprise; they enable it and enhance it, since it does not presently exist with respect to the industry and the society which it serves.

What is society entitled to expect from pharmaceutical firms? More directly, what would the market demand of ethical drug manufacturers if their products were sold in a competitive market? Based on this investigation, it is held that there are five indisputable conditions which would have to be met, namely, quality, safety, efficacy, economy, and vigorous research. Quality means that the purity and strength of the products offered for sale should be unquestionably guaranteed, since the consumer is unable to judge these for himself. Safety implies that the product should occasion minimum negative side effects, but that, since human physiology varies, the physician should be enabled to evaluate completely the desirability of use or avoidance of the product. Efficacy is the matter of assurance that the product will perform as claims for it suggest or imply. Economy requires the prices paid by the drug's consumers square with price behavior in competitive, or semi-competitive industries, and not, as is often the case, with the excessive charges resulting from monopoly power at both the firm and the final transaction points. Research demands would be reflected in the free market acceptance of new products arising from extensive R and D efforts, and modifications

of existing ones from intensive R and D efforts, with the appropriate goal in both instances being enhanced human health rather than enhanced promotional opportunities.

Clearly, the first requirement, quality, and in most cases the second, safety, have been achieved within the present economic environment as buttressed by federal legislation. The third, efficacy, is now a matter of regulatory record, although this requirement may have a distracting influence on the industry as it is presently constituted. The relative difficulty of the introduction of new ethical products, and therefore prospects for competitive vigor adequate to sustain the growth record of recent years, are now open to question.²

Even if we grant that the first three conditions can be met (i.e., that under present circumstances, firms can adjust their operations to include efficacy as they have included quality and safety in the past), we are confronted by an impasse with respect to the two final conditions, product economy and vigorous research. These must be discussed briefly at two stages--the retail sales level and the manufacturing firm level.

Retail pharmacies conduct no research. Worse, they represent the most significant barrier to the

²The industry now faces FDA attacks on the new proprietary products with which several ethical firms have diversified their activities. The substance of the FDA charge is that delayed side effects from self-medication with certain proprietaries are only now coming to light.

attainment of economy in ethical products. No matter what changes are made in the manufacturing and firm marketing process, there is no specific incentive at the final transaction point to effect a reduction in product prices. Prescription requirements, in many instances, simply serve to encourage the existence of small, inefficient retail stores, kept alive by a market core income derived from ethical drug sales. The consumer is economically powerless so long as they survive.

At the firm level, status quo--rigid patent protection, ultimate prescription sales, and extensive sales forces--suggests that, aside from attention to marketing research and thus the avoidance of non-profitable product areas, there will be little significant change in ethical drug research. In any event, as the industry frequently points out, research is expensive, whether basic research for new product ideas, developmental research to ready the promising product for market, or marketing research for greater economic advantage. Moreover, there is always the possibility that a high quality, safe, effective product--adequately patented and thoroughly promoted--may fail to find favor with the medical profession, just as a product offered under competitive conditions risks market rejection. Finally, there is always the possibility that another firm may perfect a better, more attractive substitute, thus rather abruptly terminating the life cycle of the existing product.

In this precarious state of affairs, it is unlikely that society can ever expect adequate and necessary pharmaceutical research and, at the same time, product economy. Yet, these are desirable concomitants of the first order of societal importance. They may be achieved by a thoroughgoing reform of the pharmaceutical industry.

One possibility for reform, suggested in large measure by the Kefauver investigation, would withdraw patent protection on ethical drugs and require generic or non-brand name prescription practices by physicians. By opening manufacturing rights to all firms, and by preventing the consumer trap of a prescription written in a high-cost trade name product, competition would rapidly reduce the prices of drugs to the retail pharmacist. However, the resulting loss in income to the manufacturer might cause curtailment of R and D programs, something which must be viewed as undesirable. At the same time, there is no assurance whatever that such steps would influence the prices of products at retail. The consumer would still be unable to bargain with the pharmacist who, in turn, would be under no constraint to reduce his existing price levels. The profit problem would be shifted from the manufacturer to the retailer. Thus, the ultimate effect might well be to discourage research and development, while perpetuating the primary economic difficulty.

Another solution might be that of government

procurement and distribution of all ethical pharmaceuticals. On the surface, this is an attractive proposition, since the government now purchases many products at far lower prices than are normally quoted to the retail trade. Moreover, clear operational precedent may be cited in those states which successfully maintain liquor monopolies and operate retail stores for the sale of that commodity. Despite the fact that it is impossible to argue against this program of state, or federal, control of the ethical pharmaceutical trade from plant to consumer, it is only proper to observe that such a program would be virtually incapable of legislative passage.

The first solution falls short of attaining the objectives of an economic reorganization of the industry, and the second is obviously alien to the American political climate. Fortunately, a third alternative--practical, effective, and based upon the best traditions of the American free enterprise system--will accomplish the necessary changes.

Accordingly, it is recommended that the ethical pharmaceutical industry, from production throughout the marketing process, be established as a public trust, including the rigorous control of product prices and profits.³ The pharmaceutical industry, as presently

³Basic considerations for this proposal have been thoroughly outlined in a number of sources, including the following: Eli W. Clemens, Economics and Public Utilities (New York: Appleton-Century-Crofts, Inc., 1950), pp. 12-37,

constituted, is virtually a public utility, with the exception of price and profit regulations. To include these in the industry's operational framework would require certain structural adjustments at the firm level. For one thing, it might be well to institute areas of concentration, or product group monopoly, based upon the six broad categories, hormones, antidiabetic drugs, antibiotics, tranquilizers and central nervous system drugs, vaccines, and general drugs, or such other groupings as might be desirable. This would eliminate the necessity for socially wasteful promotional and sales expenditures, since product duplication would be ruled out.

To implement the program further, it would undoubtedly be necessary to require merger, or agglomeration, of those firms presently conducting research and development programs, together with provision for including those existing smaller firms which might wish to join a specific group. Then, with product monopoly assured and market risk eliminated, the regulation of profits as a percent of production costs, including the costs of research and development, would be the most appropriate basis for price control in the industry. By including R and D as a production cost, there will be every incentive

especially pp. 25-28 and 677-80; Martin G. Glaeser, Public Utilities in American Capitalism (New York: The Macmillan Company, 1957), pp. 182-90 and 206-19; and Herman H. Trachsel, Public Utility Regulation (Chicago: Richard D. Irwin, Inc., 1947), pp. 50-69.

to mount the search for new, improved products within a firm's domain of assigned competence, rather than the present practice of concentration on product research from a potential profit standpoint.

A regulatory board, consisting of medical specialists, responsible personnel from the industry, representatives of the pharmacy profession, and other competent public and private representatives, should be instituted. It appears now that this group could be structured around the drug operatives in the Food and Drug Administration. Appropriate care must be taken to assure freedom from domination by special interest groups on this board. In part to combat this contingency, the records of the board and of the firms as then structured should be a matter of complete public documentation.

At the retail level, controlled, published prices would serve consumers by protecting them from willful or intemperate overcharges liable to accompany conditions of inelastic demand. The appropriate basis for retail price determination would clearly be a set markup over the controlled production cost. Thus, ethical pharmaceutical products--the single indispensable line in the retail pharmacy--would be relieved from their present position as margin supporters for the multitude of non-drug items found today in most drugstores. This must be emphasized, since no other retail operations are favored with a solid core of products which consumers must have, for which

they are unable to bargain, and for which, in many instances, they will pay extraordinarily high prices to obtain. That such control will do what many retail druggists fear--eliminate them as retailers--is undoubtedly true, particularly if they are incompetent businessmen. A free enterprise system makes equal allowance for the rewards of competence and of incompetence--unbounded success, on the one hand, and the risk of failure, on the other.

Heretofore, the role of the public utility, or public trust, has been reserved for firms for which monopoly is a visibly socially desirable state. Urban clutter, high fixed costs of entry and operation, and demand inelasticity have been major determinants of the evolution of this status for portions of industry. Now, because of demand inelasticity and resulting consumer exploitation, and because of the need for controlled programs of research and development without regard to profit prospects for the firm, it is time to extend the concept to the ethical pharmaceutical industry. Since the consumer can exercise some measure of choice in his selection of proprietaries, since he is free to assume whatever risks may be associated with their use if he so wishes, and since proprietary firms conduct little or no socially meaningful research, these conclusions are not concerned with them. Proprietary drugs are presently covered by all necessary legislation.

There can be no socially proper alternative to these proposed changes in the ethical pharmaceutical industry. They must be made, and they must be made promptly, not only for the sake of this country, but perhaps for the sake of the world as well.

BIBLIOGRAPHY

BIBLIOGRAPHY

- Alderson, Wroe. Marketing Behavior and Executive Action. Homewood, Ill.: Richard D. Irwin, Inc., 1957. 487 pp.
- Alexander, Ralph S., Cross, James S., and Cunningham, Ross M. Industrial Marketing. Rev. ed. Homewood, Ill.: Richard D. Irwin, Inc., 1961. 659 pp.
- Arnow, L. Earle. "A Drug is Born," Research Management, V, No. 1 (1962), 5-14.
- Badgley, Robin F. "An Assessment of Research Methods in 103 Scientific Articles from Two Canadian Medical Journals," Canadian Medical Association Journal, LXXXV (July 29, 1961), 246-50.
- Beverly, Dana M. "The Effects of Noneconomic Limitations Upon the Ethical Pharmaceutical Industry." Unpublished Master's thesis, Graduate School of Business Administration, New York University, 1963. 37 pp.
- Bixler, Harley H. The Manufacturing Research Function. New York: American Management Association, 1963. 80 pp.
- Boulding, Kenneth E. Economic Analysis. 3rd ed. New York: Harper & Brothers, 1955. 905 pp.
- Boulding, Kenneth E. The Organizational Revolution: A Study in the Ethics of Economic Organization. New York: Harper & Brothers, 1953. 286 pp.
- Boundy, R. H., and Chamberlain, L. C., Jr. "Problems and Prospects of Industrial Research," Research Management, II, No. 2 (Summer, 1959), 81-96.
- Bush, George P., and Hattery, Lowell H. (eds.). Teamwork in Research. Washington: The American University Press, 1953. 191 pp.
- Cairns, R. W. "Planning for Research: The Problems Involved," Research Management, IV, No. 2 (Summer, 1961), 107-18.

"Can Drugmakers Keep Up the Pace?," Chemical Week, XCII, No. 7 (April 20, 1963), 21-22.

Carney, Thomas P. "Research and Patents in the Drug Industry," Research Management, V, No. 3 (1962), 193-208.

Chamberlin, Edward H. The Theory of Monopolistic Competition. 7th ed. Cambridge, Mass.: Harvard University Press, 1960. 350 pp.

Clemens, Eli W. Economics and Public Utilities. New York: Appleton-Century-Crofts, Inc., 1950. 765 pp.

Cooney, Thomas M. "Ethical Pharmaceutical Promotion to the Medical Profession." Unpublished Master's thesis, Graduate School of Business Administration, New York University, 1959. 71 pp.

Cyert, Richard M., and March, James G. A Behavioral Theory of the Firm. Englewood Cliffs, N. J.: Prentice-Hall, Inc., 1963. 332 pp.

Dean, Joel. Managerial Economics. Englewood Cliffs, N. J.: Prentice-Hall, Inc., 1951. 621 pp.

De Haen, Paul. "New Products Parade--1962," Drug and Cosmetic Industry, XCII, No. 7 (February, 1963), 149-51.

De Haen, Paul. "Trends in Product Development," Drug and Cosmetic Industry, XCII, No. 2 (August, 1961), 159-60; No. 3 (September, 1961), 295-96.

Doohar, M. J., and Marting, Elizabeth (eds.). Getting the Most from Product Research and Development. New York: American Management Association, 1955. 149 pp.

Drucker, Peter F. "Twelve Fables of Research Management," Harvard Business Review, XLI, No. 1 (January-February, 1963), 103-108.

"Drug Industry Research Manpower is Rising Sharply," Oil Paint and Drug Reporter, CLXXXII (October 29, 1962), 4.

Drug Trade News--Special Section. New York: Topics Publishing Company, July 22, 1963. 40 pp.

Dunn, Charles W. Federal Food, Drug and Cosmetic Act: A Statement of Its Legislative Record. New York: G. E. Stechert & Company, 1938. 1,425 pp.

- Enloe, Cortez F., Jr., et al. A Primer of Public Relations for the Pharmaceutical Industry. New York: American Pharmaceutical Manufacturers Association, 1953. 90 pp.
- Farrell, Hugh. What Price Progress? The Stake of the Investor in the Discoveries of Science. New York: G. P. Putnam's Sons, 1926. 323 pp.
- Fellner, William. Competition Among the Few: Oligopoly and Similar Market Structures. New York: Augustus M. Kelley, 1960. 328 pp.
- Forbes Magazine. XCII, No. 9 (November 1, 1963).
- "The Fortune Directory." New York: Fortune Magazine, August, 1963. 40 pp.
- The Editors of Fortune. The Mighty Force of Research. New York: McGraw-Hill Book Company, Inc., 1956. 308 pp.
- Food Law Institute Series. Federal Food, Drug, and Cosmetic Law: Administrative Reports--1907-1949. Chicago: Commerce Clearing House, Inc., 1951. 1,446 pp.
- Freedman, Paul. The Principles of Scientific Research. 2d ed. New York: Pergamon Press, 1960. 228 pp.
- Gambs, Gerard C. "Representative Costs of Doing Research and Development," Research Management, II, No. 1 (Spring, 1959), 33-43.
- Glaeser, Martin G. Public Utilities in American Capitalism. New York: The Macmillan Company, 1957. 624 pp.
- Goodrich, William W. "FDA's Regulations Under the Kefauver-Harris Drug Amendments of 1962," Food Drug Cosmetic Law Journal, XVIII, No. 10 (October, 1963), 561-69.
- Griffin, Clare E. Enterprise in a Free Society. Chicago: Richard D. Irwin, Inc., 1949. 583 pp.
- Hackett, James W. "Proceedings of Industrial Research Institute Group Meetings. Number 7. Evaluation of Research," Research Management, V, No. 3 (1962), 177-92.
- Hampton, Charles. "Ethical Drugs," Chemical Week, XCI, No. 20 (November 17, 1962), 134-46.
- Harris, Franklin S., and Butt, Newbern I. Scientific

- Research and Human Welfare. New York: The Macmillan Company, 1924. 406 pp.
- Harris, Seymour E. The Economics of American Medicine. New York: The Macmillan Company, 1964. 508 pp.
- Hayes, Kenneth. "Research--The Key to a Healthier America," The Exchange (New York Stock Exchange), XX, No. 4 (April, 1959), 13-16.
- Hepner, Harry W. Modern Marketing: Dynamics and Management. New York: McGraw-Hill Book Company, Inc., 1955. 599 pp.
- Hertz, David B. Costs, Budgeting, and Economics of Industrial Research: Proceedings of the First Annual Conference on Industrial Research. New York: Kings Crown Press, 1951. 261 pp.
- Hertz, David B. The Theory and Practice of Industrial Research. New York: McGraw-Hill Book Company, Inc., 1950. 385 pp.
- Hinrichs, John R. Creativity in Industrial Scientific Research: A Critical Survey of Current Opinion, Theory, and Knowledge. New York: American Management Association, 1961. 39 pp.
- Hodge, Melville H., Jr. "Rate Your Company's Research Productivity," Harvard Business Review, XLI, No. 6 (November-December, 1963), 109-22.
- Hodgins, Eric. "The Strange State of American Research," in The Mighty Force of Research by the editors of Fortune Magazine. New York: McGraw-Hill Book Company, Inc., 1956. 308 pp.
- Holbrook, Stewart H. The Golden Age of Quackery. New York: The Macmillan Company, 1959. 302 pp.
- Holland, Maurice, et al. Management's Stake in Research. New York: Harper & Brothers, 1958. 143 pp.
- Howard, John A. Marketing Management: Analysis and Decision. Homewood, Ill.: Richard D. Irwin, Inc., 1957. 429 pp.
- Huxley, Julian. Science and Social Needs. New York: Harper & Brothers, 1935. 287 pp.
- Icken, Frederick T. "The Development of Marketing Research in the Ethical Pharmaceutical Industry." Unpublished

Master's thesis, Graduate School of Business Administration, Fairleigh Dickinson University, 1961. 128 pp.

Kaysen, Carl. "The Corporation: How Much Power? What Scope?" in The Corporation in Modern Society, ed. Edward S. Mason. Cambridge, Mass.: Harvard University Press, 1959, pp. 85-105.

Keezer, Dexter M., Greenwald, Douglas, and Ulin, Robert P. "The Outlook for Expenditures on Research and Development During the Next Decade," in The Research Revolution, by Leonard Silk. New York: McGraw-Hill Book Company, Inc., 1960. 244 pp.

Kelley, Eugene J., and Lazer, William. Managerial Marketing: Perspectives and Viewpoints. Homewood, Ill.: Richard D. Irwin, Inc., 1958. 508 pp.

Kemeny, John G. A Philosopher Looks at Science. Princeton, N. J.: D. Van Nostrand Company, Inc., 1959. 273 pp.

Killeffer, D. H. The Genius of Industrial Research. New York: Reinhold Publishing Corporation, 1948. 263 pp.

Kleinfeld, Vincent A., and Dunn, Charles W. Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record. 4 vols. Chicago: Commerce Clearing House, Inc., 1949-1958. 3,153 pp.

Kleinfeld, Vincent A., and Kaplan, Alan H. Federal Food, Drug, and Cosmetic Act: Judicial and Administrative Record. Chicago: Commerce Clearing House, Inc., 1962. 509 pp.

Ladimer, Irving. "Quackery and the Consumer--Responsibility of the Medical Profession," Food Drug Cosmetic Law Journal, XVIII, No. 8 (August, 1963), 436-52.

Leftwich, Richard H. The Price System and Resource Allocation. Rev. ed. New York: Holt, Rinehart and Winston, 1960. 381 pp.

Levitt, Theodore. Innovation in Marketing: New Perspectives for Profit and Growth. New York: McGraw-Hill Book Company, Inc., 1962. 253 pp.

Levitt, Theodore. "Marketing Myopia," Harvard Business Review, XXXVIII (July, 1960), 45-56.

Mackel, Michael F. "Legal Considerations in Experimental Design in Testing New Drugs on Humans," Food Drug Cosmetic Law Journal, XVIII, No. 4 (April, 1963).

- Mahoney, Tom. The Merchants of Life: An Account of the American Pharmaceutical Industry. New York: Harper & Brothers, 1959. 278 pp.
- Management of New Products. New York: Booz, Allen and Hamilton, 1960. 31 pp.
- Manufacturing Chemist. XXXIII, No. 2 (February, 1962).
- Marcson, Simon. The Scientist in American Industry: Some Organizational Determinants in Manpower Utilization. Princeton, N. J.: Princeton University Press, 1960. 158 pp.
- Mason, Edward S. (ed.). The Corporation in Modern Society. Cambridge, Mass.: Harvard University Press, 1959. 335 pp.
- Mathison, Richard. The Eternal Search. New York: G. P. Putnam's Sons, 1958. 381 pp.
- McCarthy, E. Jerome. Basic Marketing: A Managerial Approach. Homewood, Ill.: Richard D. Irwin, Inc., 1960. 770 pp.
- McKeen, J. E. "Extracts from Industrial Research," Drug and Cosmetic Industry, XC, No. 3 (March, 1962), 281-83.
- McNamee, Raymond W. "How Research Organization and Programs Have Been Developed in a Large Corporation," Research Management, I, No. 3 (Autumn, 1958), 165-72.
- McVicker, Paul. "Meeting Company Objectives Through a Successful Technology Team," in Maintaining the Product Portfolio. New York: American Management Association, 1960, pp. 75-81.
- Mees, C. E. K., and Leermakers, J. A. The Organization of Industrial Scientific Research. 2d ed. New York: McGraw-Hill Book Company, Inc., 1950. 383 pp.
- Michelfelder, William. It's Cheaper to Die: Doctors, Drugs, and the A.M.A. New York: George Braziller, Inc., 1960. 192 pp.
- Moranian, Thomas. The Research and Development Engineer as Manager. New York: Holt, Rinehart and Winston, 1963. 152 pp.
- National Research Council to the National Resources Planning Board. Research--A National Resource (Part II: Industrial Research). Washington: Government Printing Office, 1940. 369 pp.

- Offenberg, Miriam. The Federal Investigators. Englewood Cliffs, N. J.: Prentice-Hall, Inc., 1962. 348 pp.
- Oliver, Robert M. "The Marketing Concept in Developing Products for Profit," in Control of Non-Manufacturing Costs. New York: American Management Association, 1957, pp. 75-87.
- Olsen, Paul C. Marketing Drug Products. Rev. ed. New Brunswick, N. J.: Rutgers University Press, 1955. 330 pp.
- Otteson, S. F. "Research and the Science of Marketing," in Readings in Marketing, by S. George Walters, Max D. Snider, and Morris L. Sweet. Cincinnati: South-Western Publishing Company, 1962. 832 pp., esp. pp. 164-70.
- Parker, R. P. "Developing New Drugs," Drug and Cosmetic Industry, XCI, No. 6 (December, 1962), 698-700.
- Penrose, Edith T. The Theory of the Growth of the Firm. New York: John Wiley & Sons, Inc., 1959. 272 pp.
- Pharmaceutical Manufacturers--U.S.A., Canada, U.K., India. Pearl River, N. Y.: Noyes Development Corporation, 1962. 61 pp.
- Phelps, Dudley M. Planning the Product. Chicago: Richard D. Irwin, Inc., 1947. 292 pp.
- Prescription Drug Industry--Fact Book. Washington: Pharmaceutical Manufacturers Association, June 15, 1962. 24 pp.
- Quinn, James B. Yardsticks for Industrial Research: The Evaluation of Research and Development Output. New York: The Ronald Press Company, 1959. 224 pp.
- Quinn, James B., and Mueller, James A. "Transferring Research Results to Operations," Harvard Business Review, XLI, No. 1 (January-February, 1963), 49-66.
- Reeves, E. D. "Development of the Research Budget," Research Management, I, No. 3 (Autumn, 1958), 133-42.
- Roberts, Edward B. "The Dynamics of Research and Development." 2 vols. Unpublished Ph.D. dissertation, Massachusetts Institute of Technology, 1962. 514 pp. (Mimeographed.)
- Rorem, C. Rufus, and Fischelis, Robert P. The Costs of

- Medicines. Chicago: The University of Chicago Press, 1932. 250 pp.
- St. Clair, Frank J. (ed.). Moody's Industrial Manual. New York: Moody's Investors Service, Inc., 1963. 3,028 pp.
- Sanders, Marion K. (ed.). The Crisis in American Medicine. New York: Harper & Brothers, 1961. 149 pp.
- Schenck, Hilbert, Jr. "Scientific Freedom--Hah!," Science Digest, LIV, No. 6 (June, 1963), 43-47.
- Schmookler, Jacob. "Technological Progress and the Modern American Corporation," in The Corporation in Modern Society, ed. Edward S. Mason. Cambridge, Mass.: Harvard University Press, 1959, pp. 141-65.
- Science Committee, National Resources Committee. Research --A National Resource (Part I: Relation of the Federal Government to Research). Washington: U.S. Government Printing Office, 1938. 255 pp.
- Scull, C. Wesler. "Pharmaceutical Research: Success Through Failure," Drug and Cosmetic Industry, LXXXVI, No. 10 (April, 1960), 465-67.
- Shaw, Steven F., and Gittinger, C. McFerron. Marketing in Business Management. New York: The Macmillan Company, 1963. 472 pp.
- Shubin, John A. Managerial and Industrial Economics. New York: The Ronald Press Company, 1961. 518 pp.
- Silk, Leonard S. The Research Revolution. New York: McGraw-Hill Book Company, Inc., 1960. 244 pp.
- Social Science Research Council to the National Resources Planning Board. Research--A National Resource (Part III: Business Research). Washington: U.S. Government Printing Office, 1941. 70 pp.
- Standard & Poor's Industry Surveys--Drugs, Cosmetics: Basic Analysis. Section 2. New York: Standard & Poor's Corporation, December 13, 1962. 19 pp.
- Standard & Poor's Industry Surveys--Drugs, Cosmetics: Current Analysis and Outlook. Section 3. New York: Standard & Poor's Corporation, December 26, 1963. 6 pp.
- Staudt, Thomas A. "Program for Product Diversification," Harvard Business Review, XXXII (November-December, 1954), 121-31.

- Strauss, Herbert D. "How to Fail in Proprietaries Because of Not Really Trying," Drug and Cosmetic Industry, XC, No. 3 (March, 1962), 284-85.
- Strothers, George B. (ed.). Social Science Approaches to Business Behavior. Homewood, Ill.: The Dorsey Press, Inc., 1962. 183 pp.
- Suter, C. M. "Drug Bill: \$5 Million," Oil Paint and Drug Reporter, CLXXXII (April 16, 1962), 7.
- Tishler, Max. "The Scientist's Stake in the Kefauver Hearings," Drug and Cosmetic Industry, LXXXVI, No. 11 (May, 1960), 608-609.
- Trachsel, Herman H. Public Utility Regulation. Chicago: Richard D. Irwin, Inc., 1947. 538 pp.
- "U.S. Orders Drug 'War,'" Newark Evening News, February 28, 1964, p. 3.
- U.S. House of Representatives. Hearings on H.R. 6245, Drug Industry Antitrust Act (Serial No. 32) (May 17, 18, 23, and 24, 1962). 87th Cong., 2d Sess., 1962. 908 pp.
- U.S. Senate. Study of Administered Prices in the Drug Industry. Washington: U.S. Government Printing Office, 1961. 374 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Corticosteroids), December 7, 8, 9, 10, 11, and 12, 1959. Part 14, 86th Cong., 1st Sess., 1960. 519 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Corticosteroids--Appendix). Part 15, 86th Cong., 1st Sess., 1960. 527 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Tranquillizers), January 21, 22, 26, 27, 28, and 29, 1960. Part 16, 86th Cong., 2d Sess., 1960. 564 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Tranquillizers--Appendix). Part 17, 86th Cong., 2d Sess., 1960. 786 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (General: Physicians and Other Professional Authorities), February 25, 26, April 12, 13, 14, and 15, 1960. Part 18, 86th Cong., 2d Sess., 1960. 371 pp.

- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (General: Pharmaceutical Manufacturers Association), February 23, 24, and April 20, 1960. Part 19, 86th Cong., 2d Sess., 1960. 388 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Oral Antidiabetic Drugs), April 26, 27, 28, May 3 and 4, 1960. Part 20, 86th Cong., 2d Sess., 1960. 491 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (General: Generic and Brand Names), May 10, 11, 12, and 13, 1960. Part 21, 86th Cong., 2d Sess., 1960. 394 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (The Food and Drug Administration: Dr. Henry Welch), May 17, 18, June 1, 2, 3, and 6, 1960. Part 22, 86th Cong., 2d Sess., 1960. 323 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (The Food and Drug Administration: Dr. Henry Welch--Appendix). Part 23, 86th Cong., 2d Sess., 1960. 1,395 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Antibiotics), September 7, 8, 9, 12, 13, and 14, 1960. Part 24, 86th Cong., 2d Sess., 1961. 590 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Antibiotics--Appendix A). Part 25, 86th Cong., 2d Sess., 1961. 1,113 pp.
- U.S. Senate, Committee on the Judiciary. Administered Prices in the Drug Industry (Antibiotics--Appendix B). Part 26, 86th Cong., 2d Sess., 1961. 1,174 pp.
- U.S. Senate, Committee on the Judiciary. Hearings on S. 1552, A Bill to Amend and Supplement the Antitrust Laws, with Respect to the Manufacture and Distribution of Drugs, and for Other Purposes (A.M.A. and Medical Authorities--Appendix). Part 2, 87th Cong., 1st Sess., 1961. 731 pp.
- U.S. Senate, Committee on the Judiciary. Hearings on S. 1552, A Bill to Amend and Supplement the Antitrust Laws, with Respect to the Manufacture and Distribution of Drugs, and for Other Purposes (Patent Provisions), October 16, 17, 18, 31, November 1 and 19, 1961. Part 3, 87th Cong., 1st Sess., 1961. 798 pp.

- U.S. Senate, Committee on the Judiciary. Hearings on S. 1552, A Bill to Amend and Supplement the Antitrust Laws, with Respect to the Manufacture and Distribution of Drugs, and for Other Purposes (Pharmaceutical Manufacturers Association), December 7, 8, and 9, 1961. Part 4, 87th Cong., 1st Sess., 1962. 585 pp.
- Westaway, F. W. Scientific Method: Its Philosophical Basis and Its Modes of Application. New York: Hillman-Curl, Inc., 1937. 588 pp.
- Whyte, William F. "Applying Behavioral Science Research to Management Problems," in Social Science Approaches to Business Behavior, ed. George B. Strother. Homewood, Ill.: The Dorsey Press, Inc., 1962, pp. 125-40.
- Wilson, T. L. "Budget and Cost Control in Research and Development," Research Management, IV, No. 2 (Summer, 1961), 95-105.
- Wolfe, Harry D., et al. Pretesting Advertising. New York: National Industrial Conference Board, 1963. 214 pp.
- Wolfe, Dael (ed.). Symposium on Basic Research. Washington: American Association for the Advancement of Science, 1959. 308 pp.
- Ziment, Larry. "An Evaluation of Some Major Marketing Research Services Commercially Available to the Ethical Pharmaceutical Industry." Unpublished Master's thesis, Graduate School of Business Administration, New York University, 1961. 127 pp.

APPENDIX A

APPENDIX A

INTERVIEW GUIDE

(Revised Form)

Research Practices Survey

1. Describe broadly the research process as it presently exists in your company, in terms of:

a. Basic Research

b. Developmental Research

c. Marketing Research

2. In 1962, about what percentage of your total research effort would you describe as having been essentially:

	<u>Ethical</u>	<u>Proprietary</u>	<u>Miscellaneous</u>
a. Basic Research	_____	_____	_____
b. Developmental Research	_____	_____	_____
c. Marketing Research	_____	_____	_____

3. Have there been notable changes in these proportions during the past ten years?

Yes _____ (Direction & Extent)
 No _____ (Ask 5a)
 Don't Know _____ (Go to 6)
 No Answer _____

5a. Why do you say that?

4. Which time span would best characterize your programs in:

	<u>Short Run</u>	<u>Long Run</u>
Basic Research	_____	_____
Developmental Research	_____	_____
Marketing Research	_____	_____

4a. Please comment on these.

5. How do you presently budget funds for:

a. Basic Research

b. Developmental Research

c. Marketing Research

6. What provisions are made to revise your budgets?

7. Are you presently able to account for the impact of your research efforts on your profit position?

Yes _____ (Ask 2a)

No _____ (Ask 3)

Don't Know _____ (Ask 4)

No Answer _____

7a. How do you calculate this?

7b. What degree of precision do you attain in this measurement?

8. Do you presently plan substantial revisions in your research procedures in the years ahead?

Yes _____ (Ask 8a)

No _____

Don't Know _____ (Go to 9)

No Answer _____

8a. Why do you say that? (Direction & Extent)

9. Miscellaneous comments:

Name _____

Title _____

Firm _____

Date _____

APPENDIX B

APPENDIX B

TOTAL NET INCOME OF THIRTEEN SAMPLE FIRMS-- BY INDUSTRY GROUP (Millions of Dollars)

Year	All Firms		Ethical Firms		Proprietary Firms		Conglomerate Firms	
	(MM\$)	(%)	(MM\$)	(%)	(MM\$)	(%)	(MM\$)	(%)
1962	\$2,743.6	100%	\$907.6	33%	\$528.4	19%	\$1,307.6	48%
1961	2,412.9	100	800.5	33	413.0	17	1,199.4	50
1960	2,247.1	100	731.1	33	389.1	17	1,126.9	50
1959	2,126.8	100	701.0	33	354.0	17	1,071.8	50
1958	1,927.3	100	643.1	33	326.5	17	957.7	50
1957	1,818.4	100	603.8	33	294.5	16	920.1	51
1956	1,583.2	100	522.4	33	244.3	15	816.5	52
1955	1,353.3	100	469.9	35	173.6	13	709.8	53
1954	1,151.2	100	384.4	34	126.8	10	640.0	56
1953	1,093.7	100	367.3	34	117.8	11	608.6	55

Source: Moody's Industrial Manual (New York: Moody's Investors Service, Inc., 1963).

APPENDIX C

APPENDIX C

TOTAL NET (POST-TAX) PROFITS OF THIRTEEN SAMPLE FIRMS--BY INDUSTRY GROUP (Millions of Dollars)

Year	All Firms		Ethical Firms		Proprietary Firms		Conglomerate Firms	
	(MM\$)	(%)	(MM\$)	(%)	(MM\$)	(%)	(MM\$)	(%)
1962	\$276.1	100%	\$108.4	39%	\$54.7	20%	\$113.0	41%
1961	243.3	100	97.7	40	41.9	17	103.7	43
1960	227.4	100	90.0	40	39.8	17	97.6	43
1959	221.9	100	93.8	42	35.6	16	92.5	42
1958	199.1	100	86.8	44	30.7	15	81.6	41
1957	187.5	100	83.7	45	26.7	14	77.1	41
1956	155.5	100	68.7	44	19.8	13	67.0	43
1955	123.4	100	56.1	45	14.8	12	52.5	43
1954	93.2	100	39.8	43	10.9	12	42.5	45
1953	78.0	100	33.1	42	8.7	11	36.2	47

Source: Moody's Industrial Manual (New York: Moody's Investors Service, Inc., 1963).

APPENDIX D

APPENDIX D

ESTIMATED RESEARCH AND DEVELOPMENT COSTS OF THIRTEEN SAMPLE FIRMS--BY INDUSTRY GROUP (Millions of Dollars)

Year	All Firms		Ethical Firms		Proprietary Firms		Conglomerate Firms	
	(MM\$)	(%)	(MM\$)	(%)	(MM\$)	(%)	(MM\$)	(%)
1962	\$125.8	100%	\$64.8	52%	\$18.0	14%	\$43.0	34%
1961	113.0	100	58.3	52	14.8	13	39.9	35
1960	107.2	100	57.7	54	12.4	12	37.1	34
1959	100.8	100	54.6	54	10.4	10	35.8	36
1958	86.3	100	46.2	54	8.5	10	31.6	36
1957	76.7	100	39.9	52	7.2	9	29.6	39
1956	62.0	100	31.1	50	5.1	8	25.8	42
1955	52.9	100	26.3	50	3.4	6	23.2	44
1954	45.0	100	21.6	48	2.4	5	21.0	47
1953	40.5	100	19.6	48	2.1	5	18.8	47

Sources: Moody's Industrial Manual (New York: Moody's Investors Service, Inc., 1963); Kenneth Hayes, "Research--The Key to a Healthier America," The Exchange (New York Stock Exchange), XX, No. 4 (April, 1959), 13; Research Department, Merrill Lynch, Pierce, Fenner and Smith, Inc., 70 Pine Street, New York, N. Y.

APPENDIX E

APPENDIX E

RESEARCH AND DEVELOPMENT COSTS AS A PERCENT OF NET SALES FOR THIRTEEN SAMPLE FIRMS--BY INDUSTRY GROUP

Year	All Firms (%)	Ethical Firms (%)	Proprietary Firms (%)	Conglomerate Firms (%)
1962	5%	7%	3%	3%
1961	5	7	4	3
1960	5	8	3	3
1959	5	8	3	3
1958	4	7	3	3
1957	4	7	2	3
1956	4	6	2	3
1955	4	6	2	3
1954	4	6	2	3
1953	4	5	2	3

Source: Calculated from Appendixes B and D, pp. 215 and 219, supra.

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