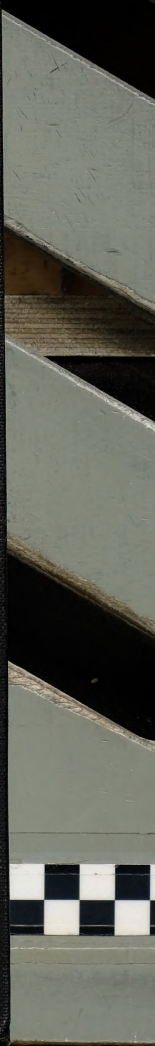
THE EFFECTS OF A GOVERNMENT INVESTIGATION ON MARKETING PRACTICES IN THE PHARMACEUTICAL INDUSTRY

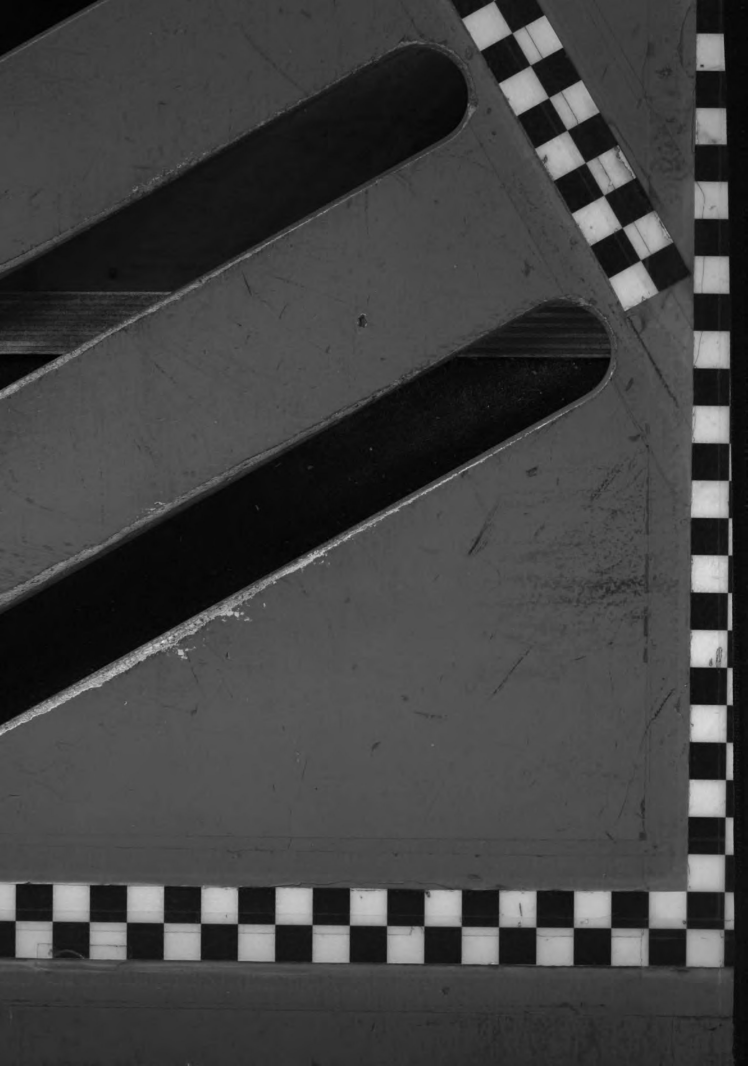
THESIS FOR THE DEGREE OF PH. D.

MICHIGAN STATE UNIVERSITY

M. DALE BECKMAN

1968





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This is to certify that the

thesis entitled

THE EFFECTS OF A GOVERNMENT INVESTIGATION ON MARKETING PRACTICES IN THE PHARMACEUTICAL INDUSTRY

presented by

M. DALE BECKMAN

has been accepted towards fulfillment of the requirements for

Ph.D. degree in Business Administration

William Lazer
Major professor

Date 15 November 1968

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ABSTRACT

THE EFFECTS OF A GOVERNMENT INVESTIGATION ON MARKETING PRACTICES IN THE PHARMACEUTICAL INDUSTRY

by M. Dale Beckman

The role of government control and influence of business practices has taken on increasing importance during the past three decades. Today, it affects virtually all facets of the firm's operation. One of the many ways government exerts control over business is through a Congressional investigation into aspects of business activity. The effects on industry of such scrutiny, publicity, and the resulting legislation can be substantial. Yet little is known of the impact of a government investigation on business practices. This study seeks to investigate the specific effects of the Kefauver Investigation of the Pharmaceutical Industry on new product development, pricing, promotion, public relations, and Industry concentration.

The late Senator Kefauver, Chairman of the Senate Sub-committee on Anti-trust and Monopoly, initiated an investigation of the Pharmaceutical Industry in 1959. The Investigation generated extensive publicity, and criticized many aspects of Pharmaceutical Industry activities. Specifically, it was concerned

with the fact that the majority of Industry sales are held by a relatively few large companies, and that prices of most brand name products are higher than those of products sold by generic name. In addition, the Investigators criticized the product development and promotional practices of the Industry.

As a theoretical basis for the research a survey of the literature concerning the history, legal status, inner workings, and the role of the press in Congressional investigations was made. This survey, coupled with an analysis of the management, operation, and accomplishments of four other Congressional investigations led to the development of a model for conceptualizing investigations. A list of operational criteria for evaluating the conduct and management of government inquiries was also established.

Primary data were obtained from a detailed case study by personal interview of eight carefully selected pharmaceutical firms. Executives directly involved with operations affected by the Kefauver Investigation were interviewed. A substantial amount of useful data was obtained from secondary sources such as government statistics, correspondence with the Food and Drug

Administration, the Pharmaceutical Manufacturers Association, and trade and business periodicals.

The Investigation and subsequent Drug Act Amendments are not associated with any observable effects on existing declining trends in new product introductions in the short run (1963 - 1967). However, the Amendments created conditions which will decrease new product development in the long run. New regulations increased the number of tests, lengthened the time before products are approved for sale, and made co-operation difficult between the Food and Drug Administration and the Pharmaceutical Industry. The findings showed that most firms in the sample curtailed research and development efforts on limited-use drugs, because of stringent and costly government requirements. The Investigation, however, is associated with the adoption of practices which increase the probabilities that new products will be somewhat safer than those introduced to the market prior to the Investigation.

The Investigation also affected the advertising area. Increased medical journal advertising costs of approximately 25 per cent to 100 per cent, and greater complexities in undertaking all promotional activities can be associated with the Investigation. The resulting new regulations demand adherence to new broadly-worded standards which the Pharmaceutical Industry has found

difficult to understand and meet. Nevertheless, more accurate drug promotion is associated with these new regulations.

Despite the considerable adverse publicity concerning the Pharmaceutical Industry, the majority of firms studied did not respond by increasing public relations efforts. Most firms do not have a public relations program aimed at the general public. Current PR activities seem to be geared mainly to provide a company and/or Industry defense -- to have appropriate answers when public criticism comes. Even after the Investigation, remarkable indifference remains on the part of the Industry to the questions and criticisms of the public conerning Pharmaceutical Industry activities.

Industry concentration trends were unaffected by the Investigation. Concentration as measured by share of Industry sales accounted for by the top four, eight, and twenty companies maintained a gradual, but steady decline from 1958 to 1966. The competitive balance, and the size gap between large and small pharmaceutical firms appear to be relatively unaffected by the Kefauver Investigation.

THE EFFECTS OF A GOVERNMENT INVESTIGATION ON MARKETING PRACTICES IN THE PHARMACEUTICAL INDUSTRY

By

M. Dale Beckman

A THESIS

Submitted to
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in partial fulfilment of the requirements
for the degree of

DOCTOR OF PHILOSOPHY

Department of Marketing and Transportation Administration

1968

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Acknowledgements

I am indebted to the Upjohn Company for supporting the research for this thesis, and especially the help of Mr. J. R. Jackson. I further wish to thank Mr. Jackson and his staff - particularly Mr. Richard Rose - for their advice, comments and assistance in obtaining information.

My thanks go to Dr. William Lazer, the Chairman of my thesis committee who devoted much time to reading and editing the several drafts of the thesis. I am grateful to Dr. W. J. E. Crissy who provided many valuable suggestions and was an enduring source of inspiration. I thank Dr. Bernard J. LaLonde who made sound and constructive comments which strengthened the study. These two men also served on my thesis committee.

I welcomed the interest and assistance of Mr. Jim Russo of the Pharmaceutical Manufacturers Association in obtaining much-needed information. I owe special thanks to the many individuals who were generous with their time and willingness to answer questions.

Most of all I owe a special debt to my wife, Roberta Beckman, for providing understanding, encouragement, and countless hours of able assistance. It is to her that this study is dedicated.

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CHAPTER I

GOVERNMENT - BUSINESS RELATIONSHIPS

Introduction to the Study

Background

The role of government control and influence of business has taken on increasing importance during the past three decades. Today, it significantly affects virtually all facets of the firm's operation.

A considerable amount of government administration is an indispensable component of a free enterprise system. Government must be concerned with such matters as private property, freedom of contract, money and credit, weight and measures, and a system of civil law for adjudicating the private disputes of individuals and organizations. Such institutions make possible an elaborate system of private planning in which individuals, rather than governments, organize and direct the production of goods and services in response to the desires of the consumers.

Government also is important in providing an atmosphere of growth and productivity. It sets the basic ground rules to guard against monopoly and other restrictive practices, the promotion of technical improvements, the use of monetary and fiscal measures to

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In the United States attitudes of society concerning government influence since the 1800's have changed. There is now an increasing acceptance that government should assume greater responsibility in overseeing business activities. Government exerts control over business in a number of ways. First, certain laws specifically direct business activities. Second, many regulatory bodies have been established to interpret the law and control business practices. Today, "a list of them takes up more than fifty pages in the Congressional Directory". [1] Third, the FTC has served as a public watchdog since it was established in 1914, and its activities have steadily increased. Fourth, as a large customer, government can affect business decisions and actions. For example, a government agency recently rejected bids of United States pharmaceutical companies and bought large quantities of antibiotics from foreign suppliers. Also, the federal government threatened to release huge stockpiles of aluminum to the market if the aluminum companies would not rescind a price increase. Fifth, and closely related, is the use of government influence to force businessmen to act in certain ways. Recently, a number of manufacturers, including pharmaceutical companies were

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[1] "Errant Policemen", Barron's, February 3, 1958.

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called to Washington and "requested" to broaden hiring practices. Further examples of informal government influence are suggested wage and price guidelines.

A more drastic method of government influence on business activities is the Congressional investigation. Such action may subject an individual, a company, or an industry to detailed scrutiny of many activities normally considered private. It can affect business through the instigation of new laws which could totally change the competitive or financial structure of an industry. Exposure of previously private information and practices to competitors can be damaging. Furthermore, the publicity resulting from an investigation can affect business through changed public opinion.

Since World War II, Congress has increasingly turned to investigation as a tool of government. [1] Investigations have been used both to attack business for some of its practices--notably pricing policies and advertising claims--and to aid industries in distress, such as mining and railroads. However, the most prevalent form of investigations has sought to attack, change, or control business in some manner.

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[1] "Congressional Probes: Lots Already, More Coming", Business Week, August 9, 1958, pp. 28 - 30.

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Scope of the Study

While the potential impact of a government investigation is large, little is known of its effects on business practices. This study will examine the effects of the Kefauver Investigation and the Drug Act Amendments of 1962 on some marketing practices in the Pharmaceutical Industry. The findings will not be applicable to all industries, nevertheless, some insights should be gained into the inner workings of congressional investigations themselves, factors leading to the initiation of an investigation, and effects on marketing practices, which may be generalized to some other situations.

Organization

This study is comprised of two parts:

1. The Background Research--The balance of Chapter I provides a description of Congressional investigations, and a means for evaluating them. Chapter II traces the rapid development of the Pharmaceutical Industry and gives some reasons why it became subject to an investigation. The actual Investigation is evaluated in Chapter III, and the main legislation arising from it is given.
2. The Empirical Study--In Chapter IV, hypotheses are presented and methodology for the empirical study is

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developed. Chapters V and VI present the findings, recommendations, and conclusions of the study.

Government Investigations

History of Congressional Investigations

The Constitution of the United States does not expressly confer upon either the House of Representatives or the Senate the power to conduct investigations. Yet in 1792, within three years of its adoption, the House of Representatives created a special committee to investigate the failure of the St. Claire expedition against the Indians of the Northwest, and in 1818 the Senate authorized its first investigation.[1] It has been estimated that since the St. Claire inquiry as many as 600 investigations have been conducted.[2]

For almost a hundred years following the St. Claire investigation, Congressional inquiries were subject to little supervision or control by the judiciary. Both the Senate and the House frequently used investigatory power not only to inquire into the honesty and efficiency of the executive branch of the government, but also to obtain information to assist

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[1] Joseph N. Smee, "One for the Money, Two for the Show: The Case Against Televising Congressional Hearings", Georgetown Law Journal, Vol. 42, No. 1, November 1953, p. 3.

[2] M. Nelson McGeary, "Congressional Investigations: Historical Development", University of Chicago Law Review, Vol. 18, No. 3, Spring, 1951, p. 425.

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[1] Ibid.,

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Review: Kilbourn

537, 1949, p. 55

Congress in its task of legislating wisely and intelligently.

Little opposition ever developed within Congress concerning its right to authorize investigations. But outside of Congress, the legality of inquiries directed at obtaining information to help enactment of laws was questioned. In 1827, however, the House gave committees the power to compel witnesses to testify in a lawmaking investigation.

The first serious challenge to the power of Congress to conduct investigations occurred in 1880. In Kilbourn versus Thompson the Supreme Court sharply narrowed the scope of power. [1] The decision required that investigations should be conducted with a clear and precise constitutional purpose. Doubt was also cast on the existence of a Congressional power to compel testimony for the principal purpose of obtaining information to assist Congress in drafting legislation. [2] In spite of this doubt, both Houses of Congress zealously continued to investigate.

From the first inquiry in 1792, one purpose of many investigations had been to embarrass the Administration or hold it in check.

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[1] Ibid., p. 428.

[2] J. Morgan, "Congressional Investigations and Judicial Review: Kilbourn versus Thompson revisited", California Law Review 537, 1949, p. 556.

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"Congressmen, when investigating . . . were frequently politically motivated; they sought actual electioneering ammunition with as much earnestness as they delved for information to aid in legislating." [1]

Over time, the Courts have granted more power to Congressional investigating committees and are liberal in allowing committees to proceed almost at will. The only criterion seems to be whether the subject under scrutiny may have any relevance and significance, no matter how remote, to some possible legislation. [2] Thus an almost unlimited mandate is given.

Legal Status

Investigations are incident to enabling Congress to perform its function of enacting legislation. All matters that will aid determination of need for, or formulation of legislation may be investigated. Wiles suggests that the purposes of every investigation by a Congressional committee fall within one or more of the following groups: [3]

a. to ascertain what new legislation is needed

b. to ascertain what existing laws should be repealed

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[1] McGeary, pp. 430 and 431.

[2] Frank E. Horack, Jr., "Congressional Investigations: A Plan for Legislative Review", American Bar Association Journal, Vol. 40, March 1954, p. 191.

[3] Walter E. Wiles, "Congressional Investigations: Re-examination of the Basic Problem", The American Bar Association Journal, Vo. 41, June 1955, p. 538.

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c. to ascertain whether enacted legislation is effectively accomplishing its purpose

d. to inquire into the fitness of nominees for office

e. to secure information on the advisability of ratifying a treaty

f. to inquire into the need for submission of a constitutional amendment

g. to police conduct of members of Congress themselves

h. to inquire into the conduct of public officers

In theory, the facts singled out in an investigation should be those most relevant to a clarification of the area under inquiry. Since most subjects can be approached from many points of view, there is usually wide latitude in any investigation for discrimination among subjects chosen for examination. Investigators can, therefore, use inquiries for political, or personal ends as well as for the public good.

As opposed to courts of law, investigations have few formalized rules to protect individuals or companies being questioned. Personal abuse, unpleasantness, or possible social and economic discrimination, arising in or from the investigation does not afford a basis for judicial intervention. The feeling is that Congress cannot legislate effectively in the absence of information, and therefore Courts have repeatedly emphasized the importance of the Congressional power of investigation. Congress recognizes that the exercise of power in many situations will infringe upon the rights of the individual to

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conduct his affairs free from government interference. An individual summoned before a Congressional committee may rely for protection against an undue invasion of his privacy only upon the requirements that 1) the investigation relate to a purpose which Congress can constitutionally entertain, and 2) the particular question asked the witness fall within the grant of authority actually made by Congress to the committee. [1] The Courts have stated that the legislators are as much guardians of the rights and welfare of the people as the Courts. Therefore they are presumed to have good judgement in the conduct of investigations.

Inner Workings of Government Investigations

To investigate effectively, a Congressional committee must have a virtually unrestrained delegation of the vast Congressional power. As a practical matter, this means that power to investigate is wielded by individuals, not institutions. Great power, without formal restraints, heightens the hazards of abuse because the restraints must be imposed by those who also wield the power. [2]

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[1] "Congress vs. the Courts: Limitations on Congressional Investigation", University of Chicago Law Review, Vol. 24, Summer, 1957, p. 740.

[2] J. W. Fulbright, "Congressional Investigations; Significance of the Legislative Process", The University of Chicago Law Review, Vol. 18, Spring 1951, No. 3, p. 442.

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One of the most important circumstances determining the character of a particular investigation is the official motivating influence behind the investigation. "Since almost any problem may be a governmental problem these days, it can be quite generally agreed that there are no limits to the fields with which Congress may concern itself. It would follow that there is no limit to the ideas which may officially motivate an investigation." [1]

How do Congressional investigations get started, and how are they, in general, conducted? Some investigations are undertaken because of a need for information to guide legislation. Other investigations are instigated for purely political reasons - to discredit members of an opposing party. Others are authorized because Congress is angry or unhappy with the actions of some Executive agency, or organization. [2] Investigations are frequently begun because some member of the House or Senate believes he has found a field of inquiry which can gain public attention, or because some member who is popular with his colleagues wants to be chairman of an investigating committee. [3]

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[1] Ibid.

[2] Congressional Probes: Lots Already, More Coming", Business Week, August 9, 1958, pp. 28 - 30.

[3] Jerry Voorhis, "Congressional Investigations: Inner Workings" The University of Chicago Law Review, Vol. 18, Spring 1951, No. 3, p. 456.

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Despite varying motivations, investigations may be beneficial. However, there is a much greater chance of a worthwhile outcome if the investigation is begun with a public-spirited motivation.

The member of Congress who believes an investigation should be conducted and puts forth a resolution to that effect is automatically placed in the position of chairman of an appointed committee. After this, a number of critical decisions are made. First, a staff must be engaged. Ideally, a number of meetings of the committee would be held where applicants are carefully screened. But often the chairman presents staff personnel of his choice to the committee for approval. "In such cases the proposed staff members are altogether likely to be 'deserving' persons from the chairman's home district. Sometimes they are even blood relatives." [1] Generally the committee members acquiesce to the chairman's choice.

The effectiveness of the investigation also depends, in large measure, upon how well the general plan of the investigation is developed. As mentioned earlier, the problem can be attacked from many different perspectives, and it is important to establish major divisions for study, what witnesses to call, and how to divide the work in some logical manner. The chairman usually dominates

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[1] Voorhis, "Inner Workings", p. 458.

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[1]Ibid.

[2]Ibid.

the proceedings, often choosing subject matter and time and place of hearings without consultation with committee members. Subject matter of political consequence to some member of Congress may receive attention out of all proportion to its other significance. [1]

Committee work is not easy. All members have other schedules and adequate committee participation requires time for preparation and attendance at the hearings. Unless members take their assignments seriously, a committee tends to be heavily dominated by the chairman. Each member must study diligently to keep pace with the subject matter of the investigation. Each may be under pressure from people across the country, most of whom will have preconceived ideas of what the investigation should produce. At the same time, the committee member is under constant intra-committee pressure to go along peacefully.

> The effectiveness of Congressional investigations - as distinguished from the amount of publicity they receive - is dependent upon five principal factors. These are: The character and capabilities of the committee chairman; the care with which committee reports are prepared and the extent to which emphasis is placed on the official reports rather than interim statements by individual committee members; the calibre of the committee staff; the degree with which fair and judicious rules of procedure are adopted and observed; and the absence of partisan or political bias. [2]

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[1] Ibid.

[2] Ibid., p. 460.

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The Role of the Press in Government Investigations

Much information disclosed in an investigation is made known to the public by the press. However, abuses also emanate from methods used by the press and investigators to handle the dissemination of information.

Newspapers seek the unusual. For example, charges of exorbitant profit margins in the case of pharmaceuticals were displayed in sensational headlines.

> As costs of publishing mount, the proportion of advertising space is high, with the result that space for news is frequently reduced. So it is that the direct news from Congressional investigations always gets printed. As a rule, denials receive less attention than the charges. Even proof of innocence may never catch up with the assertions of guilt. Indeed, proof of innocence may come so late as to be almost unrelated to the original charges. [1]

Sensational display of news has been explained in terms of newspaper competition for readers. However, competition within the newspaper field has declined as the merging of many newspaper interests has been observed.

> Yet even the most devoted editor is not entirely a free agent on the side of truth . . . even though the editor knows a certain item is a lie, he must print it because it is spoken by a prominent public official. The public official's name and position make the lie

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[1]Erving Dillard, "Congressional Investigations: The Role of the Press", The University of Chicago Law Review, Vol. 18, Spring 1951, p. 587.

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[1]Ibid.

> news . . . Also, it is difficult to know where truth is in all cases. Furthermore, it is not the editor's duty as a presentor of the news to deal also in opinion. He must leave the sorting of the lies, in part at least, to those under attack. By printing the denials and the evidence to support the denials he can help bring truth to light. [1]

Editors are responsible for exposition of other viewpoints by expressing doubts, asking questions, and giving reasons for their disbelief. They may disprove a statement if evidence is available. Editorials ought to make plain what the newspaper itself thinks about news which it feels obliged to print.

Press practices and habits lend themselves to exploitation by Congressional investigators. Reporters have deadlines at which to report news and astute investigators can manipulate the release of sensational news at times most convenient for reporters. Rebuttal arguments can be postponed to less convenient times during a hearing, reducing the likelihood that they will ever catch up with original accusations. The original motives of the investigator determine whether such manipulation will occur.

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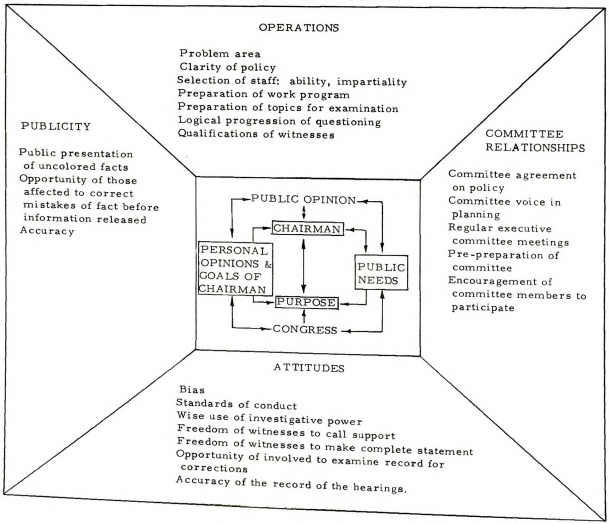
[1] Ibid., pp. 587 and 588

EXHIBIT 1

A MODEL FOR CONCEPTUALIZING THE FORCES AND INTERRELATIONSHIPS OF A GOVERNMENT INVESTIGATION

EXHIBIT 1

A MODEL FOR CONCEPTUALIZING THE FORCES AND INTERRELATIONSHIPS OF A GOVERNMENT INVESTIGATION



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The Management of Government Investigations

A Model for Conceptualizing Investigations

Exhibit 1 presents a model for conceptualizing the forces and interrelationships of a government investigation. The chairman, as the central figure empowered by Congress, determines the purpose, provides leadership, direction, and the motivating force to initiate and bring an investigation to its ultimate conclusion. He is influenced by, and seeks to influence, public opinion, public needs, and Congress. According to personal goals and opinions he may use an inquiry to affect any of these elements.

One chairman may use an investigation to alleviate a public need (e. g. crime). Another may use an investigation into a public problem primarily for political purposes, or to "prove" preconceived notions.

The force emanating from the foregoing relationships depicted at the core of the model significantly influences the overt characteristics: operations, committee relationships, attitudes, and publicity.

Operational Criteria for an Investigation

Government investigations are a necessary part of the legislative process, and can be valuable if properly conducted. However, there are often severe weaknesses. Since the purpose of this study is to evaluate some effects of a specific investigation,

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and provide a basis for the development of future opinions, and activities, a list of criteria for its evaluation and management will be presented. These criteria were developed from a consideration of the material in the foregoing discussion of investigations, plus an analysis of the management, operation, and accomplishments of four different Congressional investigations.[1] The criteria will provide one basis for understanding and evaluating the Kefauver and other investigations and may also guide those participating in future inquiries.

The following criteria are presented under similar sub-headings to the overt characteristics of the model for interrelating them with it. Following their presentation, a format for using the criteria for evaluation of an inquiry will be suggested.

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[1] This list of criteria was independently developed by this author from an analysis of literature concerning investigations, as well as an examination of the activities of four different investigations: The Un-American Activities Committee, Senate Preparedness Sub-Committee, House Select Committee on Lobbying Activities, and the House Sub-Committee on Monopoly Power. However, the literature abounds with similar lists. The concepts embodied in the criteria developed for this study correlate closely with the other proposals. One such list by George B. Galloway, Senior Specialist in American Government in the Library of Congress is reproduced in Appendix A. It is a compilation of criteria proposed by fourteen different individuals, groups, or organizations. The names of these sources are also included in Appendix A.

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I. Purpose

1. Investigations should be launched because of a specific need of the nation to gather knowledge concerning a certain field and not for political, personal, or vindictive reasons.

II. Chairman

1. Because of the important nature of subjects to be discussed by Congressional committees, chairmen should be selected according to character and capabilities for managing an investigation.

III. Operations

1. A clear statement of policy should be developed before other activities are undertaken. It should be established by agreement of all the members of the committee and include the proper definitions and scope of the subject.

2. The first step in organizing a study is the preparation by the whole committee of a general plan and work program in outline form. It should contain a complete summary of the policy expression previously formulated. Public presentation of the study will then cover all aspects of policy considered worthy of

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public discussion. The effectiveness of the investigation depends in large measure on such pre-planning.

3. Subject matter should receive attention in proportion to its significance to the study. Topics of political consequence to some members should not be overplayed.
4. To insure depth of topic coverage, a hearing should be organized in detail as well as in general outline form. A primary tool for this part of the preparatory work is a list ot questions carefully composed and keyed to the several factual studies already undertaken by the staff.
5. Careful selection of investigative staff is vital. Members should be chosen on the basis of ability and impartiality to the subject matter. Screening by committee members is desirable.
6. Extensive and complete staff work must be undertaken before the hearings are held so all committee members will be well informed concerning the subject of discussion.
7. Examination of witnesses should be the result of careful preparation, so questioning can be thorough and the truth brought out. This will eliminate the common "fishing expedition".

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8. A series of questions should be set up designed to get to the core of each problem, by a process of logical reasoning.
9. Accurate stenographic record must be kept of all testimony at public hearings. Furthermore, material included in the record should be representative and unbiased.

Committee Relationships

1. Once underway, executive meetings should be regularly held to evaluate the work done so far, and to discuss material to include in the final report.
2. Committee members should be encouraged to take their assignments seriously, and prepare themselves for the hearings.
3. Attendance of all committee members should be encouraged.
4. Members of the committee should keep written notes, during the hearings, to which they can refer later.

Attitudes

1. The power of inquiry is unquestioned, and its possession is a great public trust. Committees should strive to

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evolve appropriate standards of conduct for the undertaking of such investigations.

2. While the committee must be free to investigate a topic thoroughly, procedures should not jeopardize or endanger the freedom of the individual.
3. When public testimony defames or adversely affects any person's reputation, reasonable opportunity should be given to him to call witnesses in his own behalf and otherwise to answer the charges adequately.
4. Witnesses should be entitled to make a full and fair presentation of the matter under investigation; to obtain advice of counsel; and other assistance necessary to protect their rights.
5. Witnesses should not come before a commission without having some substantial contribution of facts or policy.
6. Witnesses representing all sides of an issue should be given equal opportunity to testify.

Publicity

1. After the investigation is completed, those affected should be shown a draft of the report and afforded opportunity to correct mistakes of fact inadvertently set forth. Only after this may the report be made public.

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2. The committee should strive diligently to present the public with unbiased facts.

Conclusions

1. The shortcomings of Congressional investigations lie largely in the abuse or misuse of investigative power. The hope of overcoming these abuses lies in education, understanding, and development of accepted rules and practices. To date, few concerted, positive steps have been taken in these areas.
2. Publicity has played a dominant part in many investigations. Herman Finer astutely puts this phase of investigations into perspective: "Publicity is the antiseptic of the democratic body politic. It ought to be administered in appropriate doses at the proper time, preventively if possible. But the body will be ravaged and tortured into disgust and stupidity, it might even be killed, if vitriol is thrust down the patient's throat, the vitriol of despotic temper and savage persecution." [1] This is an appropriate warning for all investigations.

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[1] Herman Finer, "Congressional Investigations: The British System", The University of Chicago Law Review, Spring, 1951, Vol. 18, p. 521.

Evaluation of the Management of an Investigation

Based on the foregoing criteria, Figure 2 presents a format for evaluating the management of an investigation. For each criterion, it is possible to indicate, by a check the degree of conformance with the ideal. When completed, a ready summary picture materializes.

This evaluation chart is used in Chapter 3 (p. 84) to assess the management of the Kefauver Investigation.

Criteria

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FIGURE 2

INVESTIGATION EVALUATION CHART

Criteria	In accordance with criteria*		Not in accordance with criteria		
Purpose					
Selection of Chairman					
Clarity of policy and committee agreement					
Preparation of work program					
Committee voice in planning					
Selection of staff:					
- ability					
- impartiality					
- committee's voice					
Pre-preparation of committee					
Regular executive meetings of committee					
Encouragement of committee members to participate					
Preparation of topics for examination of witnesses					
Logical progression of questioning					
Standards of conduct					
Freedom of witnesses to call support					
Freedom of witnesses to make complete statement					
Qualified witnesses called					
Witnesses from all significant viewpoints					

Criteria	
Accuracy and c of record	
Opportunity of examine reco correctness	
Bias	
Wise Use of in power	
Public present uncolored fac	

[a]As in the serr at each pole.

FIGURE 2 -- Continued

Criteria	In accordance with criteria*			Not in accordance with criteria	
Accuracy and completeness of record	____	____	____	____	____
Opportunity of involved to examine record for correctness	____	____	____	____	____
Bias	____	____	____	____	____
Wise Use of investigative power	____	____	____	____	____
Public presentation of uncolored facts	____	____	____	____	____

*As in the semantic differential technique, the extremes are indicated at each pole. Marks in the center column indicate neutrality.

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CHAPTER II

DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY: PROGRESS TOWARDS SUCCESS AND CRITICISM

This chapter has three main objectives:

1. To show the recency of growth and contributions of the Pharmaceutical Industry by briefly tracing its history.
2. To show how rapid growth led the Industry into:
   a) a "success position" ripe for criticism,
   b) practices and attitudes open to criticism.
3. To outline briefly the structure and practices of the Industry.

The Early Years of Pharmaceutical Production

The history of the Pharmaceutical Industry is associated with the development of medications. Advancement of medical therapeutics, however, was slow for many years. With the exception of the discovery of insulin by Banting and Best at the University of Toronto in the early 1920's, little progress in new product development was made in the period from 1900 to 1934. The pharmaceutical products available to a physician in the 1920's was little better than that of his predecessor a century earlier. There were only three basic drugs in the 1920's :

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aspirin, phenacetin and caffeine -- which were combined with codeine, quinine and belladonna in various ways -- to account for an estimated sixty per cent of all prescriptions written. Pneumonia was still treated with vapor baths, kaolin, poultices and fumigations of the sickroom.[1]

> Thus, at the end of the 1920's although the groundwork had been laid for the impending chemotherapeutic revolution, the chances of surviving most serious illnesses were not very much better than a century earlier. Every third victim of pneumonia died. Tuberculosis was still a major killer. Post-operative infections could still prove fatal all too often. To be smitten by streptocci was often a death sentence. There was no hope for victims of pernicious anemia. Significant advances over the previous half-century had been improvements in sanitation and public health measures. Also available was a range of vaccines, sera, and anti-toxins with which to prevent or treat a limited number of infectious diseases.
>
> Few then complained about the price of medicines because most were galenicals which had been available in some form or other for centuries. Only a handful, such as quinine and digitalis, had any specific effect on disease. The few synthetic drugs, such as aspirin and the barbiturates had been available for a generation. Apart from Salvarsan for the treatment of syphilis, the synthetics were able only to relieve symptoms or induce sleep. For anaesthesia, ether, chloroform and nitrous oxide were still being used as for the past 90 years.

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[1] Michael H. Cooper, Prices and Profits in The Pharmaceutical Industry, (London: Pergamon Press, 1966), p. 5.

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> Since there were so few specifics available doctors were mostly in fact, treating symptoms with sedatives, stimulants, tonics, trying to help the body to rally its natural resistance to the invasion of some infection. Even where prospects of a more direct attack on disease were brightest, the difficulties were immense. For example, to treat pneumonia with sera, over thirty different types of pneumococci had been identified and a separate anti-serum had to be prepared for each one. [1]

The Pharmaceutical Industry itself progressed only a little faster than the development of medications. In the mid-1800's a number of the presently known pharmaceutical companies became established. Their work was usually characterized by some special formulation which became extremely popular (e. g. of a laxative) or by the development of a better format for current medications (e. g. tablets, capsules, or friable pills). The demand for such products during the Civil War enabled such firms to expand and develop their operations to a significant size.

With a developing economic base, companies could afford to organize and develop chemical and pharmaceutical research. Product lines and sales expanded over time. Consistent sales and advertising programs enabled doctors across the country to learn about the new products, which further expanded sales and financial stability.

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[1] F. H. Happold, Medicine At Risk, (London: The Queen Anne Press Ltd. 1967), pp. 33 - 34.

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During the late 1920's, pharmaceutical companies continued to grow, and gradually added a number of full time Ph. Ds and other assistants in research work. The Industry was also improving manufacturing processes, and learning how to assure purity and consistency in each product.

By 1930, although significant pharmaceutical preparations were scarce, an elaborate foundation had been laid to serve as a launching pad for future developments. Most firms had experienced and well trained research staffs. Research information was being accumulated both from within and without the Industry. Many firms had achieved substantial size, and, therefore, could afford to perform significant research on their own. Additionally, they had developed sales and distribution facilities which could readily accommodate new product developments.

The Birth of the Modern Pharmaceutical Industry

Before 1935 the main cause of death has been systemic microbial infections. In that year a sulfonamide Prontosil -- the first successful antimicrobial agent was developed. This marked the beginning of the pharmaceutical revolution [1] and

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[1] Cooper, Prices and Profits, p. 5.

heralded a new therapeutic era, stimulating the research efforts of many scientists. The organization and experience of the pharmaceutical manufacturers enabled widespread distribution of the new product, and encouraged further development of this breakthrough. Many scientists applied the methodological approach of Ehrlich by testing various derivatives of the basic sulfanilamide until useful derivatives were found. Within a remarkably short time by earlier standards, more than 5,000 compounds were synthesized in academic and commercial laboratories. Many were useless, but a few showed promise.[1] Their use resulted in dramatic declines in deaths from lobar pneumonia.

This achievement of the Pharmaceutical Industry had wide repercussions, pointing the Industry's way forward to a more dominant role in new product development and therapeutic progress. The Industry began spending more on research and production facilities for sulfa drugs. Since the early sulfas had their limitations, competition was keen between firms to improve on existing products and to find radically new ones. This has been a significant Industry trait ever since.

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[1] Happold, Medicine At Risk, p. 36.

The search for more antibiotics led to the development of penicillin, which met a tremendous need, especially during World War II. However, there were formidable problems in developing an adequate supply. A massive effort on the part of the U.S. Pharmaceutical Industry, the U.S. government, and academic laboratories finally resulted in a method of producing enough to meet military and civilian needs.

Almost every important drug manufacturer began a search for improved forms of the present anti-infectives and new antibiotics. The discovery of streptomycin, the first effective drug against tuberculosis, was made in 1943. Since then a flood of other new antibiotics have been developed.

Pharmaceutical researchers found that further manipulation of the sulfanilamide molecule resulted in totally different drugs. Other substances and studies were re-examined for therapeutic properties in other indications. The efforts of preparation, study, research, and investment of past years, now began to come to fruition in a number of areas where there had previously been no treatment.

The Golden Era

The years 1948 to 1959 could well be described as the
en Era of the Pharmaceutical Industry for it was marked by
ost rapid development of its activities.

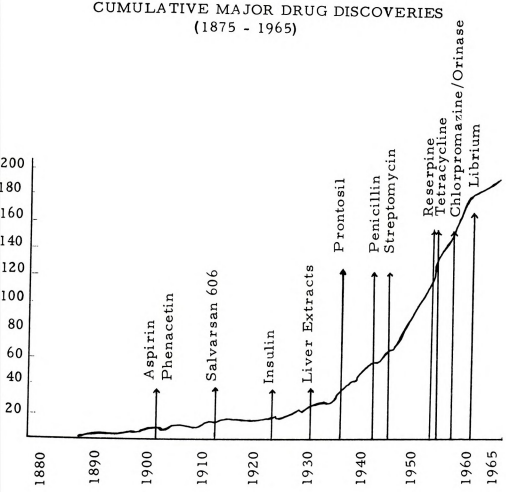
From 1940, when nine single chemical entities were
duced, the numbers tended to increase each year in a
eable trend through 1959, when the alltime peak of 63
ances were introduced. Figure 1, which cumulates major
discoveries from 1875 to 1965, clearly indicates the rapidly
ding product range upon which the sales and expansion
ties of the Pharmaceutical Industry were based.

Table 1 shows that while the antibiotic market increased
y from 1950, there were other new outstanding areas of growth.
e of the most significant were: diabetic therapy (+ 247 percentage
s), diuretics (+ 1,859 percentage points), and psychoterapeutics
,654 percentage points). Total sales of twenty major thera-
c classes increased by 37 percentage points from 1951 to 1955,
y 119 percentage points from 1951 to 1960. Comparable data
ter years is not available, however, continued rapid sales
h (Table 2) indicates a continuation of these trends.

Source:

FIGURE 1

CUMULATIVE MAJOR DRUG DISCOVERIES
(1875 - 1965)



ırce: Cooper, Prices and Profits, p. 7.

TABLE I

SALES INDEX OF U.S. MARKET CHANGE *

(1951 = 100)

Therapeutic Classes	1955**	1960
Analgesics	122	250
Antacids	178	323
Antibacterials and antiseptics	124	249
Antibiotics	100	140
Antihistamines	149	234
Antiobesity preparations	248	470
Antispasmodics and anticholinergies	142	226
Biologicals	105	247
Cardiovascular preparations	384	503
Cough and cold preparations	156	276
Dermatologicals	157	217
Diabetic therapy agents	130	347
Diuretics	325	1,959
Hematinics	100	82
Hormones and nonhormonal antiarthritics	159	204
Laxatives	117	125
Psychotherapeutics	2,150	10,754
Sedatives and hypnotics	174	206
Sulfonamides	115	157
Vitamins and nutrients	114	126
Average, 20 therapeutic classes	137	219

*Index reflects change in sales dollar volumes.
**Statistics for other years not available.
Source: Pharmaceutical Manufacturers Association, Prescription Drug Industry Fact Book (Washington, 1967), p. 11.

What of Industry sales? Whereas consumer expenditures for drugs only increased $7 million from $513 to $520 million in the ten years between 1929 and 1939, they jumped $812 million in the following decade, to total $1,322 million in 1949. In the next ten years they increased by $1,611 million to a new high of $2,943 million in 1959. The trend has continued; 1966 consumer expenditures for drugs were $4,303 million. Assuming similar growth conditions, 1975 consumer expenditures are projected to be $5,610 million.[1] Table 2 provides details concerning this dramatic growth picture.

Profits

Sparked by patent-protected new inventions and swiftly climbing sales, profits of drug corporations have been substantial in the past two decades. For example, return on sales ranged between 10.2 and 10.8 per cent from 1961 to 1966. Out of twenty major industry groups, drugs have been amont the top three in return on sales and invested capital since 1961.

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[1] See Figure 2 for a description of the projection.

TABLE 2

CONSUMER EXPENDITURES FOR DRUGS [b]

Year	Expenditures (millions)	Year	Expenditures (millions)
1929	$ 513	1962	$3,410
1939	520	1963	3,516
1949	1,322	1964	3,677
1950	1,461	1965	3,934
1951	1,682	1966	4,303
1952	1,749	1967	4,250*
1953	1,816	1968	4,420*
1954	1,839	1969	4,590*
1955	2,008	1970	4,760*
1956	2,262	1971	4,930*
1957	2,534	1972	5,100*
1958	2,716	1973	5,270*
1959	2,943	1974	5,440*
1960	3,066	1975	5,610
1961	3,195		

[b]Government reports consumer expenditures for "drugs and sundries", 15 per cent of which is attributed to "sundries" by the U.S. Department of Commerce, Office of Business Economics. Above data are derived by subtracting expenditures for sundries from the broader category of "drugs and sundries". Of the consumer retail expenditures for "drugs" in 1966, PMA estimated that prescription pharmaceuticals accounted for about 70 per cent. These government data do not represent the total amount spent directly on drugs since drugs used in physicians' offices, government health facilities, and hospitals are excluded.

*See Figure 2 for a description of the projection.

Source: Pharmaceutical Manufacturers Association, Prescription Drug Industry Fact Book (Washington, 1967), p. 58.

FIGURE 2: CONSUMER EXPENDITURES FOR DRUGS

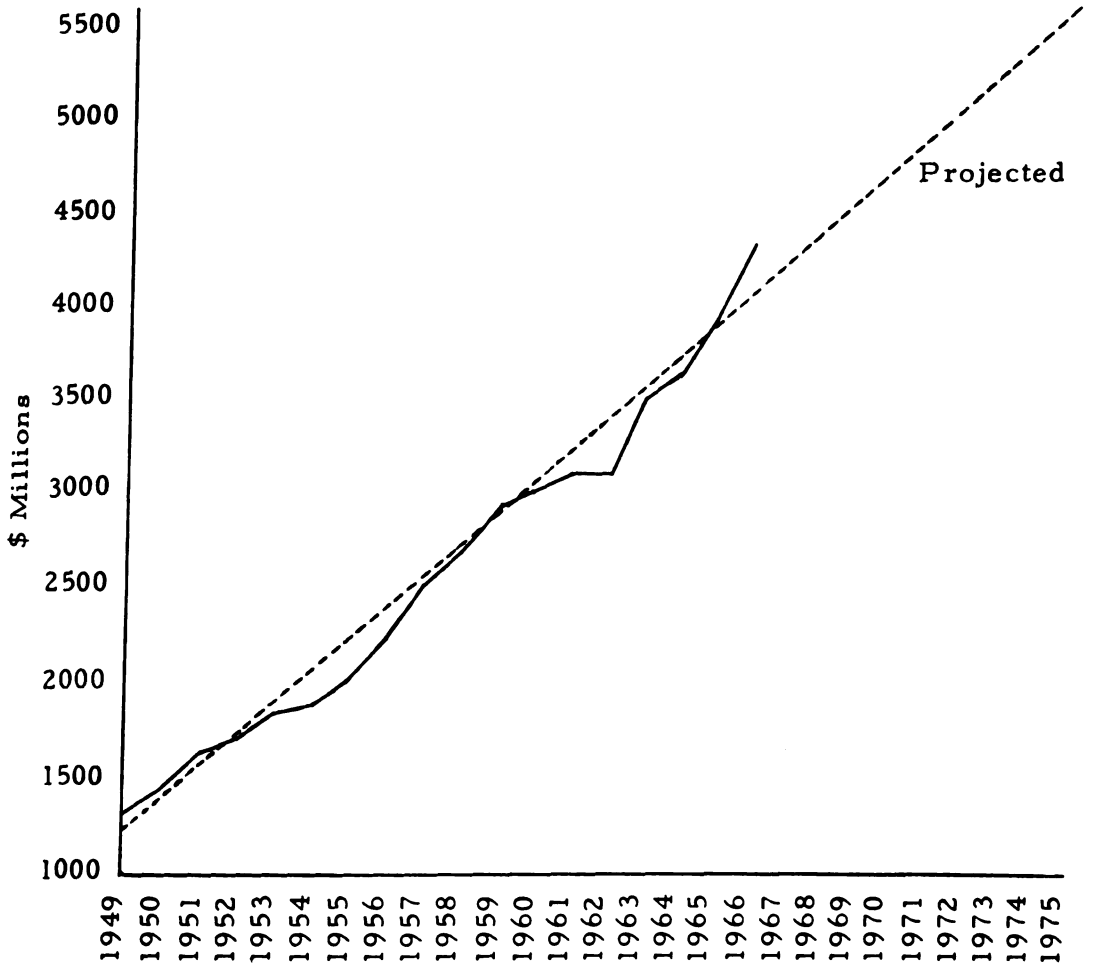

Figure 2 shows consumer expenditures for drugs from 1949 to 1966 and an estimate of these projected to 1975. The time period selected as the basis for projection is 1949 to 1966. [1] During this time a relatively steady pattern of growth, unmarked by substantial breaks in the trend was evident. Prospects seem good that it will continue, for people are becoming more medication conscious, population is rising, and elderly people (subject to more sickness) will constitute a gradually expanding proportion of the population, (See Table 6)

Consumer expenditures for drugs from 1949 to 1966 can be adequately characterized by a straight line. The least squares line is $Y_C = 1190 + 170X$, where X represents the time period of one year, and Y_C is the trend value for period X.

The least squared projections to 1975 are shown in Table 2. R, the coefficient of correlation between the actual data points and the least squares line is .99 and the proportion of total variation explained by the least squares line is $r^2 = .98$.

[1] The latest available data.

Source: See Table 2.

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Table 3 compares median return after taxes on sales and invested capital of the Pharmaceutical Industry, the chemical industry, and "all industry".

But while return on sales has increased for all industry, there has been a slight decline for the Pharmaceutical Industry from 1961 to 1966. Return on invested capital increased less for the Pharmaceutical Industry than for all industry (+ 2.6 percentage points vis. + 4.4 percentage points) for the same time period. However, return on invested capital for the Pharmaceutical Industry has continued to be substantially higher than that for all industry. These glittering profits attracted both new competitors and public scrutiny.

Risks

The relationship between expected risk and the level of return on investment is a factor which affects the most fundamental decisions of an industry such as investments, pricing and profit level goals. Until recently, many such evaluations have been little more than intuitive. Currently there is a trend to formulate risk factors in a systematic and quantitative manner. Conrad and

TABLE 3

MEDIAN RETURN AFTER TAXES ON INVESTED CAPITAL AND SALES

Year	Pharmaceutical Industry		Chemical Industry		All Industry	
	R. O. Capital	R. O. Sales	R. O. Capital	R. O. Sales	R. O. Capital	R. O. Sales
1961	15. 8%	10. 5%	8. 3%	5. 3%	8. 3%	4. 2%
1962	14. 4	10. 5	9. 5	6. 1	8. 9	4. 2
1963	14. 7	10. 6	10. 2	6. 0	9. 0	4. 4
1964	16. 3	10. 8	12. 1	6. 6	10. 5	5. 0
1965	18. 0	10. 3	12. 6	7. 5	11. 8	5. 5
1966	18. 4	10. 2	12. 6	6. 8	12. 7	5. 6

Source: Fortune Directory (New York: Time Life Publishing Co., various years).

Platkin[1] formulated a system for measuring risk/return relationships and applied it to each of 59 major S.I.C.[2] fields of business. A basic assumption is that return should increase proportionately with risk.

Industries such as aerospace, publishing, cosmetics, pharmaceuticals, and automobiles are found at the top of the list in both risk and rate of return. Those industries generally characterized as being fairly stable, such as coal, tires, steel and railroad equipment are found near the bottom in both respects.

Risks which are somewhat peculiar to the Pharmaceutical Industry are:

1. The development of a competing product superior to one of a company's major products which causes virtual replacement of it in a short time.
2. The discovery of unanticipated side effects of a drug which lead to an immediate limiting of the physical indications for which it may be prescribed.

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[1]Statement of Irving H. Platkin before Monopoly Sub-Committee of the Senate Select Small Business Committee, December 19, 1967.

[2]Standard Industrial classification.

3. The discovery that a drug may be misused in ways that create a significant social problem, which then leads to limitations on its marketability or possible removal from the market.

4. The withdrawal or restriction of a new drug by the Food and Drug Administration until additional evidence of safety or efficacy is produced.

5. The development of a quality control problem which necessitates withdrawal of a product from the market until the problem is traced and alleviated.

ceutical manufacturers are geared to taking such risks through cial development and introduction of new drugs of unknown value. They have in prospect the high rewards that encourage k taking. These rewards are evidenced in the actual returns d in Table 3.

The Pharmaceutical Industry may not have experienced as gh risk problems as were apparently anticipated when ing premium prices. The Industry has maintained high on sales and capital from 1961 to 1966. These returns have ner than those of the chemical industry or "all industry".

In such a case, the possibility of lowering prices and still obtaining adequate returns, returns more closely equated with "normal" industry profits, may exist. It is noteworthy, however, that return on sales for the Pharmaceutical Industry has declined slightly since 1961, while the same returns have risen slightly for the chemical industry and "all industry".

Product Development

The Industry realizes that new products are the key to rapid growth. Continuing research and development is needed by each company as new product introductions make present products obsolete. In 1951 research and development expenditures for ethical products were $50 million. By 1967 the budgeted figure was $460 million, approximately nine times the amount expended in 1951.[1] Figure 3 shows the growth in R & D expenditures for ethical products from 1951 to 1967.[2]

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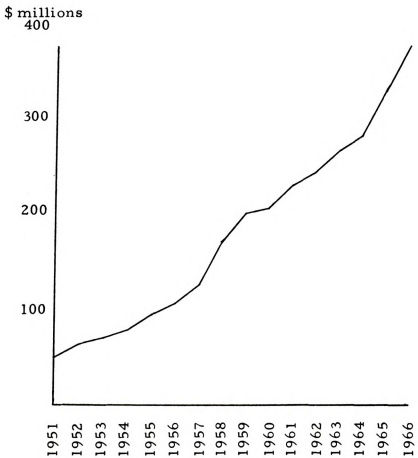
[1] PMA, Fact Book, pp. 37 - 39.

[2] A more detailed discussion of factors relating to current research and development, as well as a projection of future expenditures are presented in Chapter V, page 135 infra.

FIGURE 2

RESEARCH AND DEVELOPMENT EXPENDITURES

FOR ETHICAL PRODUCTS 1951 - 1966



Source: PMA, Fact Book, p. 39.

Structure of the Industry

The Pharmaceutical Industry can be divided into broad divisions according to the way in which the products of each are promoted and sold: the ethical, proprietary and veterinary divisions. In the ethical branch of the Pharmaceutical Industry, products are available to the ultimate consumer only at the direction of a licenced physician or dentist. Retail outlets for these so-called "ethical" products are primarily registered pharmacies. Traditionally, these prescription drugs have been promoted only to the prescribers and purveyors, but not to the public at large. In contrast, the proprietary division of the Industry handles products which are sold directly to the consumer, and consequently, are promoted and advertised extensively to the general public. Proprietary products are generally safer, and are sold not only through drug stores, but also through many convenience goods outlets, such as food stores and department stores.

Many drug firms have interests in both the ethical and proprietary fields, and others are establishing new divisions to service both sectors of the Industry. In general, the ethical area is attractive because of the rapid growth and high profits available from a successful product. Product sales in the proprietary area are usually more stable, and products generally experience longer life cycles.

However, lower margins in the proprietary area usually necessitate a large volume to break even.

Approximately half of the drug Industry sales in the United States comprise ethical products, used in finished dosage form by humans. About 25 per cent to 30 per cent of total Pharmaceutical Industry sales are accounted for by veterinary products, bulk shipments and exports of ethicals. Proprietaries make up the remainder. [1] This study will deal only with the ethical Pharmaceutical Industry.

Domestic U.S. ethical sales in 1966 were 3.4 billion dollars. [2] Thus in comparison with 1966 sales of even large single companies such as General Motors ($20.2 billions), Standard Oil of New Jersey ($11.2 billions) and Dupont ($3.2 billions), [3] the total of ethical sales of the Pharmaceutical Industry is moderate in size.

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[1] Standard and Poor's Industry Surveys - Drugs, Cosmetics: Basic Analysis (New York: Standard and Poor's Corporation, May 4, 1967, p. D. 8.

[2] Fact Book, p. 10.

[3] Fortune Directory, 1967, passim.

The Pharmaceutical Industry is comprised of approximately 1,300 firms. [1] In 1966, four companies accounted for 24 per cent of total Industry shipments. The eight largest companies accounted for 41 per cent, and the top twenty firms accounted for 72 per cent of total shipments. [2] Thus a substantial number of pharmaceutical firms account for sales of much less than a million dollars each.

The Industry's small firms,(those with sales of less than $10 million) are not generally engaged in producing the new, or more complicated drugs. Large firms with sales of $10 million and over do most of the expensive research and development; small firms, at best, usually conduct minimal research to produce related competitive products or to compound common products. Table 5 which relates company size to most-prescribed products, shows that small companies with annual sales of less than $10 million had no product sales in the

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[1] PMA, Ethical Pharmaceutical Industry Operations and Research and Development Trends 1960 to 1966 - A Report based upon PMA Annual Surveys of Member Firms (Washington: Pharmaceutical Manufacturers Association, 1967), p. 9.

[2] See p.232, Chapter V, infra.

top fifty products prescribed in 1965 [1] and only eight in the top 200. The top fifty products account for 34 per cent of all prescriptions written, and the top 200 account for 63 per cent. Consequently, there may be a substantial difference in operations of those companies comprising the bulk of Industry sales, and the many small peripheral firms. An industry dominated by a relatively few large firms which achieve substantial profits is a potential subject for investigation.

Methods of Operation

Research and Development

The Drug Industry has distinguished itself as a leader among United States Industries in research and development. [2] The "firsts" with which the National Science Foundation credits the Industry are as follows: [3]

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[1] Latest available figures.

[2] National Science Foundation Report, "Research and Development in Industry", Quoted in "Prescription Drug Industry Fact Book", p. 40.

[3] Ibid.

TABLE 5

COMPANY SIZE AND MOST-PRESCRIBED PRODUCTS

	Small Co. *	Large Co. **	Percentage of all prescriptions
Top 50 products	0	50	34%
Second 50 products	4	46	14%
Third 50 products	3	47	10%
Fourth 50 products	1	49	5%
	8	192	63%

*Sales less than $10 million

*Sales greater than $10 million

Source: American Professional Pharmacist, April 1966, pp. 23 - 27.

1. It finances almost all of its R & D with its own funds, thus accepts the least amount of Federal Government R & D funds.
2. Has the highest percentage among all industries of R & D funds for basic research investigation for the advancement of scientific knowledge without specific commercial objectives.
3. Has the highest percentage among all industries for R & D funds for applied research (53 per cent) as distinguished from basic research and developmental work.
4. Has the highest ratio of company financed R & D to net sales.
5. Has the highest amount of company financed R & D per employee.

comparison of the corporate financing of R & D by various ustries in Table 5 further illustrates the research entation of the Industry. The Pharmaceutical Industry anced 96 per cent of its own R & D whereas private industry a whole financed only 45 per cent. The remaining 55 per t of total private industry R & D was government-supported.

TABLE 5

CORPORATE FINANCING OF R & D BY INDUSTRIES, 1965*

Industry	Total (millions)	% Industry financed	% government financed
All private industry	$13,838	45	55
Prescription items	365	96	4
Petroleum refining and extraction	435	84	16
Industrial chemicals	928	84	16
Motor vehicles	1,238	74	26
Machinery	1,129	77	23
Professional and Scientific instruments	387	67	32
Electrical equipment and communications	3,167	37	62
Aircraft and Missiles	5,120	12	88

*Excludes R & D financed by companies but performed by outside organizations, colleges, universities, research institutions and other non-profit organizations.

Source: PMA Fact Book, p. 40.

Research and development activities in the Pharmaceutical Industry are complex and costly. An example of the elaborate steps involved in developing and determining the safety and efficacy of new drugs is given in a description by one manufacturer, Merck, concerning one new product--a hypertensive:

> (1) use of a background of discoveries that blood pressure was affected by the body's output of two specific hormones; (2) formulation of an hypothesis that production of a hormone might be blocked by its a -methyl analogue based on Merck discoveries of a blocking property in the a -methyl analogue of another amino-acid; (3) demonstration of such blocking action in the test tube; (4) after years of refinement in techniques necessary to prove biochemical reactions in animals, demonstration of such blocking action in the animals by two of some fifteen outside researchers to whom Merck had furnished samples of the drug; (5) further tests of efficacy and also of safety in animals, conducted respectively by researchers at one of the U.S. National Institutes of Health and by Merck; (6) safety in animals having been demonstrated by Merck, exploratory clinical trial of the drug conducted on ten human patients by the NIH researchers; (7) long-term study initiated with several species of animals to demonstrate safety for chronic administration of the drug; (8) preclinical report issued, based on known information, to interest clinicians in testing the drug on humans; (9) clinical trials initiated in leading medical centers in Europe as well as trials expanded to involve more than 200 physicians in 32 countries and nearly 2,000 patients; (10) continuation of clinical trials and application for clearance of the drug by the U.S. Food and Drug Administration. [1]

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[1] The Merck Review, Special Issue, "Testing New Drugs", Spring 1963. As quoted by Audrey T. Sproat in "A Note on the United States Drug Industry" (Boston, Mass., Harvard Business School, 1963) p. 14.

Such research efforts are costly. It is difficult for small firms to support these heavy research expenditures. Consequently, larger firms seem best suited to develop new products. Successful development of new drugs by large firms add to corporate growth and enhance their dominant position in the Industry.

Quality control procedures in reputable ethical pharmaceutical firms are also very elaborate, as exemplified in the following testimony:

> In building quality into Seconal Sodium, a total of 808 different kinds of quality checking operations are employed. These are distributed among ten basic processing categories, as listed in the flow (sic) chart below:
>
> Different Kinds of Quality Checks in Manufacturing Seconal Sodium Capsules, 100 mg.

Preparation of Materials		Filled Capsule Manufacturing	
Chemical Manufacturing of sodium secobarbital	198		
Starch receiving from supplier	35	Weighing and dispensing	20
Starch processing	22		
Empty Capsule Manufacturing	94	Capsule filling	55
Package materials receiving	61	Bottling and labelling	94
Label printing	167	Distribution	62
Total	577		231
Grand Total	808		

> *Many of the different quality checks listed are performed dozens of times, depending upon manufacturing lot size and related factors. [1]

[1] Henry F. DeBoest, Testimony Before the Monopoly Sub-Committee of the Senate Select Committee on Small Business, September 29, 1967, Washington, D. C.

The foregoing research and quality control procedures have resulted in understandable Industry pride, as well as premium pricing. In fact, this pride could have led to complacency in regards to public criticism of drug pricing and promotional activities prior to the Investigation.

Marketing

By the early 1950's, the methods of marketing ethical pharmaceuticals had become well established. Products are promoted to the medical profession primarily, but pharmacists and hospital personnel are also contacted. The advertising media are limited mainly to professional journals, direct mail literature, and samples distributed either by mail or representative. The greatest reliance to transmit the company's highly technical message is placed on sales representatives. Frequencies of call on doctors vary as a matter of company policy, however, most firms try to make a contact approximately every six weeks.

The brand name of the patented product is stressed in the sales contact. This is done through a scientific service procedure, whereby the doctor is informed of medical and clinical research, provided with various aids, and encouraged to prescribe a specific brand.

The pricing of new drugs must take into consideration the research costs of both the current drug and of those which did not reach the market, the very high quality standards already described, and the expected life of a product. Product life cycles are often short, high innovation rates lead to low probabilities of product lives exceeding five years in many cases. In 1948, for example, Aureomycin had 100 per cent of the broad spectrum antibiotic market; by 1958, other improved products slashed its share to 1.6 per cent. Chlorpromazine followed a similar path; 100 per cent of the market in 1954; 12 per cent in 1959.[1] Thus, prices of new drugs are set relatively high to insure, as far as possible, earning more than the development costs before the new product is outmoded.

A great drive to develop new products continues to exist. The first company with a distinctively new product usually enjoys a substantial competitive advantage for a time. Until a substitute or variation offering clear advantages is introduced physicians are reluctant to switch if they have been obtaining satisfactory results from the original product.

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[1] Hampton, Ethical Drugs, p. 140.

Another practice is selective cross-licencing of competitors. This allows a greater market penetration of a product, brings in additional revenue, and opens the door to reciprocal relationships, which can serve to round out each company's line of products. Thus, there may be more than one supplier even for a patented drug.

While pharmaceutical products are specified by the physician, the ultimate purchasers are the people who buy them for "their own" consumption. A significant factor for future volume is the increase in the number of potential customers, and the variety of market segments. An especially important segment comprises those 65 years and older (see Table 6). They have the highest incidence of chronic illness, hence have the greatest need for medication. Average drug charges for the group 65 years and over are approximately $22 annually compared with $11 for the 35 to 54 age group.[1] The advent of government-paid medicine for the elderly has the possibility of increasing the potential in the geriatric market, for the absolute number of prescriptions written should increase.

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[1] Standard and Poor's, December 13, 1962, p. D-9. (latest figures available).

TABLE 6

. U.S. POPULATION TRENDS

	1955	1960	1965	1970*	1975*
ɔtal (millions)	165.3	180.0	195.7	213.8	235.2
ge 65+ (millions)	14.1	16.6	17.6	19.5	21.9
ge 65+ (percentage of :al)	8.5	9.2	9.0	9.1	9.3

Assumes 1955 - 1957 level of fertility will continue.

ırce: U.S. Bureau of the Census, "Current Population Reports"
ed by Department of Health, Education and Welfare, Health,
ucation and Welfare Trends, (Washington: U.S. Government
inting Office, 1961).

Production

The Pharmaceutical Industry is characterized as having relatively high gross margin figures. It also exhibits relatively low cost-of-goods-sold ratios, resulting from relatively small expenses for direct labor and materials, and a relatively low investment in depreciable fixed assets, as is suggested by the data in Tables 7 and 8.

Relatively low costs of production facilities facilitate relatively easy entrance into the Pharmaceutical Industry. Since the potential profit returns are significant, a large number of entrants would be expected. This provides one explanation for the large number of firms in the Industry mentioned earlier. Despite relatively low capital and production costs, however, research and marketing costs are substantial. It is the lack of funds for these essential activities that keep most Industry entrants small. Consequently most pharmaceutical sales are made by a relatively small number of firms -- a factor of interest to the late Senator Kefauver.

TABLE 7

COMPARATIVE LABOR COSTS, 1961

	All Manufacturing	Chemicals and Allied Products	Drugs
otal payroll ($ million)	$ 88,164	$ 4,528	$ 633
otal wages ($ million)	54,803	2,516	272
ages/payroll (%)	62.2%	55.6%	43.0%
alue added by manufacturer million)	163,801	14,768	2,440
ages/value added (%)	33.5%	17.0%	11.1%

urce: U.S. Bureau of the Census, 1961 Annual Survey of Manufacturers
ovember, 1962.

TABLE 8

COMPARATIVE MATERIALS COSTS, 1961
(dollars in millions)

	Cost of Materials	Value of Shipments	Materials/ Shipments
			%
Drugs *			
Biological products	$ 37	$ 101	36.6
Medicinals, botanicals	147	293	50.2
Pharmaceutical preparations	696	2,920	23.8
Other Chemical Products *			
Organic chemicals	1,817	3,944	46.1
Inorganic chemicals	1,427	3,108	45.1
Plastic materials	1,163	2,124	54.8
Synthetic rubber	406	696	58.3
Soap, detergents	894	1,898	47.1
Paints, varnishes	1,142	2,033	56.2
Fertilizers	887	1,234	71.9

*The total value of shipments and cost of materials for Industry groups are not published because of extensive duplication arising from shipments between establishments in the same Industry classification.

Source: U.S. Bureau of the Census, 1961 Annual Survey of Manufacturers, November 1962.

Industry Attitudes

Attitudes Concerning Promotion

Promotion of most branded ethical pharmaceutical products by detailing, journal advertising and direct mail has become increasingly aggressive. Before 1950, the ethical Pharmaceutical Industry promoted its products to doctors on an "ethical" plane. It was conservative in its promotional techniques, and relied on a combination of personal, friendly selling, plus the dissemination of the details of indications and contraindications of products. In the early 1950's, a few new large conglomerate companies entered the Pharmaceutical Industry. The orientation of these firms had been different. They employed more aggressive techniques, such as directly criticizing a competitor's product, and increasing the frequency and aggressiveness of current Industry promotional efforts. Other companies responded in kind. Even very conservative companies felt it necessary to at least keep up with competition. The increased promotional pressures on customers was noticeable.

Product Orientation

The Pharmaceutical Industry has been oriented to new product development. Industry leaders realize that much of their recent success is attributable to new products. From the 1930's on, they began to expect, and often obtained, major product breakthroughs. Since physicians tend to maintain their use of a product until a new one with demonstrable advantages is discovered, new products are perceived of as the way to increase sales and gain market share.

Numerous outstanding therapeutic advances occurred from 1946 on. Many new variations of existing drugs were developed. Many combinations of single chemical entities were compounded which substantially increased the number of new products available. For certain indications, the assortment of products available to the physician is large. In the ten years from 1951 to 1960, 3,568 products were introduced.

When a revolutionary discovery is made, many companies rush to capitalize on the new research breakthrough. They attempt to develop analogous competitive products by screening similar chemical structures. Critics have contended that this activity diverts attention from the important task of basic research, from which most important developments

emanate.[1] At the time of the Kefauver Investigation it seemed as though the dominant concern of the Industry was to develop as many new products as possible, then promote them as aggressively as possible, with little consideration of whether new products were needed in certain indications.

Pricing Attitudes

Prior to the Kefauver Investigation, there was little concern for lowering drug prices in the Industry. Because of the short life cycles of many new products, innovating firms knew that they must recover costs before superior substitutes reduced market share. Adequate margins were required to continue research and marketing activities. Even though four or more similar products might be on the market, competing firms realized, that there was little elasticity of demand in this field. They also faced an oligopolistic type of situation, where a reduction in the price of one product would immediately create the possibility of severe price competition. Furthermore, firms were separated from whatever

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[1] James Balog, "Pharmaceuticals New and Old", from a Speech Delivered Before the Pharmaceutical Manufacturers Association, Research and Development Section, Colorado Springs, Colorado, N. A.

immediate consumer criticism of prices existed, and the physician was more concerned with therapeutic efficacy than price. Such conditions are largely the same today.

Industry leaders also were well aware of the economic benefits accruing to the patient from the advent of modern pharmaceutical therapy. They pointed out that the average prescription price was only around $3.00 and that most people only purchased a prescription three or four times a year. Indigents and some elderly customers were the major groups affected significantly by drug prices. The Industry did not feel that the financial problems of the few should be its sole responsibility. The investigators, however, felt that Pharmaceutical Companies had consistently charged too much.

The Industry was only willing to lower prices substantially to government purchasers. While the regular prescription market comprised the bulk of sales, government agencies periodically bought large quantities of drugs. Little work was involved in gaining these sales, the quantity was attractive, and consequently the Industry was willing to sell

on a marginal cost basis. The differences between retail and government prices were substantial, a fact later seized upon by Industry critics.

Public Relations Attitudes

Prior to the Investigation, the driving concern of each company was to orient public relations efforts to the professionals, to enhance its image, and to develop a preference for its products. Industry leaders knew consumers had to buy whatever the doctor prescribed. Public relations activities were aimed directly at the physician who controlled purchase decisions, and at the pharmacist. With a few exceptions, the Pharmaceutical Industry did not communicate directly with the public at large. The Industry was usually careful not to "go over the doctor's head" to promote drugs to the public. They believed this was necessary to maintain professional relationships, and in any case had little concern for the public itself.

A Subject for Investigation

Why was the Pharmaceutical Industry selected for investigation? Economic, social and political factors made

it an ideal subject. In the space of a few years the Pharmaceutical Industry achieved spectacular therapeutic breakthroughs resulting in outstanding growth, sales and profits. Despite obvious Industry merits, some pharmaceutical products seemed overly profitable and even exorbitant to the public. The Industry did not make significant efforts to inform the public of the costs of research, production and distribution of drugs, nor of the contributions made to society through pharmaceutical treatment.

Governments became more concerned with the costs of providing adequate health services to some segments of society and began to question drug pricing practices. The price of medication affected significantly the standard of living of chronically ill elderly people. In addition, society increasingly accepted the concept that a certain minimum standard of welfare is an inherent right. Ironically, this occurred at a time when all other health costs were rising more rapidly than drug prices.

Industry structure also paved the way for criticism. The Industry consisted of a few rather large, profitable firms, surrounded by many small firms. The large firms often charged significantly higher prices to the consumer than did

smaller firms, yet their extensive promotion practices earned them most of the business. [1]

The Pharmaceutical Industry was so concerned with perpetuating its success that it paid little attention to the above factors. Despite many Industry contributions to public welfare, the aforementioned economic, social and political conditions required Industry attention. To most of the public, the Industry was a faceless entity, an ideal subject for a public investigation.

CHAPTER III

THE KEFAUVER INVESTIGATION : BACKGROUND, OPERATIONS AND OUTCOME

Introduction

This chapter has four main objectives:

1. To outline the background, preparation and preliminary thinking of the Kefauver Investigation.
2. To develop an understanding of what actually went on during the Investigation by describing some of the main activities.
3. To evaluate the Investigation using the list of operational criteria for an inquiry developed in Chapter I.
4. To outline the immediate effects and legislation arising out of the Investigation in order to complete the background for the hypotheses which follow in the succeeding chapter.

Background

The general problem of monopoly was a lifetime interest of the late Senator Kefauver. Even as a lawyer handling business cases in Tennessee, he was concerned about the number of small

business failures. He felt that the important economic decisions were made in the central cities, small businessmen could not do much about them, and the way to change the trend was to control big business and so increase competition. [1] In describing his background Mr. Kefauver said, "I believe that a man who is elected by the people to serve in Congress ought to pick out something that is in the public interest and specialize in it whether or not it is popular, so when I took my seat in the House in 1939, I made anti-trust matters my specialty." [2]

Through the years, Kefauver achieved only limited notice and success in his efforts to curb what he believed to be the undue concentration of economic power. In January 1957

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[1] Richard Harris, The Real Voice (New York: The MacMillan Co., 1964), p. 7.

A substantial portion of the background material for this chapter was taken from the writings of Richard Harris, who firstly chronicled in the New Yorker, the events surrounding the Kefauver Investigation, and the passing of the Drug Act Amendments of 1962. He then developed this material into a book, The Real Voice. His purpose in writing on the subject was to portray the many steps involved from the genesis of an issue to the passing of legislation concerning it.

Senator Kefauver aided Harris substantially to obtain the material. Harris obviously held Senator Kefauver and the goals of the Investigation in very high regard.

[2] Ibid.

he became the new chairman of the Senate Subcommittee on Anti-Trust and Monopoly, as a result of the usual Senate seniority system. During the next two years he held hearings on pricing policies of the steel, automobile, and bread industries. "But neither the public nor Congress showed much interest in his findings, and none of the hearings led to legislation. In the end, about all he accomplished was to make a lot of enemies in business and government." [1]

> Nevertheless, he (Kefauver) kept searching for a dramatic way of illustrating the evils of economic concentration, and late in 1958, he gave a tentative go ahead to two members of the Subcommittee's staff who wanted to look into the drug industry, which appeared to be making phenomenal profits. At first, Kefauver was reluctant to investigate an industry so arcane, with an all but impossible nomenclature and with no background of available data but after his staff had uncovered a few elementary facts about the Industry, he began to come around. Among the earliest discoveries the staff made was that 90 per cent of the industry's total volume of business . . . went to . . . 22 pharmaceutical firms out of a total of a thousand or so. Another discovery was that in the third quarter of 1958 . . . the industry's net profit, after taxes, came to 18.9 per cent of net worth and 10.8 per cent of sales - or twice as much, by either yard stick, as the average for the rest of the nation's manufacturers. [2]

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[1]Richard Harris, "Annals of Legislation, Background and History of the Drug Industry Antitrust Bill", The New Yorker, Vol. 40, March 14, 1964, p. 48, infra.

[2]Ibid.

Seemingly, Kefauver felt that the Pharmaceutical Industry would be a useful subject to demonstrate his notions of the evils of economic concentration. Furthermore, it is noteworthy that he turned to his chief staff members for advice on the next subject of investigation. These individuals had been attempting to instigate an investigation of the Drug Industry since 1951 (prior to working with Kefauver). Their desire to do so was based on their personal observations that the cost of certain prescriptions of which they were aware seemed expensive. [1]

Kefauver's staff began to work on background research. It came across a sensational article which exposed a tasteless advertising campaign of one pharmaceutical company. It began to dig into costs of drugs, and found that costs of raw materials and manufacture comprised a small fraction of the retail price of drugs. These factors convinced Kefauver that here was something worth looking into. Significantly the staff did not come across any convincing information from the Pharmaceutical Industry explaining prices, costs, or profits, or the important

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[1] Ibid.

[2] Ibid., Passim, pp. 1 - 14.

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job it was doing. Kefauver seriously considered the political risks[1] and decided to go ahead with the Investigation. Previously (Chapter II, p. 64 , supra) it was noted that the Industry apparently was too busy, or unconcerned, to clarify these matters, and now it was too late.

Conduct of the Investigation

Selection of Staff

Senator Kefauver alone chose the main staff members for the subcommittee.

> . . . It did not take him long to choose his two principal assistants; Paul Rand Dixon, an F. T. C. lawyer from Tennessee, with a reputation for vigorous trust busting, became his staff director and chief counsel, and John Blair became his chief economist. The Senator and Blair had known each other since 1945. . . . from time to time, Kefauver had called on Blair to do some economic spade work in the anti-trust field, and over the years had come to rely on him more and more.[2]

These key staff members had similar attitudes toward big business, and their goals were apparently compatible with those of the chairman. Another key member of the staff, Dr. Irene Till, was a previous employee of Dr. Blair.

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[1] Richard Harris, The Real Voice, pp. 40 and 41.

[2] Ibid., p. 11

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No record was found that the rest of the committee were involved in the selection of staff.

The backgrounds of the staff suggest that they would not be very objective in an investigation of big business practices. For example, the minority, [1] in referring to the selection of Blair as a staff member, commented:

> Obviously . . . objectivity as well as scrupulous concern for developing the truth, whether it coincides with one's preconceived ideas or not, was apparently not a prime requisite. Unfortunately, unlike some other economists, who had extreme anti-business views in their earlier years, many of the theories propounded by Dr. Blair in his book, Seeds of Destruction, in 1938 apparently (still) influence his approach to the business community. [2]

Both Blair and Dixon formerly worked for the Federal Trade Commission and "their old associates say that both were frustrated because they could not hit big business hard enough under the formal, legal procedures of the FTC". [3] Regarding

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[1] The minority members of the Senate Subcommittee chaired by Kefauver.

[2] Report of the Committee on the Judiciary Subcommittee on Anti-Trust and Monopoly, Administered Prices: Drugs, (Washington: U.S. Government Printing Office, 1961), p. 364.

[3] Printers Ink, "The Shame of Congress: How Probes Can Kill Marketing", August 19, 1960, p. 5.

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The minority members of the Committee expressed bewilderment at the entire series of hearings and the assumptions concerning administered prices around which much of the Investigation revolved. [1] In its report, the minority expressed dissatisfaction with not being consulted, indicating that one staff member directed too large a portion of the Investigation.

> . . . unfortunately, a large portion of the planning for the subcommittee's investigation of drug industry was delegated to its chief economist, Dr. John M. Blair. [2]

Co-operation of Chairman and Staff with Committee Members

If a committee is delegated the task of studying a topic, that committee as a whole should be aware of the relevant policies, procedures, and subject matter, and have a voice in formulating them. In fact, however, minority members of the Kefauver Subcommittee were not even shown material to be used in the sessions until a few minutes before they convened. The majority's defense to criticism of such

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[1] Report, Administered Prices: Drugs, p. 295.

[2] Ibid, pp. 364 and 365.

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activities was that the Subcommittee's files were always open to the minority. The sheer quantity of documents, however, made it impossible to determine what would be used and how. [1] Mr. Chumbris, the minority counsel, finally developed the habit of visiting the Senate press room just before the hearings began each morning. From press releases handed to reporters, he attempted to familiarize himself with what was coming, and to prepare his own questions. [2]

The final report was prepared by the staff; again, committee members were by-passed.

> (Blair said) We simply had to sit down in one meeting after another among ourselves at first, and then, when we had something concrete to propose, with Estes (Kefauver) and try to hammer out from this vast body of material an instrument of control that would be in the public interest. [3]

Standards of Conduct

There are no formal standards or rules controlling the way an investigation is to be conducted (Chapter I, p. 15 , supra).

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[1] Richard Harris, "Annals of Legislation", p. 75, infra.

[2] Printer's Ink, "Shame of Congress", p. 26.

[3] Richard Harris, "Annals of Legislation", p. 78.

The treatment of witnesses, and objective selection of information to be obtained rest solely on the investigators. A regular practice of Kefauver was to give witnesses little or no advance information on the topics to be discussed. His staff made a policy of asking only questions to which they knew the answers, [1] thus, seemingly, limiting the public forum to a means of confirming preconceptions. Sometimes the investigators showed haste to dismiss or discredit testimony by independent witnesses that might reflect favorably on Drug Industry contributions. [2] On the other hand, testimony of witnesses hostile to the Drug Industry was a source of quotation and requotation for the Investigators. [3]

Kefauver and his staff apparently did not question witnesses with the idea of bringing out testimony affirmative to the drug field. Only the three minority members and their counsel did. [4]

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[1] Ibid., p. 78

[2] U.S. Senate Committee on the Judiciary, Administered Prices in the Drug Industry (General: Generic and Brand Names) May 10, 11, 12, 13, 1960. Vol. 21, 86 Congress, Second Session, 1960, pp. 41, 81, hereafter would be reported, Hearings, 21:41, 81.

[3] See Congressional Record - Senate, p. 5791.

[4] Printer's Ink, p. 26.

In reality, the investigators ignored Industry explanations and answers. The same allegations were repeated many times. For instance, charges of mark up percentages of many thousand per cent were continuously repeated, although it was known that terminology concerning "mark up" was confused with "profit" by the press and public.

A major consideration during Congressional hearings is the tremendous power held by investigators. A result is that the Investigation became a shattering ordeal for Industry witnesses.

> A Washington lawyer, who has been steeled to the practices in some committees, was moved to deep sympathy, by the interrogation of one company president . . ., 'here is a . . . man of great integrity, a man who can command respect and assume leadership in any other situation. In this overbearing situation, he is held responsible for every act of his company, every advertisement it has produced, and the functioning of an economy in which it is difficult for some persons to afford drugs . . . It pained me to see him so shocked and helpless.'
>
> A company president who testified said, 'I never dreamed that a Senator could hold so much unrestrained power.' [1]

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[1] Printer's Ink, p. 25, August 19, 1960.

One observer of the hearings referred to another company witness and said, "This man has not recovered from the shock and humiliation experienced at the hearings to this day." [1]

Qualifications of Witnesses

The minority report strongly indicted the qualifications of witnesses, and contended that a representative sample were not asked to testify.

> In other hearings I have followed . . . the usual and approved format has been to invite and hear the heads of the Federal agencies having jurisdiction over the matters involved; then, the heads or official representatives of the industries or companies involved, . . . then national, state, or regional trade associations (and others) . . . and then such other witnesses who desire to be heard individually within reason and balance as to number and as to nonrepetition . . . Differing notions and opinions of representative groups and officials should be gathered so that a balance can be achieved without harmful bias and premature judging . . . Such a pattern, however, has been thoroughly disregarded here. No Federal agency officials have been called so far. (This report was written at the conclusion of the Investigation). With the exception of Dr. Austin Smith of the Pharmaceutical Manufacturers Association, no professional or trade groups have been allowed to appear.

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[1] From a confidential interview conducted by this author.

> No broad and competent basis has been laid for these hearings and this inquiry.
>
> Instead, we have had a series of doctors who are individual members of a profession numbering in excess of 200,000. These witnesses have not been representative, either officially or in fact, of their profession. In the main, they have presented nonconforming, antagonistic views, clearly not held by the great preponderance of their professional brethren . . . In fact, uptil now there has been a deliberate attempt, in my judgement, to inflict devastating and irreparable damage (to the Pharmaceutical Industry) . . . by trying hard to shatter public confidence in it upon the basis of a biased, distorted, and incomplete record. [1]

One witness called was Mrs. Mildred Edie Brady, Editorial Director of Consumers Union, who made a plea for tighter controls and inspection procedures to eliminate substandard drugs. [2] Yet, at the beginning and close of her statement, Mrs. Brady declared her organization had no experience in the prescription drug field, and stated they had not tested or reported on any prescription drugs. On other occasions, publicity and preference was given to the testimony of a layman and/or a lesser qualified doctor over those of renowned physicians. [3]

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[1] Report on Administered Prices: Drugs, pp. 366 and 367.

[2] Hearings, 28: 5208 - 5209.

[3] Hearings 8: 1651 - 1652, 8: 1710, 4: 854 - 855.

The Subcommittee did not solicit views of organizations able to speak for broad and knowledgeable segments of the health professions. The American Medical Association did not testify; nor did the American College of Physicians, American College of Surgeons, The American Academy of General Practice, nor any other professional medical organization. The National Institute of Health, whose function it is to be aware of, and to give leadership in, all phases of medicine, was notably absent. [1]

Use of Publicity

It appears that Kefauver used the Investigation as a forum to stir up the public. When asked after the hearings, whether he had held them to get or to give information, he answered, "Primarily to get information. But naturally you have to give information if you hope to get public support for legislation." [2]

Kefauver, who had what one observer called "a genius for publicity creation", made it a point to bring out his most sensational allegations about one-half hour before the reporters

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[1] Report on Administered Prices: Drugs, p. 367.

[2] Richard Harris, "Annals of Legislation", p. 46, infra.

had to leave to file their stories--ordinarily 11:30 a.m. for afternoon paper men, and 4:30 p.m. for morning paper men. [1] He repeatedly moved in at critical movements to restate a point in a way that would make it perfectly clear to the press. [2] It is generally accepted that Kefauver timed damaging charges carefully to coincide with newspaper headlines, and conversely, scheduled friendly testimony when it was least likely to get public attention. [3] On one of the occasions when he was a witness, Dr. Smith (of the Pharmaceutical Manufacturers Association) did not testify until after midnight. The hearings were so arranged that almost daily a new charge against the Industry broke at press time. When testimony did not seem to be leading up to the point quickly enough, Kefauver would interrupt, drop a charge that would make a good headline, and then resume the testimony. [4]

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[1] Ibid., p. 43.

[2] Ibid., p. 44.

[3] Printer's Ink, "Shame of Congress", p. 25.

[4] Ibid.

Rebuttals seldom caught up with accusations. Kefauver, Blair and Dixon were often able to make a new charge before the last one could be challenged.[1]

The above information challenges the objectivity of the committee. Many additional examples could be given, however, one additional quotation from the individual report of Senator Wylie[2] will suffice.

> I do not share this extreme suspicion of business which has been evidenced in many of the documents of this Subcommittee . . . Reading the conclusions contained in this report on the drug industry, I am not certain that they contain an unbiased evaluation of the economic facts of the pharmaceutical industry and I feel it is incumbent upon myself to comment on several issues which I believe have been either completely overlooked, or else have been improperly emphasized in the majority views.[3]

Reaction of the Industry

Through the years the Pharmaceutical Industry largely ignored the function of informing the public about its methods

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[1] Ibid.

[2] Ibid.

[3] Senator Wylie was one of the minority members of the Subcommittee.

of operations, risks, profits, and contributions to human welfare. This was one reason it became the subject of an investigation. Seemingly, it did not recognize the seriousness of an inquiry and was poorly prepared to undergo close scrutiny by Senator Kefauver and his staff. "The industry prepared its case before the investigation in a mood of high confidence. Apparently, it anticipated that the taciturn Kefauver could be easily handled." [1]

The first Industry witnesses attempted to defend drug prices largely on the basis of therapeutic benefits to patients. The Committee quickly countered by relating costs of materials to retail prices. Industry representatives then appealed to costs of research as reasons for their prices. When the Committee pointed out that this was still a relatively small percentage of sales, the Industry did not seem to be able, or willing, to show clearly numerous other legitimate costs of doing business, the great risks involved, or the fact that actual profit percentages were neither exorbitant nor

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[1]Richard Harris, "Annals of Legislation", p. 6, infra.

shocking. Such basic considerations should have been anticipated. They were not and Kefauver gained the upper hand immediately. The Industry was never able to muster an adequate response. The prevalent Industry attitude toward independence and isolation from public intercourse affected its efforts.

The Kefauver Investigation Evaluated on The List of Criteria

How can we judge the effectiveness of an Investigation? What criteria should be employed? A list of criteria was developed by first scrutinizing in depth a cross-section of the literature concerning investigations in general, and second analyzing the management, operation, and accomplishments of four different Congressional investigations.

How does the Kefauver Investigation compare with these standards? Figure 1 presents a graphic description. Later chapters will provide additional evaluations by describing some effects on business practices.

The criteria listed in Figure 1 suggest several main operating guides:

1. That investigations should not be launched for political, personal, or vindictive reasons, but because of a specific public need to gain knowledge.
2. That the entire committee should participate in establishing clear policy statements as to the problem and subject areas to be investigated at the outset of the investigation, and that they be kept informed of the staff work and management of the investigation as it progresses.
3. That the entire committee should participate in the selection of the committee staff members, and the staff should be selected on the basis of their ability and impartiality.
4. That great self restraint and objectivity must be practiced by investigators in the conduct of an investigation.
5. That qualified witnesses should be called which represent all significant viewpoints.
6. That public presentation should be made of uncolored facts concerning the findings of the investigation.

FIGURE 1

EVALUATION OF THE KEFAUVER INVESTIGATION BY COMPARISON WITH CRITERIA [1]

Criteria [a]	In accordance with criteria*			Not in accordance with criteria	
Purpose				X	
Selection of Chairman					X
Clarity of policy and committee agreement					X
Preparation of work program					X
Committee voice in planning					X
Selection of staff:					
- ability		X			
- impartiality					X
- committee's voice					X
Pre-preparation of committee					X
Regular executive meetings of committee					X
Encouragement of committee members to participate					X
Preparation of topics for examination of witnesses		X			
Logical progression of questioning		X			
Standards of conduct					X
Freedom of witnesses to call support		X			
Freedom of witnesses to make complete statement				X	
Qualified witnesses called				X	
Witnesses from all significant viewpoints				X	

FIGURE 1 -- Continued

Criteria	In accordance with criteria *			Not in accordance with criteria	
Accuracy and completeness of record				X	
Opportunity of involved to examine record for correctness					X
Bias					X
Wise use of investigative power					X
Public presentation of uncolored facts					X

[a]Authors ranking.

[1]See Chapter I, p.17 , infra.

*As in the semantic differential technique, the extremes are indicated at each pole. Marks in the center column indicate neutrality.

Figure 1 illustrates that the Kefauver Investigation did not meet these criteria. For instead of determining how well the Drug Industry was serving public needs, Senator Kefauver and his staff primarily isolated and magnified Industry practices which deviated from their own idealized conceptions. The Investigation was planned and conducted by Kefauver and his staff, with little or no consultation with members of the committee. Rather than the committee selecting the staff on the basis of ability and impartiality, the staff was selected by Kefauver personally. The staff selected held negative opinions of big business. As a result of ignoring the committee members for most decisions, effective integration of talents, abilities and experience of the entire committee was not accomplished. And instead of using restraint in their investigating practices, the record of the hearings shows that Kefauver and his staff used the power of inquiry indiscriminately in controlling testimony, selecting witnesses and presenting facts supportive of an anti-Industry point of view.

In summary, an evaluation of the Kefauver Investigation by comparing with a list of operational standards revealed that it was deficient in almost every respect.

Kefauver's Goals

The stated objective of the Investigation was to increase competition and to lower prices. Kefauver hoped to increase competition by changing the patent structure, forcing greater use of generic names, having all production facilities licensed (thereby giving a doctor greater confidence in prescribing generically), and stimulating public pressure against drug prices.

The record of the hearings shows that Kefauver was against many pharmaceutical advertising practices, particularly the amount spent on advertising. He endeavored to change the function of advertising to that of education and information, and to limit promotional claims. He considered trademarks to be monopolizing forces, and sought their dilution.

Kefauver was also troubled by the proliferation of products. He was sceptical of many therapeutic claims made for similar types. He sought greater powers for the Food and Drug Administration and the specification of provisions requiring proof of efficacy as well as safety for all new products.

When Kefauver drafted the changes he wanted into a proposed Bill, Senate committees quickly erased the patent revision proposals. Other aspects of his legislative proposals

were not received with much enthusiasm, and it appeared that most would never get out of committee. However, the unfortunate thalidomide incident (whereby some deformed babies were born of mothers taking a new sleeping pill containing thalidomide) stirred the concern of the nation and moved politicians to action. After many committee meetings, hearings and compromises, the Bill was finally passed through the House Rules Committee.

The Industry faced a moment of truth as the Bill was in the House Rules Committee. The first committee vote was six to six which meant defeat. When this result was announced, the PMA [1] reconsidered its opposition, realizing that sooner or later some Bill (possibly more demanding) would be passed. Therefore they let it be known they would support the Bill. On that basis, two votes in the committee changed, a rule was granted, and the Bill went to the House floor and on to enactment. [2]

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[1] Pharmaceutical Manufacturers Association.

[2] John T. Kelley, "Three Years Later", Food, Drug Cosmetic Law Journal (Chicago: Commerce Clearing House, Inc.) January 1966, pp. 22 - 23.

Legislation Arising Out of the Investigation

The Drug Amendments of 1962 to the Federal Food, Drug and Cosmetic Act became law October 10, 1962. In essence, the new law established these provisions.

1. Safety and effectiveness must be established in a new drug application. In previous practice, the FDA [1] did consider effectiveness in relation to safety; however, under the new law, determination of effectiveness was isolated as a specific end, and largely transferred from the physician to a government agency. From now on, before new drugs are approved for marketing, it must be shown, by "substantial evidence" that the drug will have the effect it purports, or is represented to have. The burden of proof is on the manufacturer. Moreover, the FDA's power to take drugs off the market was expanded. The Secretary of Health, Education and Welfare can remove a drug if he fears an "imminent hazard to public health".

[1] Food and Drug Administration.

2. Manufacturer's quality controls must meet good current practice. Existing authority of the FDA was thus broadened to allow inspection of all manufacturing practices and procedures which have a bearing on the quality of drugs. The aim of this provision was to give doctors greater confidence in obscure producers, thereby encouraging generic name [1] prescribing.

3. There is no longer automatic clearance of new drugs by lapse of time without FDA action, as under previous law. A new drug cannot be marketed until the FDA approves it. Under the previous law, the FDA had a maximum of 180 days after receiving an application (i.e. 60 days initially, which could be extended to 180 days) to make a decision. The new law, however, allows 180 days for initial consideration of the application. If within that time the FDA is

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[1] The common name, as opposed to the trade name.

not satisfied that a drug is approvable, it must give notice of opportunity for hearing. Appeal provisions can lengthen that period by 210 days.

4. Before a new drug may be tested on human beings, the manufacturer must supply to the FDA the information specified as a "notice of claimed investigational exemption for a new drug", known as an "IND". The IND is required to include, among other things, the following information:

- complete composition of the drug, its source, and manufacturing information adequate to show that appropriate standards exist to insure safety.
- results of all preclinical investigations, including animal studies, which are mainly directed toward defining its safety rather than its efficacy.
- a description of the investigation to be undertaken.

- information regarding training and experience of the investigators.
- investigators are required to fill out a government-supplied form showing their experience and qualifications.
- copies of all informational materials supplied to each investigator.
- certification that "informed consent" will be obtained from the subjects or patients to whom the drug will be given.

5. Generic names must be printed on labels and used in drug advertising. They must appear in type at least half as large as the trade name, and the FDA has authority to designate generic names for drugs. These are requirements designed to make generic names more prominent, easier to spell, and thereby to encourage generic-name prescribing.

6. Prescription drug advertisements and other descriptive printed matter are required to show:

a) the "generic name" of the drug, if one exists, in type at least half as large as that

used for the brand name ;

b) the drug's quantitative formula to the extent required on the drug label; and,

c) the inclusion of a true and nonmisleading "brief summary" of information as to adverse side effects, contraindications, and effectiveness of the drug for the guidance of physicians.

Regulations hold that there has to be at least mention of all the warning ideas in the package insert (which must present complete information). The information of side effects and contra-indications must be adequately prominent and presented in reasonably close association with the information concerning effectiveness. Also, a "fair balance" between promotional claims and cautions must be maintained within the promotional message of the advertisement.

7. All antibiotic drugs to be administered to humans are made subject to batch-by-batch testing and certification by the FDA for identity, strength,

quality, and purity, to assure they are safe and effective before they are released for sale. The manufacturer must bear the expense of such testing.

8. Drug producers must register with the Health, Education, and Welfare Department annually. Each must be inspected by FDA inspectors at least once every two years. This proviso was also aimed at encouraging generic-name prescribing by giving the doctor confidence in small manufacturers.

9. Regulations were authorized to require adverse effects and other clinical experience and relevant data concerning drugs already on the market to be recorded by the manufacturer and reported promptly to FDA.

10. On request from the Commissioner of patents, the Secretary of Health, Education and Welfare is required to furnish information concerning drugs which are the subject of a patent application,

and is authorized to conduct, or cause to be conducted research in connection therewith. [1]

These regulations did not fulfil Senator Kefauver's wishes concerning lower drug prices. The regulations however, are generally beneficial for consumers since they are primarily concerned with assuring product safety. The direct results should be safer products and more accurate product information. The provisions concerning mandatory inspection of manufacturing seem long overdue.

Summary

As part of a continuing quest to reduce the size and power of big business, Senator Kefauver, as Chairman of the Subcommittee on Antitrust and Monopoly and several accordant staff members undertook an investigation of the Drug Industry. Foci of the Investigation were prices, profits, promotion practices, product safety and effectiveness, and Industry concentration.

When the Kefauver Investigation was evaluated by comparing it with the list of operational criteria for

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[1] United States Department of Health, Education and Welfare, Summary of The Drug Act Amendments of 1962, (Washington: Food and Drug Administration, 1963), 9 pp.

conducting an investigation, it was found to be inferior in almost all aspects.

The Drug Act Amendments of 1962 resulted from the Investigation. They are primarily concerned with increasing the power of the FDA, by providing: more rigid controls for the development of new products, additional labelling requirements, new controls over advertising, and powers for registration and inspection of manufacturing plants in operation.

CHAPTER IV

HYPOTHESES AND METHODOLOGY

Development of the Hypotheses

The Pharmaceutical Industry, confronted with the results of the momentous investigational and legislative battles of 1959 to 1962, faced a future somewhat different from the previous decade. The most serious challenge of Senator Kefauver's attack for the Industry - weakened patent protection--was met and turned back. But the turmoil of the Investigation and Drug Act Amendments promised to change considerably the future climate of operation of drug firms. A new era of expanded governmental control and continuing, intense public scrutiny had begun.

Because of the great publicity surrounding the Investigation, the general public was now highly conscious and critical of drug prices, mark ups, and Industry promotion practices. Even greater impact on professional relations could be expected. Some doctors and pharmacists would undoubtedly be in sympathy with the Industry, but a great number would exhibit varying degrees of antagonism. The Industry would have to surmount serious new obstacles in trying to promote interest, recognition, and sales.

The new Drug Act Amendments and subsequent regulations added to the cost and complexity of doing business. Additional proof of safety and efficacy required more time and money. Increased space was necessary for many product advertisements to include the added information required by the new law. Additional care in the preparation of advertisements and promotional literature was necessary to be certain they discussed only product information approved by the Food and Drug Administration. Many steps in the promotional program now involved increases in expenditures and administrative efforts.

Although the Investigation vigorously attacked pricing, promotion policies and Industry concentration there is reason to believe that it had little or no success in changing these factors in the manner planned by the investigators. Pricing will likely remain unaffected for these reasons:

1. The Investigation and Drug Act Amendments increased the cost of doing business.
2. The investigators ignored Industry-recognized realities that a high risk venture demands higher than average returns, and that relatively expensive promotion is necessary to generate adequate sales.

An increase in Industry concentration is likely. Numerous additional costs resulting from new activities imposed by the new regulations will fall most heavily on the many small firms having limited resources. It is doubtful whether a number of such firms will be able to survive under the new conditions.

The number of new products available for the treatment of disease may substantially decrease because of increased costs and administrative difficulties imposed by the new regulations. These regulations require significantly more toxicological and clinical testing before the release of a new product.

These factors elaborated in the succeeding sections, lead to the following general premise which this study seeks to verify.

The Kefauver Investigation of the ethical Pharmaceutical Industry, and the subsequent Drug Act Amendments of 1962, substantially affected company marketing programs. Controls introduced resulted in higher costs and greater difficulty of operation, but had little effect in changing pricing, promotion policies, and industry size in the manner desired by the investigators; and these controls resulted in fewer products becoming available for the treatment of disease.

Product Development

The major new product development restrictions and requirements have already been noted (Chapter III, p. 89 infra). The greater number and extent of toxicological and clinical studies and oonsequent extended administration and supervision escalated costs. Added time involved in testing lowered the productivity of scarce clinical investigators.

Pharmaceutical companies faced the additional task of trying to prove the safety and efficacy of new products to government employees, whose chief function was to find flaws in the studies and products presented to them for approval. Because opinions concerning treatment and effects are still to a large extent judgmental, consensus is often difficult to achieve, and differences of opinion are common, even among experts. Consequently, negative, rather than co-operative, attitudes between Industry and government may readily develop.

In summary, the main effects of the Investigation on new product development appear to be:

1. That fewer drugs will be released by the Food and Drug Administration.
2. That the time from inception of an idea for a new product until it is released for marketing will be extended.

3. That the costs of bringing a new drug to the market will be greater.

4. That those new products released after the Investigation will be somewhat safer for human use than those released previously.

Industry statistics [1] indicate that the number of new chemical entities released to the market have decreased since 1962. The foregoing factors lead to the hypothesis that:

H_1 There is a positive association between the substantial reduction in the number of new ethical pharmaceutical products (i. e. new chemical entities) being introduced annually to the United States market, and the Kefauver Investigation and subsequent Drug Act Amendments of 1962.

Pricing

Concern over drug prices was one of the main factors in undertaking the Investigation. Senator Kefauver and his staff concentrated heavily on this problem, and created much publicity concerning the subject of pricing practices.

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[1] Paul deHaen, New Products Parade 1967 (New York: Paul de Haen, Inc. 1967), p. 5.

In its attempt to lower prices the committee had these alternatives:

1. To create adverse public opinion strong enough to force price reductions.
2. To cause the enactment of legislation which would control prices directly, or affect them indirectly by reducing patent protection.
3. To increase competition by introducing legislation insuring more reliable manufacturing practices, and to cause generic names to be displayed along with trade names; thereby encouraging generic name prescribing.

Considerable political pressure and social upheaval is required to effect legislation directly establishing control over drug prices. Too many other interested parties rise up against actions so obviously "against the free enterprise system". It is not surprising therefore, that efforts to change the patent structure of the Pharmaceutical Industry were defeated. The only means of affecting prices left to the Kefauver Committee were: 1) publicity against pricing practices, and 2) attempts to increase competition by legislating the use of generic names and insuring that generics would be safer by inspection of manufacturing facilities and processes.

It was suggested earlier that the new regulations increased costs of doing business. Such increases are not conducive to lower prices. Likewise, the sensational headlines condemning prices generated during the Investigation were unlikely to create enough public opinion pressure to affect them because:

1. The acquisition of drugs through prescriptions does not enable the public to be very selective in giving or withholding patronage.
2. The nature of the distribution channel is not conducive to strong feedback which might ultimately affect pricing policies.
3. The Pharmaceutical Industry remained relatively insensitive to the pressure of public opinion.

These factors lead to the next two hypotheses:

H_2 No substantial decline in prices of ethical pharmaceutical products can be associated with the Investigation and Drug Act Amendments of 1962.

H_3 After the Investigation, the introductory prices of newly released drugs (for corresponding categories) were not substantially lower than those of similar drugs introduced prior to the Investigation.

Advertising

Nearly all of the Pharmaceutical Industry's advertising dollar goes into journal advertising and direct mail. Since the use of other mass media is not acceptable in the advertising of ethical pharmaceuticals, journal advertising becomes a major factor in the promotion of drugs.

During the extensive Investigation and legislative hearings which preceded the passage of the Drug Act Amendments, much attention was paid to advertising as the primary source of medical information for the physician. It was shown that busy doctors frequently rely on the claims made by pharmaceutical manufacturers about new or established drugs. Kefauver first objected to what he considered to be large expenditures on promotion. Secondly, he contended that medical advertisements should have a better balance of information about possible bad effects, compared with the claims of benefits, from use of the drugs.

The resulting advertising provision of the Drug Act Amendments of 1962 required that medical advertisements show fairly the effectiveness of the advertised drug, and also list all side effects and contraindications in an adequately prominent manner. The latter must also be presented in reasonably close association

with the information concerning effectiveness and a "fair balance" must be maintained within the promotional message of the advertisement itself.

In reality, for even a "safe" product such as aspirin, a list of the nature of side effects and contraindications can be very long. Many advertisements now require one or one-half additional pages of space to transmit the same advertising message as one page previous to the Drug Act Amendments. Similar increases occurred in all printed media, but the cost is most significant to the area of journal advertising. It is, therefore, hypothesized that:

H_4 The relative cost of promoting a product in the ethical drug industry increased after 1962; and the increased costs can be associated with the Kefauver Investigation and Drug Act Amendments of 1962.

Public Relations

Business firms are most concerned about relationships with those who make purchasing decisions. In the Pharmaceutical Industry, the prime decision maker is the physician, and substantial funds are spent on influencing him; however, the actual purchaser is largely ignored.

The unique aspect of the channel relationships in the Pharmaceutical Industry is that the decision maker who is not the buyer has arbitrary powers to "force" the purchaser (the patient) to forego much of the privilege of searching and price comparing. The buyer often has only the option of buying or not buying, and if he is sick enough, this second option is not really available. A common complaint goes something like, "I paid $10.00 for ten little pills! How costly!"

In the usual channel relationship, the same type of complaint occurs, but the element of "buy or die" is not present and the buyer usually has knowledge of options. Furthermore, the price complaint can be handled more readily because re-assurance and price acceptance is easier when dealing with a customer who wants to buy a product. Also, the purchaser accepts prices more readily because he is normally more aware of the company, or at least the brand, and has some feeling of confidence and familiarity resulting from advertising, or public relations efforts.

Although pharmaceutical companies went to great efforts to be known and welcomed by decision-makers (physicians), they remained relatively unknown to the public until the early 1960's.

Little concern was evident for relationships with the ultimate purchaser because "he is forced to buy".

The Industry finally awoke to realize that the consumer's complaints about high drug prices had fallen on the ears of politicians. Neither consumers nor politicians had been made aware of the other side of the story of "high" drug prices. There was, therefore, little real opposition to the instigation of an inquiry into drug industry practices.

It is reasonable to assume that the Industry, finding itself in the midst of adverse publicity, would change its focus, and attempt to refashion its fallen image. It needed to build up support, and refute the many damaging claims made throughout the Investigation.

A further assumption is that once the Kefauver Investigation was over, and the Drug Act Amendments passed, the Industry experienced a great sense of relief after more than two years of public pressure. Once the pressure was reduced there were many things to capture the attention of Industry leaders other than improving public relations. Included were:

1. The large task of adjusting to the new regulations.
2. The day to day problems of management, which would often be given greater priority than long range questions.

3. The professional focus of the Industry which tended to cause management to forget about the importance of public relations efforts for the general public.

It seems that public relations efforts consequently would probably tend to decline from post-Investigation peaks. The following two hypotheses sum up this reasoning:

H_5 Since the Investigation, the public posture of the Industry changed from a rather insular attitude toward public opinion and information disclosing activities to a positive attitude, as demonstrated by increased activity and expenditure on public relations.

H_6 The public relations efforts of the Industry decreased substantially from the post-Investigation peak to 1966.

Industry Structure

In the foregoing sections, comments have been made about the following difficulties of doing business, additional expenses and consequences resulting from the Kefauver Investigation and Drug Act Amendments:

1. A reduction in number of new drug entities released.
2. An increase in costs of bringing a new drug through the various tests until it is finally passed.

3. An increase in costs of advertising and promotion.
4. A reluctance of qualified investigators to undertake research because of increased complexities and possible legal implications.
5. An increase in competitive marketing pressure resulting from slower influx of new products.

Such effects probably fall most heavily on smaller companies in the Industry. Consider for example, some of the additional expenses involved in bringing a new product to the market. Sustained toxicological and clinical experimentation are required to meet the increased safety requirements, and to prove product efficacy. Funds will be used in a number of ways:

1. To provide grants to experimenters to pay for the costs of research.
2. To hire new professionally competent personnel to conduct and oversee research (e. g. only four more doctors @ $25,000 results in a fixed cost of $100,000 per year).
3. To pay for increased administrative costs.
4. To pay for carrying the burden of research investment over several more years because of greater trials and slower release of drugs.

Unless a smaller firm is certain that its chemical research has produced a truly new "breakthrough" (which is rare) they must seriously consider whether they have enough resources to carry the added costs of developing a product. A larger firm would likely already have the resources to handle much of the extra work involved.

A smaller company, given its limited resources, must compare other alternatives to the risks and high costs of new product development. One logical area would be to attempt the maximization of sales of existing products. Another possibility would be to deemphasize efforts in the ethical market and move into other related areas less subject to the stringent regulations of the ethical industry such as the proprietary drug business. It is very competitive, however, and there are heavy financial demands for national advertising and promotion. Merging, or selling out, provide other alternatives. In conclusion, the future could be made more uncertain for smaller companies because of the effects of the Kefauver Investigation and Drug Act Amendments. From this, a final hypothesis is proposed:

H_7 The Investigation and Drug Act Amendments of 1962 can be associated with a substantial increase in concentration in the Pharmaceutical Industry since 1962.

Summary Listing of Hypotheses

In previous sections a number of hypotheses were put forward concerning the effects of the Kefauver Investigation and subsequent Drug Act Amendments of 1962. Here is a complete listing:

H_1 There is a positive association between the substantial reduction in the number of new ethical pharmaceutical products (i. e. new chemical entities) being introduced annually to the United States market, and the Kefauver Investigation and subsequent Drug Act Amendments of 1962.

H_2 No substantial decline in prices of ethical pharmaceutical products can be associated with the Investigation and Drug Act Amendments of 1962.

H_3 After the Investigation, the introductory prices of newly released drugs (for corresponding categories) were not substantially lower than those of similar drugs introduced prior to the Investigation.

H_4 The relative cost of promoting a product in the ethical drug industry increased after 1962; and the increased costs can be associated with the Kefauver Investigation and Drug Act Amendments of 1962.

H_5 Since the Investigation, the public posture of the Industry changed from a rather insular attitude toward public opinion and information disclosing activities to a positive attitude, as demonstrated by increased activity and expenditure on public relations.

H_6 The public relations efforts of the Industry decreased substantially from the post-Investigation peak to 1966.

H_7 The Investigation and Drug Act Amendments of 1962 can be associated with a substantial increase in concentration in the Pharmaceutical Industry since 1962.

Methodology

Primary Data

Two feasible methods were available to gather the primary data, personal interviews and mail questionnaires. A detailed case study by personal interview of a small but carefully selected number of pharmaceutical firms was chosen. Executives directly involved with operations affected by the Kefauver Investigation were interviewed. Personal interviews were selected over a mail questionnaire because:

1. A greater willingness to answer verbally, rather than complete a complex questionnaire, was anticipated.
2. A recollection of conditions which would often be forgotten can be encouraged through the interactive process of an interview.
3. A personal interview enables the interviewer to probe for deeper, more complete answers.
4. A better assessment of Industry attitudes is possible through personal interviews.

Secondary Data

A substantial amount of data was obtained from secondary sources. These were especially valuable because they emanated from a wide range of interest groups and represented a broad spectrum of opinions. The following major sources were surveyed:

1. Correspondence with the Food and Drug Administration, and also their published information.
2. Published and unpublished materials from the Pharmaceutical Manufacturers Association, as well as personal communications with them.

3. Publications and surveys by consultants to the Pharmaceutical Industry, and firms specializing in Industry research.
4. Testimony from a wide variety of witnesses as found in transcripts of the Kefauver and Nelson hearings.
5. U.S. Government Statistics.
6. The Trade and Business press.

In many cases, statistics normally not divulged by individual companies are more accessible through the above agencies. Often they are able to elicit information in confidence, and release useful aggregate data. Furthermore, such data are often collected and presented on a more uniform basis than would be possible through a private aggregation of individual company statistics. A description of the major sources of secondary data is found in Figure 1.

The Field Survey

Boundaries of the field survey were determined by defining areas where secondary data was unavailable or insufficient. On this basis, an interview schedule was developed to determine:

1. The changes in company policies regarding the thrust of new drug research over time (i.e. changes

in emphasis on basic or developmental research; increases or decreases in number or product areas researched).

2. The changes, if any, encountered by the company after the Investigation and Drug Act Amendments in:
   - product research
   - advertising
   - other areas
3. The typical research costs from discovery to time of marketing a product over the past ten years, if possible.
4. The number of new drug applications and time until approval for each firm over the past ten years.
5. The attitudes of marketing executives towards pricing.
6. The public relations activities undertaken in the past, and future plans.
7. The opinions of responsible executives regarding public relations.
8. The attitudes of the Industry toward the Kefauver Investigation, and investigations in general, and the role of Industry in these investigations.
9. The details of individual company experiences from the Investigation and new regulations.

FIGURE 1

MAJOR SOURCES OF SECONDARY DATA

Name	Source	Description
Administered Prices in the Drug Industry	U. S. Senate, Committee on the Judiciary	The "Kefauver Hearings" -- Data and testimony given under oath by many different sources.
Competitive Problems in the Drug Industry	U. S. Senate, Committee on Small Business	The "Nelson Hearings" -- Data and testimony given under oath by many different sources.
The Pink Sheet	FDC Publishing Co.	A weekly publication reporting all available information concerning activities of the food, drug and cosmetic industries -- oriented for these industries. The most complete running commentary of such events available.
PMA Fact Book	Pharmaceutical Manufacturers Association	A compilation of pertinent facts on the Pharmaceutical Industry from industry surveys, government statistics, and other sources.
FDA Reports	Food and Drug Administration	A publication designed to inform and educate the public as to the activities of the Food and Drug Administration.
Compendium of Medical Advertising	Food and Drug Administration	A compilation of speeches on advertising by FDA officials; also descriptions of codes of ethics and FDA regulatory actions - designed to show the intent of FDA concerning regulation of advertising.
Statistical Abstract of the U. S.	U. S. Government	Abstract of U. S. statistics.
Fortune Directory	Time-Life Publishing Co.	A listing of the top 500 companies as well as some statistics on top industries and their earnings.
Current Industrial Reports	U. S. Dept. of Commerce	Reports on sales of various S. I. C. categories annually.

Name	Source	Description
New Products Parade	Paul deHaen, Inc.	Annual collection of statistics on new product developments by a leading Industry consultant. Best such statistics available.
Red Book	Drug Topics Publishing Co.	A listing of wholesale and retail prices of all products handled in drugstores. Includes supplements within years.
Physicians Desk Reference	Medical Economics	A reference manual containing essential prescription information on major products. Manufacturers specify and pay for products to be included, and write the descriptions.
Summary of Drug Act Amendments	U. S. Dept. of Health, Ed. & W.	Summary of Amendments
Firms specializing in collection of Industry statistics	Anonymous	Firms reliably monitor and report company activities and sell this information to subscribing firms.

The Interview Schedule

A series of topic questions was developed for an interview with selected executives. This format allowed probing, provided deeper coverage of the subjects, and led to discussion of important related areas. The interview pattern moved from nondirective questions in specific areas such as advertising, product development and public relations, to direct questions concerning the Kefauver Investigation and Drug Act Amendments.

The stated purpose of the interview was to discuss "changes in the Pharmaceutical Industry in the past ten years". Unless a respondent introduced the subject of the Kefauver Investigation it was not mentioned until the final two questions. Consequently, the respondent was free to name changes which he considered most important, and was not induced to cite effects of the Investigation out of proportion to other factors.

After preliminary drafts of the interview schedule were developed and revised, it was sent to the Marketing Research Department of an interested pharmaceutical company which was aware of the nature and purpose of the total study. The knowledgeable members of this firm assisted in judging the suitability of the topic questions--whether or not a pharmaceutical company could, or would respond. An overall evaluation of the methodology was also obtained. The interview guide was revised again, and similarly

evaluated once more. Although there was some doubt whether certain numerical information requested could or would be given, it was considered worthwhile to retain these questions.

The interview schedule was then pretested. The company selected for pretesting was approached, first by mail,[1] then by telephone, and appropriate executives interviewed, according to the plan of the study. The interview schedule worked well. Questions asking for numerical information were the only incomplete portion, and enough information was obtained in these areas to justify continued use of them.[2]

During the study, good co-operation was obtained from all respondents. The interview schedule led to a discussion of the necessary topics, and adequately served the purposes for which it was designed. The main shortcoming was that respondents were unable in most instances, and unwilling in a few, to provide all the numerical data requested. This deficiency was not crucial, however, for appropriate data were obtained from secondary sources.

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[1] See Appendix C for the letter.

[2] See Appendix B for Interview Schedule.

The Sample

To select cases for study a purposive sample was utilized, based on the following criteria:

1. The firms selected should be American owned, as are most pharmaceutical companies in the United States.
2. The firms selected must have been selling ethical pharmaceuticals before 1955.
3. To observe effects on companies of varying size the selected firms should range from very small (less than $2 million sales annually) to large (more than $300 million sales annually) although a majority of pharmaceutical business is handled by larger companies (see Table 1).
4. The firms selected should be "typical" of those conducting the majority of the pharmaceutical business (there are very many extremely small firms technically classified as being part of the Industry which have almost no significance for the total Industry). This selection should be determined on the basis of a personal knowledge of the Industry, and through consultation with other Industry executives.

The results from this non-random, but carefully selected sample, are not projectable to the Industry as a whole. However, the extent and depth of information obtained from these interviews disclosed a substantial portion of the effects of the Kefauver Investigation and Drug Amendments on the Pharmaceutical Industry. This assertion is supported by the finding that after approximately one-half of the scheduled interviews were completed, a continuing similarity in responses was found.

Marketing Managers and Directors of Product Research, or their delegates were selected to be interviewed in each firm. In a number of companies, opportunity was also afforded to interview Public Relations Managers, Washington Representatives, and other informed executives. As many as seven people in one company were interviewed. In two companies, only one individual was interviewed. A total of 25 individuals were interviewed. Table 1 shows the number of interviews in firms of varying size.

Reference to the identity of firms interviewed will be eliminated or disguised. The sample comprised eight companies ranging from small to large and is illustrated in Table 1. Only two refusals were experienced, and these were substituted with two other companies of similar size and characteristics. Each

TABLE 1

CHARACTERISTICS OF SAMPLE

No. of Companies	Sales Range ** ($millions)	Numbers of individuals interviewed
1	$300 - 400	4
1	250 - 300	1
1	250 - 300	7
1	200 - 250	2
1	100 - 150	2
1	50 - 100	4
1*	3 - 25	4
1	1 - 2	1

*Company used for pretest included because questionnaire and approach unchanged.

**Sales are ranged to preserve company anonymity.

interview lasted from one to one and one-half hours and resulted in a combined total of approximately eighty typewritten pages of notes. The interviewing was conducted by this author in April and May of 1968.

Research findings will be presented and related to the hypotheses in the following chapter. As this is a case study, data will be somewhat descriptive. Time series analysis will be applied to appropriate segments of the data to provide some insights into future implications of the effects of the Investigation.

CHAPTER V

RESEARCH FINDINGS

The findings of this study are presented in this chapter. The chapter is divided into five parts, each relevant to a particular research area concerning the impact of the Investigation:

1. Effects on New Product Development.
2. Influences on Pricing.
3. Effects on Promotional Activity.
4. Effects on Public Relations Activity.
5. Changes in Industry Concentration.

PART I

EFFECTS ON NEW PRODUCT DEVELOPMENT

This section presents findings concerning the following hypothesis:

H_1 There is a positive association between the substantial reduction in the number of new ethical pharmaceutical products, (i. e. new chemical entities) being introduced annually to the United States market, and the Kefauver Investigation and subsequent Drug Act Amendments of 1962.

Effects on new product development will be considered from two broad perspectives:

1. A discussion of statistics concerning numbers of new products introduced over time, research and development funds available, trends in costs of new product development, and time required to develop a new product.
2. A discussion of changes in research and new product development practices since the Investigation experienced by individual companies surveyed.

Analysis of Trends in New Product Introductions since 1955

Since 1955, both annual new drug applications submitted to the Food and Drug Administration and total new products released yearly declined steadily, with the exception of small increases in new drug applications in 1965 and 1966. From the all-time peak in 1955, to 1967, new drug applications fell 76 per cent and new product introductions plunged 80 per cent. This is shown in Table 1 and Figure 1.

TABLE 1

PHARMACEUTICAL SPECIALTIES MARKETED

IN THE UNITED STATES

r	New Drug Applications [a]	Total New Products [a]	New Chemical Entities [a]	Average Days Required for Approval of NDA
4	NA	380	41	NA
5	501	403	36	NA
6	438	401	45	NA
7	445	400	51	NA
8	344	370	44	102
9	369	315	63	106
0	368	306	45	136
1	262	260	39	191
2	282	250	27	NA
3	179	199	16	327
4	160	157	17	NA
5	221	112	23	NA
6	216	80	12	NA
7	120	82	25	460

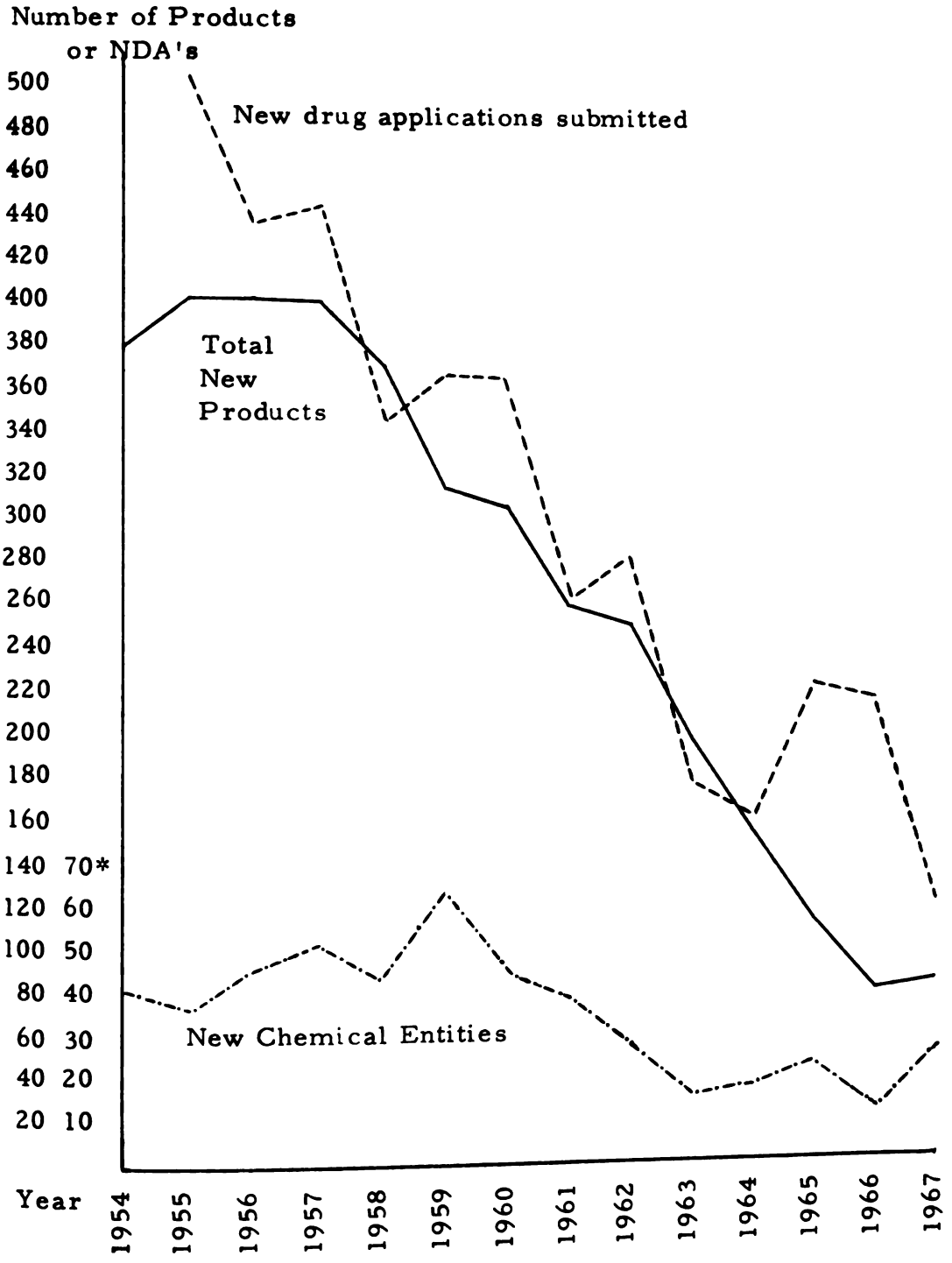
Chemical Entities - indicates products which are new single chemical agents not previously known, including new salts.

l New Products - includes new chemical entities, duplicate single products, combination products and new dosage forms.

ces: (a) Paul deHaen, New Products Parade, 1967 (New York: Paul deHaen, 1967, p. 19.

(b) Pharmaceutical Manufacturers Association and Food and Drug Administration data.

FIGURE 1: PHARMACEUTICAL PRODUCTS MARKETED IN UNITED STATES 1954 - 1967



*Scale for new chemical entities.

Source: Paul deHaen, New Products Parade.

As would be expected, there is a close correlation ($r = .94$) between the two trends. The proportion of total variation in new product introductions not explained by new drug applications ($1 - r^2$) is only .14. Consequently, an evaluation of new drug application trends might provide a good indication of forthcoming new product introductions. The small increases in new drug applications in 1965 and 1966 appear to be reflected in the slight increase in new products in 1967.[1] The year 1968 might possibly also show a slight increase. However, the decline in new drug applications which reached a new low in 1967 indicates that overall new product introductions will likely decline after 1968.

The best index of pharmaceutical research efficiency is probably the annual number of new chemical entities introduced.[2] It also declined steadily from a peak in 1959, through 1963, a decline of 75 per cent. In 1959, 63 new entities were introduced, and 16 were marketed in 1963. From 1964 to 1967, production of new entities fluctuated at relatively low levels between 12 and 25

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[1] Considering a 1 - 2 year lag (see p. 140 infra)

[2] New product development is dependent on the discovery of new entities.

as is shown in Table 1 and Figure 1. The introduction of new entities is associated with the number of new drug applications between 1959 and 1967, having an r of . 82.

The proportion of variation in introduction of new entities not explained by new drug applications is . 33, considerably larger than that for total new products. Although an indication of the future number of new entities can be gained from observing new drug applications, [1] there are other factors, such as recency of basic scientific discoveries, which also affect the number of new entities introduced.

The decline in introduction of all new products began well before any influence from the Kefauver hearings and Drug Act Amendments of 1962. From the data presented in Table 1 and Figure 1, it is not possible to observe any association between the Investigation and the decline in either total number of new products, or new chemical entities. Both declined steadily since 1955 and 1959, respectively, even though research expenditures continued to increase.

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[1] Considering an approximate two year lag.

Why have the number of new products declined? Apparently, the steady decline in new products is more a function of other causes than of any regulatory change. One reason may be that relatively few developments from extant knowledge are possible. The proliferation of new products since 1935 was based largely on knowledge accumulated over the preceding 50 years, as was discussed in Chapter II. The concepts of medicinal chemistry were new at the turn of the century, and many basic discoveries took place from 1890 to 1940. The demands of World War II accelerated the drive to develop improved therapeutic agents, and basic research knowledge which had been developed through the years was applied to produce many new products.

It is possible that fewer new products are being introduced because much attention was diverted from expanding basic research to the pursuit of analogue development. Since the sulfonamide breakthrough, the Pharmaceutical Industry diligently screened substances chemically similar to newly developed chemical entities for promising analogues. [1]

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[1] Lewis H. Sorett, "Basic Research at Merck and Company" in Proceedings of a Conference on Academic and Industrial Basic Research, sponsored by National Science Foundation, 1960 (Washington: U.S. Government Printing Office, 1960), p. 28.

After 1955, the fruitfulness of such research apparently diminished.

The decline in new products may also be related to the complexity and lack of understanding of remaining therapeutic problems. To achieve further fundamental progress, significant breakthroughs in understanding basic causes of disease and biochemical techniques are apparently needed. [1] The products developed up to the mid-1960's fall into surprisingly few basic therapeutic categories -- antibiotics, antihistamines, corticosteroids, tranquilizers, anti-diabetics and hormones, being the main ones.

Although the data showing declining new product introductions cannot be associated with the Investigation and Drug Act Amendments, other associated effects on new product development are evident. One of these effects is a substantial increase in product development costs. Table 2 shows that while research and development costs per new entity increased steadily from 1954 to 1962, they almost

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[1] Interviews with Research Directors indicated that fundamental biochemical discoveries are needed for further substantial progress.

	Mean Cost per	New Entities

TABLE 2

RESEARCH AND DEVELOPMENT RELATED TO

PRODUCTION OF NEW ENTITIES

	Industry R & D ($ millions) [a]	New Entities [b]	Mean R & D Cost per Entity ($ millions)	Mean Cost per Entity with 4 year Lag ($ millions)	New Entities Per $100 million Invest. in R & D
1954	78	41	1.9		52.1
1955	91	36	2.5		39.6
1956	105	45	2.3		42.8
1957	127	51	2.5		40.0
1958	170	44	2.9	1.77	29.9
1959	197	63	3.1	1.44	31.9
1960	206	45	4.6	2.34	21.8
1961	227	39	5.8	3.28	17.3
1962	238	27	8.8	6.3	11.7
1963	267	16	16.7	12.3	6.0
1964	278	17	16.4	12.9	6.1
1965	328	23	14.3	9.9	7.0
1966	374	12	31.2	19.8	3.2
1967	460*	25	18.4	10.7	5.4
	***		**		

[a] PMA Fact Book, p. 39.

[b] Paul deHaen, New Products Parade.

* Budgeted for 1967.

** See Table 3 for projection.

*** See Table 4 for projection.

doubled (from $8.8 to $16.7 million) between 1962 and 1963, the year following the Drug Act Amendments. The higher level of research and development expenditures per new entity continued to 1967. A projection of this new trend in Figure 2 indicates that total expenditure of $31.8 and $44.7 million may be reached by 1970 and 1975, respectively.

Research and Development Related to Sales

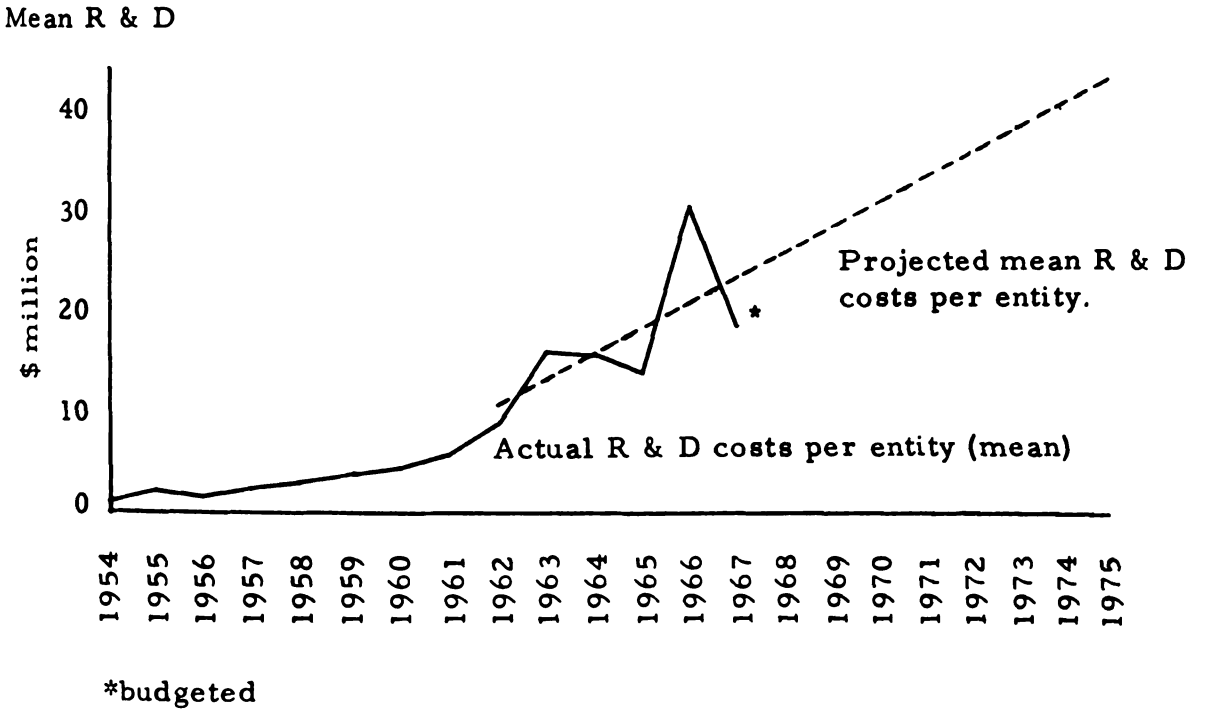
While total Pharmaceutical Industry sales have risen steadily since the 1940's, research and development expenditures also have expanded proportionately. There is a .96 correlation between research and development expenditures and sales. Research and development expenditures, in fact, account for a gradually increasing percentage of sales through the years. Data in Table 4 indicate that changes in total research and development expenditures, appear more closely related to sales than to external regulatory factors. The proportion of total variation in R & D expenditures explained by Industry sales, r^2 is .92.

At first glance, research and development expenditures appear to have increased somewhat faster since 1962 than they did in previous years. However, when this notable

FIGURE 2

MEAN RESEARCH AND DEVELOPMENT EXPENDITURE

PER CHEMICAL ENTITY IN THE ETHICAL PHARMACEUTICAL INDUSTRY



*budgeted

Figure 2 shows mean R & D expenditures per new entity from 1954 to 1967, and an estimate of these expenditures projected to 1975. The time period selected as the basis for projection is 1962 to 1967. The trend in mean R & D expenditures per new entity rose sharply after 1962. While there are substantial fluctuations after 1962, a continued period of higher expenditures is evident (see p. 8 infra).

By the method of least squares, research and development expenditures from 1962 to 1967 were represented by the least squares line $Y_c = 11.18$ ($ million) + 2.58 X, where X represents the time period of one year and Y_c is the trend value for period X.

The least squared projections of mean R & D expenditures

TABLE 3

PROJECTED MEAN R & D COST PER ENTITY

($ MILLIONS)

1954	. .	1.9	1965	. .	14.3
1955	. .	2.5	1966	. .	31.2
1956	. .	2.3	1967	. .	18.4
1967	. .	2.5	1968	. .	26.7*
1958	. .	2.9	1969	. .	29.2
1959	. .	3.1	1970	. .	31.8
1960	. .	4.6	1971	. .	34.4
1961	. .	5.8	1972	. .	37.0
1962	. .	8.8	1973	. .	39.6
1963	. .	16.7	1974	. .	42.1
1964	. .	16.4	1975	. .	44.7

Source: Paul deHaen, New Products Parade, PMA Fact Book, p. 39.

*From 1968, figures are projected.

per new entity to 1975 are shown in Table 3.

Considering the actual data points and corresponding ones from the least squares line, the correlation coefficient is .92. The proportion of total variation explained by the least squares line is $r^2 = .85$. It is therefore quite a good representation of mean R & D expenditures per new entity over a period of time. However, as these expenditures have fluctuated considerably in the past few years, the projection for any one year could be somewhat higher or lower.

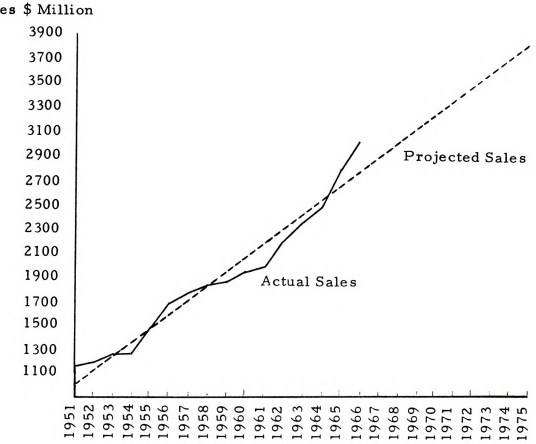
increase is considered as a percentage of sales, it is evident that it is associated with a proportionate growth in sales over the same period. In fact, research and development expenditures reached 11.3 per cent of sales in 1961, and were not as large a proportion again until 1965.

Assuming similar favorable growth conditions as in the past one and one-half decades, sales were projected to approximately $3,251 million by 1970, and $3,835 million by 1975 (see Table 4). As a percentage of sales, research and development expenditures increased at an increasing rate from 1954 to 1957 and since then have increased, but at a decreasing rate. Research and development expenditures as a percentage of sales were projected to 1975, as shown in Table 4, and expected research and development outlays were calculated from the sales and percentage projections. Expenditures in 1970 and 1975 should be approximately $410 and $518 million, respectively.

Looking at new product development from another perspective, it appears that the Industry cannot afford to carry as many products in research and development programs since the Drug Act Amendments of 1962. While research and

FIGURE 3

INDUSTRY SALES



Industry sales from 1951 to 1966 and an estimate of sales projected
5 are shown in Figure 3. During this time a relatively steady pattern of
, unmarked by substantial breaks in the trend was evident. The prospects
inued steady growth are apparent. Population is increasing, including
pportion of elderly people who are subject to more illness (see Table 6,
r II).

Industry sales from 1951 to 1966 can be adequately described by a
t line. As it appears that the rate of growth from 1967 to 1975 will
e in a similar manner to the period 1949 to 1966, a projection of this
ould provide a reasonable picture of sales in the period 1968 to 1975.
quently a least squares line Y_c = 1,849 ($ million) + 116.8 X was fitted
lata.

Where X represents the time period of one year, and Y_c is the trend
or period X.

The actual data points are very closely correlated with corresponding
om the least squares line with r = .998. The proportion of total

TABLE 4

RESEARCH AND DEVELOPMENT EXPENDITURES

RELATED TO SALES 1951 - 1975

Year	Domestic Ethical Sales ($ millions)	Research & Development ($ millions)	R & D as[a] percentage of sales
1951	1,148	50	4.36
1952	1,175	63	5.36
1953	1,213	67	5.66
1954	1,252	78	6.22
1955	1,457	91	6.26
1956	1,676	105	6.27
1957	1,742	127	7.30
1958	1,802	170	9.44
1959	1,850	197	10.65
1960	1,905	206	10.80
1961	1,954	227	11.63
1962	2,199	238	10.84
1963	2,317	267	11.53
1964	2,479	278	11.21
1965	2,779	328	11.81
1966	3,011	374	12.43
1967 *	2,908 *	352 *	12.1*
1968	3,017	371	12.3
1969	3,134	392	12.5
1970	3,251	410	12.6
1971	3,367	431	12.8
1972	3,484	453	13.0
1973	3,601	472	13.1
1974	3,718	495	13.3
1975	3,835	518	13.5

Source: PMA Fact Book, pp. 8, 39.
* Subsequent figures are projected.
[a] See Figure 4 for projection.

variation explained by the least squares line is thus $r^2 = .996$.

FIGURE 4

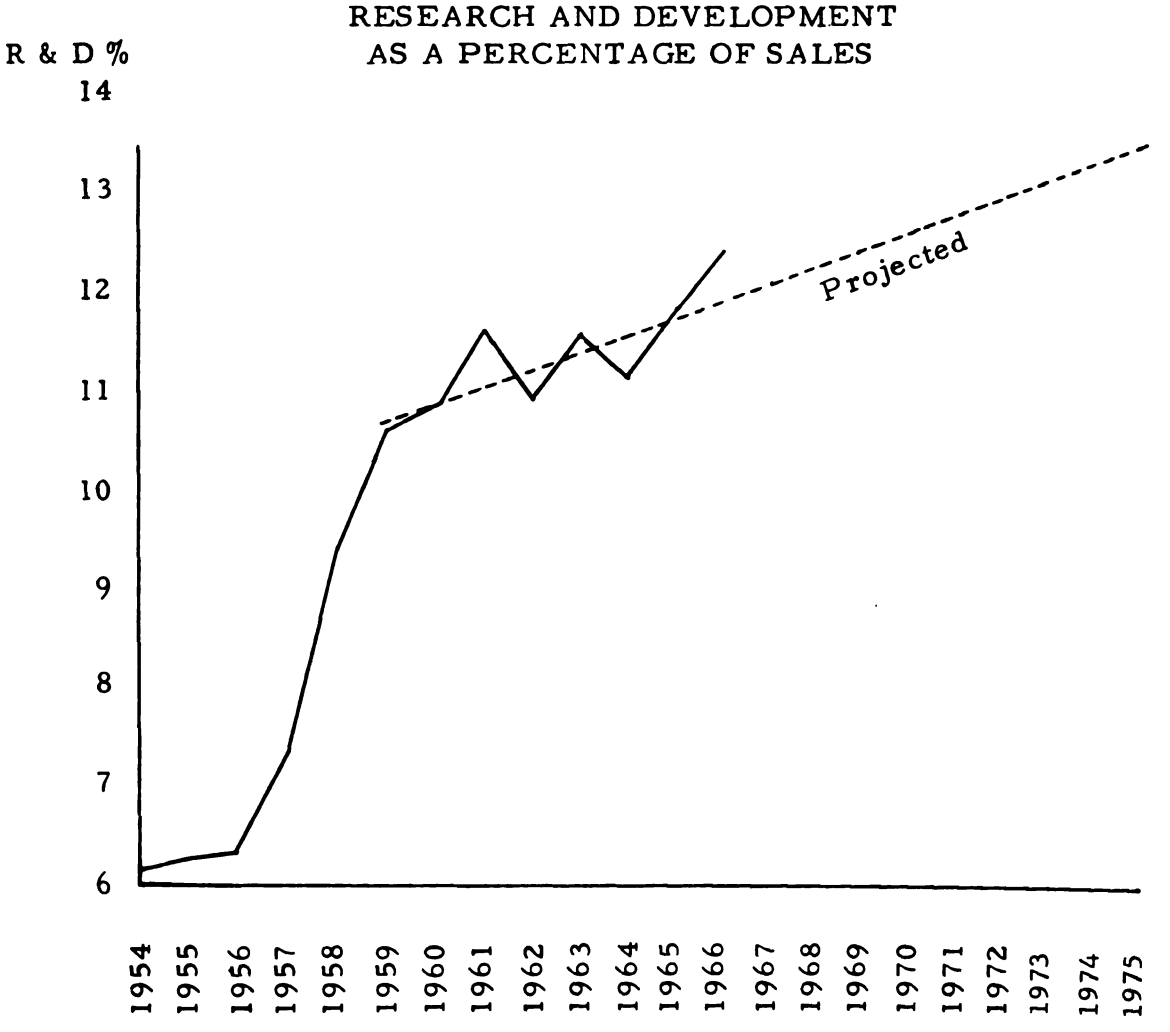


Figure 4 shows research and development as a percentage of sales from 1954 to 1966, and an estimate of these percentages projected to 1975. The time period selected as the basis for projection is 1959 to 1966. The trend in R & D as a percentage of sales changed substantially after 1959, and has increased more gradually since then.

By the method of least squares, the line $Y_c = 10.8 + .166\ X$ was fitted to R & D as a percentage of sales from 1958 to 1966.

Where X represents the time period of one year, and Y_c is the trend value for period X.

The least squared projections to 1975 are shown in Table 4.

The correlation coefficient r, is .85, and the proportion of total variation explained by the least squares line is $r^2 = .73$.

development expenditures per product increased steadily for many years, they nearly doubled between 1962 and 1963. However, total dollars spent on research and development have not increased proportionally. For example, in 1962, research and development expenditures of $238 million would theoretically produce 27 new entities (theoretical cost per entity: $8. 8 million). Despite an increase in research and development expenditures to $267 million in 1963, the cost per entity increased so much that only 16 new entitites were produced (theoretical cost of $18. 4 million per entity). It is recognized that other factors, such as the state of basic knowledge and availability of trained researchers, also affect new product development; however they in turn, are partially affected by expenditures of research funds.

In view of the foregoing circumstances, the Industry can be expected to be more selective in research and development efforts. A greater emphasis on more profitable items should become evident. Consequently products with valuable therapeutic effects, but having limited market potential may not receive adequate developmental attention from pharmaceutical firms.

Time Required for Product Development

At least four years usually elapse from the time a product shows promise in the laboratory until it is marketed. This is more than double the time taken before the Drug Act Amendments. The time required for testing and research before making a new drug application increased from approximately one, or one and one-half years, to three years.[1] The FDA has also taken substantially longer to process new drug applications (NDA). Although complete statistics are not available, the average number of days required for approval of an NDA jumped from 191 in 1961 to 327 in 1963, an increase of 49 per cent, and further increased to 460 in 1967. This data was presented in Table 1.

Field Survey Findings

Trends Toward Basic Research

Basic research may be defined as a search for primary or elemental truths not discovered previously. An example would be a discovery that a certain group of chemical substances enters the cell of an infectious microorganism and interferes

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[1] This was a figure given by several research directors in the survey.

with its reproduction. Developmental research applies the findings of basic research to particular problems. It would utilize the findings about chemical effects on microorganisms to refine and isolate the most effective and safe drug, and determine necessary dosage. In the pharmaceutical field both types of research are necessary.

All companies surveyed, except the smallest one, expanded the proportion of funds allocated to basic research in the 1960's. One reason is the increased probability of returns from basic research through advances in instrumentation and scientific knowledge over the 1950's. Another is that requirements of the Drug Act Amendments stimulated more basic research. First, more extensive toxicological studies were required. Such research into the nature and reasons for untoward actions of drugs studied tended to focus studies on primary knowledge. Second, FDA requirements induced companies to restrict development of products similar to those already on the market because prooof of safety and efficacy through the same expensive techniques and processes as for new products must be made. Consequently, it is often not worthwhile to introduce an analogue because research funds

of this magnitude may be allocated better developing new products. Third, basic research became more important because there is informal FDA pressure against introducing new analogues. If this is so, the economic implications may be a decrease in competition, perhaps higher prices, fewer product improvements, and poorer service to the medical profession, and ultimately, the patient.

In summary, the Industry increased basic research expenditure because:

1. Advancements in scientific instrumentation and knowledge increased probabilities for success in the quest for significant new products.
2. The Drug Act Amendments increased testing requirements which changed the focus of research, and made developmental research less profitable.

Changes in Research Costs

The foregoing change in research emphasis increased costs. This survey revealed the major cause of increased costs to be the new regulations from the Drug Act Amendments. First, many new toxicological and clinical tests

were prescribed. Second, these tests, and application approval, required more time. Testing normally continues even while waiting for FDA approval. Thus greater research costs are extended over a longer period (see p. 17 infra) . Third, scientific personnel are also committed for longer periods to the same project, limiting other developmental activities.

The one small company surveyed did not increase basic research expenditure because the burden of such a program was considered too costly. For this small firm then, new product development through basic research is not a feasible possibility. Further research is needed to determine whether the other smaller sized firms had similar experiences.

Research Efforts Concentrated on Fewer Products

Given increased research costs, pharmaceutical manufacturers have four major feasible strategies in allocating total research and development expenditure.

1. To continue research in all therapeutic areas of interest, and finance increased costs by restricting other programs, such as marketing.
2. To continue research in all therapeutic areas of interest, but allocate less funds

3. To spend more in all research areas without restricting other activities, where possible.

4. To concentrate research funds in selected areas; providing adequate resources for some product development.

In reality, all but one of the research firms surveyed have followed the latter alternative. One company reported cutting research from 43 product categories to about one-half [1] of these. Another large company restricted the general areas of research to four, whereas they attempted previously to work in all [2] areas. Furthermore, they now have a smaller number of specific products under research. Six of the seven companies actively engaged in research reported a substantial concentration in number of research projects since 1962.

Reduction in research areas could have these ramifications:

1. For the company, risks are greater. New developments may occur in other

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[1] The precise number is not available.

[2] The exact number is not available, however, one common Industry breakdown of research areas is 15, (see p.171)

areas, precluding the firm from early entry into areas of rapid growth. However, if growth occurs in company-selected areas, substantial market shares may be gained.

2. For the consumer, slower progress and a continuing small number of new products may be developed. Products developed and patented by a smaller number of specialty companies than presently exists could decrease competition, with the possibility of higher prices and decreased service to physician and patient.

Development of Products with Limited Market Potential

The Pharmaceutical Industry has a moral responsibility to bring beneficial products to the market. On the other hand, a pharmaceutical company may not be able to afford development of products with limited potential. The Industry, therefore, faces a dilemma in considering whether or not to proceed with the development of new products which will obviously serve very limited markets.

Under the present administration of regulations of the Drug Act Amendments of 1962, it costs as much to develop a product serving the needs of one hundred people as one serving those of one million. In view of the risks previously discussed[1] it might be expected that companies would limit the development of small volume products. Since the passing of the Drug Act Amendment this is apparently what is happening. Seven of the eight companies surveyed decided to limit developmental efforts of such products. One company reported restrictions on the development of a product with very limited potential in a special area of cancer treatment. The respondent said, "With the potential of additional expensive studies being demanded by FDA every six months or so)on the basis of past and present experience), the costs would be too great; and, therefore, this product was dropped".[2]

Companies are concerned about this matter, but the realities of existence must also be considered. A new approach, therefore, is necessary. One alternative is for government

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[1]See Chapter 2, p.27 , infra.

[2]Personal confidential interview.

subsidy of research into limited-use products. But the establishment of precedents for future government intervention may not be very attractive to the Pharmaceutical Industry.

There are also two immediate difficulties. First, there is the difficulty of proving the need for a subsidy. Second, there is the potential loss of product control when government has invested in its development. Another approach would be a re-assessment by FDA of all requirements to determine whether there are costly, but minimally-essential ones which might be waived in the above circumstances. In drugs designed for treatment of certain terminal diseases, requirements for chronic toxicity tests might be reduced or eliminated.

One medium-sized company has set an arbitrary potential sales volume of $1-1/2 million as the point below which they will not proceed with development of a new product. A larger company established this point at approximately $4[1] million. But even then, based on the findings of the previous section, it is doubtful whether such sales would be profitable.

In summary, increased costs of new product development are associated with the Drug Act Amendments of 1962. These increases in turn have resulted in decisions not

[1] From confidential interviews during the study.

to develop some products with limited potential. This finding supports H_1; that there is a positive association between the Kefauver Investigation and the reduction in number of new ethical pharmaceutical products.

FDA - Industry Relations and New Product Development

Changing Relationships

The activities of the Pharmaceutical Industry and the FDA as members of the health team are inextricably related. The survey revealed that a change in this relationship was one of the most important effects of the Kefauver Investigation on new product development. Previously, there was a great deal of co-operation and communication which facilitated relatively smooth processing of new drug applications. Since the Investigation, co-operation and communication has mostly become limited to formalities.

During the Investigation some FDA activities were questioned, and close liaison with the Pharmaceutical Industry was criticized. While the spotlight of political activity now focuses intermittently on the Pharmaceutical Industry, the FDA faces continuing political scrutiny. Politicians, now aware of

public sensitivity to health issues, constantly scrutinize and evaluate activities of the FDA. [1] Seemingly these influences affect FDA attitudes and decisions.

The FDA was required to establish and police new regulations. In protecting itself against future political criticism and inquiry, the temptation to set extremely rigorous standards was great. Furthermore, it was difficult to hire additional professional staff. Often, more attractive salaries and more interesting jobs were available elsewhere. The FDA consequently fell behind in its work load.

> Provisions were made for increasing the staff of the Bureau of Medicine, but implementation of these provisions was slow. In June of 1963, the available staff was barely adequate to deal with the increased work involved. In that month alone, approximately 1,000 Notices of Claimed Investigation Exemption for Investigational Drugs were received. By the end of the year, it was apparent that the majority of New Drug Applications could not be reviewed within the statutory 180 days.
>
> The term "backlog" began to be applied to New Drug Applications which had been in process in excess of the 180 days allowed. The problem was most critical in the medical area . . .

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[1] Interview with former high ranking FDA official.

> Various measures were taken to remove applications from the backlog. But the FDA backlog grew from virtually none in 1962 to 98 on January 1, 1967. On that date, a total of 301 New Drug Applications was under review; many of these were only weeks away from the 180-day limit. [1]

In conclusion, frustration and antagonism between the FDA and the Pharmaceutical Industry were caused by changed relationships, new rigorous regulations, and because the FDA fell behind in its new duties.

Recommendations

Based on the foregoing findings on new product development it is recommended:

1. That the Pharmaceutical Industry increase the proportion of funds allocated to basic research. The decline in new product development is associated with a lack of basic knowledge, and an increased emphasis on basic research is needed. Pharmaceutical research firms should

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[1] Robert M. Hodges, "The Review and Processing of New Drug Applications" FDA Papers, July - August, 1967, p. 28 .

allocate more than the current sixteen per cent of research and development funds which is channeled into basic research.[1] In other industries, firms known for their research accomplishments have found that the allocation of 30 per cent of their research and development budgets to basic research is a useful norm.

> Almost all of the larger corporations have independently found that about thirty per cent of their research funds should be budgeted to basic research to get maximum long-range profits . . .[2]

2. That firms select carefully basic research areas which will yield to investigation, and result in important subsequent applications. One way of accomplishing this is for company basic research scientists to participate actively in contemporary currents of scientific thought. Thus they can be aware

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[1] PMA Fact Book, p. 41.

[2] Augustus B. Kinzel, Vice President of Research, Union Carbide Corporation in National Science Foundation, Academic and Industrial Basic Research, p. 4.

of, and stimulated by worldwide activity in the sciences relevant to pharmaceutical development.

3. That management recognize the marketing possibilities in longer product life cycles as the rate of new product introductions declines. The following strategies might be considered:

   a) For existing products, promotional efforts should be designed to protect and improve the present competitive position. After a product has been on the market for a period of years, consideration should be given to reviving interest and improving it through innovations such as new dosage forms, combination with other products and improved packaging.

   b) For new products, investment in promotional funds may be greater, because of the possibility of larger returns over a longer period. On the other hand, a gradually expanding campaign as market acceptance becomes known is also feasible.

c) For products with long life cycles, a gradually declining price pattern may be developed to discourage competitors from entering the market.

4. That the Industry and the FDA discuss ways to bring important, but limited-use products to the market.

a) One alternative might be a selective reduction of less essential FDA requirements such as chronic toxicological studies for products treating terminal diseases, and a co-operative approach by the FDA to expedite approval of such products.

b) Where it is impossible to ease costly requirements, government should subsidize the development of these products, since they are of benefit to society as a whole and not to the company or stockholders. In these cases, where commercial risks are reduced, a corresponding reduction in the risk-premium element of prices should follow.

5. That the FDA should not discourage the introduction of analogues as long as they meet established requirements for safety and efficacy. In this way, competition may be increased, prices may be lowered, and greater service and selection should be provided for the physician and his patient.

6. That processing of new drug applications be accelerated. This might be accomplished by making FDA approval decisions from carefully prepared summaries of Industry research. The total research findings on which the summaries are based should be submitted also, and random spot checks by FDA staff members could be made to verify that the summaries represent adequately all significant findings. The FDA and the Pharmaceutical Manufacturers Association should meet to work out procedures and requirements.

7. That the Federal government expand its support of basic research considered too risky by

Industry. Since industrial firms must consider the possibilities of return on research funds expended, high-risk long-term research projects may not receive adequate attention. The Federal government has an advantage in such cases because public resources can be committee to long-term projects necessary to solve fundamental problems.

Conclusions

From 1955 to 1967, the yearly number of new drug applications, and new products introduced, declined from 501 to 120 and 403 to 49, respectively. Annual introduction of new chemical entities continued to increase to a peak of 63 in 1959 but declined steadily to 16 in 1963, and fluctuated at low levels to 1967. An evaluation of the steady decline found in each case, indicates that the Kefauver Investigation and Drug Act Amendments had no apparent effect on these pre-existing trends.

However, since the Kefauver Investigation, the cost of introducing a new chemical entity nearly doubled, the time required to bring it to the market increased from one or two

years to more than four years. Also poor working relationships between the FDA and the Pharmaceutical Industry exist. These factors coupled with the fact that the FDA now discourages the introduction of products which are similar to others currently on the market, inhibit the development and introduction of new products.

Since the Investigation, research and development costs per new entity have increased more rapidly than research funds. Higher relative costs resulted in fewer research projects. Consequently a smaller number of new products appear in the offing. Most of these will be products having substantial sales potential.

PART II

INFLUENCES ON PRICING

A major thrust of the Kefauver Investigation centered on tempts to lower drug prices. The investigators sought to prove at prices were too high; and through public pressure and legis- tion to force them down. Previous discussion (Chapter IV, p.103) d to the following hypotheses suggesting that the investigators ere unsuccessful in these efforts.

H_2 No substantial decline in prices of ethical pharmaceutical products can be associated with the Investigation and Drug Act Amendments of 1962.

H_3 After the Investigation, the introductory prices of newly released drugs (for corresponding categories) were not substantially lower than those of similar drugs introduced prior to the Investigation.

To test H_2, three different approaches will be undertaken:

1. An evaluation of whether prices of a sample of products changed significantly after the Investigation.

2. An evaluation of price index movements.

3. An evaluation of trends in average prescription prices.

An analysis of actual prices of new products before and after the Investigation will be presented in evaluating H_3.

Pricing History of Major Products

Table 1 traces prices from 1957 to 1967 of the top five products (as measured by sales volume) of each company surveyed. These are probably the most significant products for each company. We are interested in whether prices changed substantially after the Investigation. A comparison of prices between the periods 1957 to 1962 and 1963 to 1967 should provide an indication of any changes which might be associated with the Kefauver Investigation and Drug Act Amendments.

Prices of forty products were traced from 1957 to 1967. [1] The fact that prices of 82.4 per cent of the top products of companies surveyed remained the same or increased after 1962

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[1] "Current" rather than "real" prices are used because changes in prices brought about by management can be seen more readily. This facilitates conclusion-drawing concerning the effects of the Investigation on prices. Furthermore, Table 2 shows that the wholesale price index of all commodities rose only 1.6 points between 1957 and 1963, the year following the Drug Act Amendments.

TABLE 1

CHANGES IN PRICES OF TOP PRODUCTS 1957 - 1967

	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Company A											
Product 1	1.39	-*	-	-	-	-	-	-	-	-	-
2	-	-	-	6.63	-	-	-	-	-	-	-
3	-	-	-	6.83	-	5.84	4.95	-	-	-	-
4	-	-	11.88	-	-	8.91	7.57	-	-	-	-
5	-	-	5.24	-	-	5.64	-	-	-	-	-
Company B											
Product 1	1.85	-	-*	-	-	1.57	-	-	-	-	-
2	.71	-	-	-	-	-	-	-	-	-	-
3	3.56	-	-	-	-	-	-	-	-	-	-
4	1.90	-	-	-	-	-	-	-	-	-	-
5	-	14.85	-	-	-	11.14	9.45	-	-	-	7.43
Company C											
Product 1	4.55	-	-	-	-	-	-	-	-	-	-
2	5.15	-	-	-	-	-	-	-	-	-	-
3	4.39	-	-	-	-	-	-	-	-	-	-
4	-	-	6.60	-	-	-	-	-	-	-	-
5	-	5.00	-	-	-	-	-	-	-	-	-
Company D											
Product 1	1.15	-	-	-	-	3.12	-	-	-	-	-
2	2.03	-	-	-	-	-	-	-	-	-	-
3	-	-	-	-	13.02	-	-	-	-	-	-
4	1.98	2.28	-	-	-	-	2.43	-	-	-	-
5	3.27	-	-	-	-	-	2.82	-	-	-	-

Source: Drug Topics Red Book, (New York, Topics Publishing Company Inc.) Annual Editions 1957 to 1967.

* Indicates no change.

** All prices are modified by a constant, to disguise them.

TABLE 1 -- Continued

	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Company E											
Product 1	-	-	-	-	-	3.47	-	2.89	-	-	-
2	8.91	-*	-	-	-	-	-	-	-	-	-
3	1.19	-	-	1.39	-	-	-	-	-	-	-
4	11.29	-	-	-	-	-	-	-	-	-	-
5	-	-	-	-	6.93	-	-	-	9.90	-	-
Company F											
Product 1	2.89	2.97	-	-	-	-	-	-	-	-	2.31
2	-	-	-	-	9.90	-	-	-	-	-	-
3	4.95	8.17	-	-	-	-	-	-	-	-	-
4	2.48	5.36	-	-	-	-	-	-	-	-	-
5	4.54	4.95	-	-	-	-	5.28	-	-	5.78	-
Company G											
Product 1	3.30	-	-	-	3.47	-	-	-	-	3.65	-
2	11.00	-	-	-	11.63	-	-	-	-	-	-
3	4.95	-	4.21	4.95	-	-	-	3.43	3.89	-	-
4	33.00	-	-	-	-	24.75	-	-	-	-	-
5	-	-	-	-	-	4.54	-	-	-	-	-
Company H											
Product 1	19.80	-	-	-	-	-	-	-	-	-	-
2	2.97	-	-	-	-	-	-	-	-	3.56	-
3	6.44	-	-	-	-	-	-	-	-	-	-
4	2.57	-	-	-	-	-	-	-	3.22	-	-
5	4.21	-	-	-	-	4.32	-	-	-	-	-

Source: Drug Topics Red Book, (New York, Topics Publishing Company Inc.) Annual Editions 1957 to 1967.
* Indicates no change.
** All prices are modified by a constant, to disguise them.

supports the hypothesis that there was no substantial decline in prices after the Investigation. Prices of only seven (17.6 per cent) products decreased after 1962. Prices of nine (22.5 per cent) increased, and twenty-four (59.9 per cent) remained unchanged. This study, therefore, shows that the Kefauver Investigation cannot be associated with substantial decreases in drug prices in the sample.

Price Indexes

Price indexes are designed to measure the changes in prices over time for the universe of commodities which the index is meant to represent. The index number does not, for example, show the effect on a market basket when cake mixes are substituted for the separate ingredients, or frozen packaged vegetables for a sack of potatoes. It does not indicate whether more or less expensive commodities are being used than in the past. It does indicate, whether components once introduced into the index have risen or fallen in price from one period to the next along with the components of the market basket. Index numbers are designed to show the amount and direction of price movements in the aggregate, for it is not feasible to discuss the net effect of the many and diffuse movements of all items. It is

therefore necessary to select a representative sample of the many variables involved.

The Bureau of Labor Statistics (BLS) Wholesale Price Index (WPI) is designed to measure changes in the prices of all commodities sold in commercial transactions in primary markets of the United States. A Primary Market is defined by the BLS as the first commercial transaction for a product, to avoid confusion with subsequent wholesale transactions.

Ethical and proprietary pharmaceutical preparations account for 0.9 per cent of the total importance of commodities in the WPI. [1] There are 31 drug and pharmaceutical materials (all other product classes of the drug and pharmaceutical subgroup), 55 ethical pharmaceuticals divided into 15 subproduct classes, and 24 proprietary pharmaceuticals divided into eight subproduct classes, making a total of 110 products. [2] The Bureau collects actual price quotations on a sample of about 2,300 representative items from manufacturers and other producers. A

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[1] John M. Firestone, Statement made before Monopoly Sub-Committee of the Senate Select Small Business Committee, December 19, 1967.

[2] Ibid.

proportionate share for pharmaceuticals would be 0.9 per cent of the entire 2,300 products, or 21. The drug category is therefore probably better represented than most other categories of like weight.[1]

Before 1961, the BLS index had fallen behind in including relevant representation of important new products. Because of this, and in order to construct a more inclusive index, the Pharmaceutical Manufacturers Association retained Professor John Firestone, an authority in developing indexes,[2] to develop an index of the ethical Pharmaceutical Industry (Prescription Specialties Producer Price Index). He used confidential research data available only to the Pharmaceutical Industry, and included four to six times as many products, which resulted in a broader based and more representative index than that of the BLS. However, there is a great similarity between the revised BLS index (from 1961) and the Prescription Specialties index.

Table 2 and Figure 1 compare the two indexes as well as the index of all commodities (except farm and food). The comparisons show that the BLS and the Prescription Specialties Producer Price indexes are quite similar from 1961 to 1966.

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[1] Ibid.

[2] Professor Firestone, is a specialist in price statistics and indexes. He served as consultant to the United States Bureau of Labor Statistics, and has designed and developed price indexes for the War Department, the National Housing Agency, and for other organizations.

TABLE 2

WHOLESALE PRICE INDEXES
(1961 = 100)*

Year	Bureau of Labor Statistics		Rx Specialties Producer Price Index** (Firestone Index)
	All Commodities (except farm & food)	Ethical Pharmaceutical Preparations	All Rx drug Products
1949	79.3		111.5
1950	82.2		106.9
1951	90.7		107.2
1952	88.6		103.7
1953	89.2		103.7
1954	89.6		102.3
1955	91.6		101.9
1956	95.6		101.9
1957	98.3		103.3
1958	98.7		103.7
1959	100.5		101.9
1960	100.5		103.0
1961	100.0	(Jan) 100.0	100.0
1962	99.9	96.9	97.2
1963	99.9	95.7	96.1
1964	100.4	95.4	95.9
1965	101.7	94.7	96.1
1966	103.9	94.2	95.8

* Base shifted to 1961 (=100) by PMA staff.

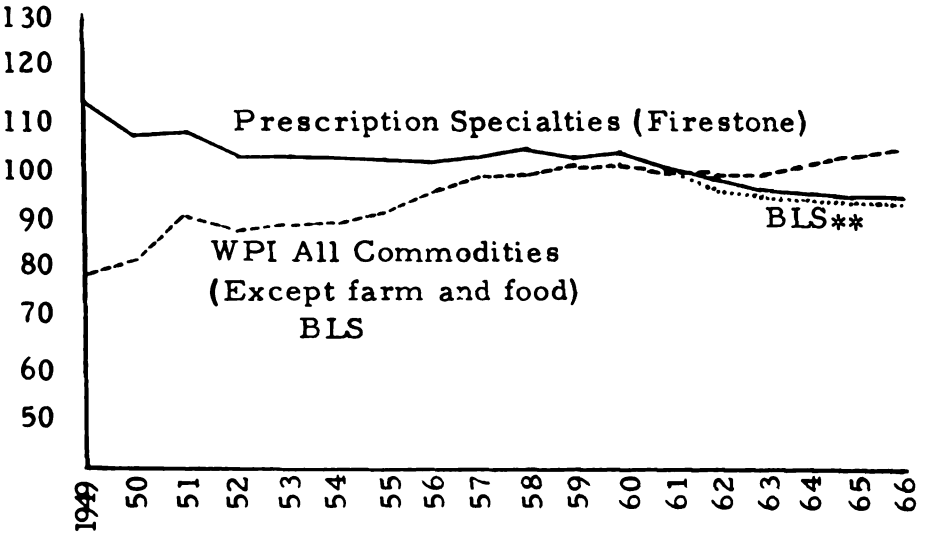
** The Prescription Specialties Producer Price Index has been prepared periodically by Professor John M. Firestone of the City College of the City University of New York. Until 1961 the Bureau of Labor Statistics did not publish a separate wholesale price index to indicate the trend in ethical drug prices. However, a broader-based government index for ethical pharmaceuticals was introduced in January 1961 (=100). This latter index closely approximates the trend shown by the Prescription Specialties Producer Price Index.

Source: PMA, Prescription Drug Industry Fact Book, (Washington, PMA, 1967, p. 19.

FIGURE 1

WHOLESALE PRICE INDEXES

1949 - 1966



* 1961 = 100 (base year)
** Commences with 1961 revision.

Source: Agnes W. Brewster, Testimony, before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate on Present Status of Competition in the Pharmaceutical Industry, (Washington: U.S. Government Printing Office, 1967), p. 1427.

In the 17 years covered by the Prescription Specialties index there has been a total decline of 15.7 per cent for all prescription drug products. This decline has occurred during a time when prices, in general, have been rising. For example, the government "all commodities" index steadily declined from 1949 to 1955, then rose slightly during the period 1959 - 60 followed by a decline to 1966.

The rate of decline of the prescription specialties index in the 1962 - 66 period was less than the rate of decline in the period 1960 - 62. If the Kefauver Investigation would have accomplished its goal of influencing price reductions, the 1962 - 66 trend should have declined more rapidly than it did in the previous period. On the contrary, the rate of decrease lessened after 1962.

In conclusion, an analysis of wholesale price indexes also supports the hypotheses that no substantial decline in prices of ethical pharmaceutical products can be associated with the Investigation and Drug Act Amendments.

Average Prescription Prices

Another way of considering changes in drug prices is by observing the trend in average prescription price over time, although such measurements have inherent dangers in attributing too much significance to average prescription prices. [1] In

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[1] The average prescription price is calculated by:

1. Finding the average per capita expenditure for prescription drugs by dividing the total amount spent by consumers for prescriptions by the United States population.

2. Dividing the per capita expenditure for prescription drugs by the number of prescriptions per capita.

contrast with a price index, average prescription price can be affected by the constantly changing mix of prescriptions, as well as changes in the price of drugs. For example, the average prescription price would vary as the mix reflects greater or lesser emphasis on higher priced drugs. However, the direction of the trend in average prescription prices provides another perspective for evaluating whether or not lower prices may be associated with the Kefauver Investigation.

The overall real average prescription price rose gradually from 1959 to 1966 (see Table 3). The total increase over this eight year period was 5.8 per cent. A least squares line is fitted to this data in Figure 2. Projections indicate that average prescription prices will likely continue to rise in the future. This likely increase in average future prescription prices also supports the hypothesis that the Investigation cannot be associated with any substantial price decreases.

In conclusion, a survey of actual prices showed no substantial decline in prescription drug prices between the periods 1957 to 1962 and 1963 to 1966. Both the BLS Index and the Prescription Specialties Producer Price Indexes of drug prices show a steady decline, commencing several years before

TABLE 3

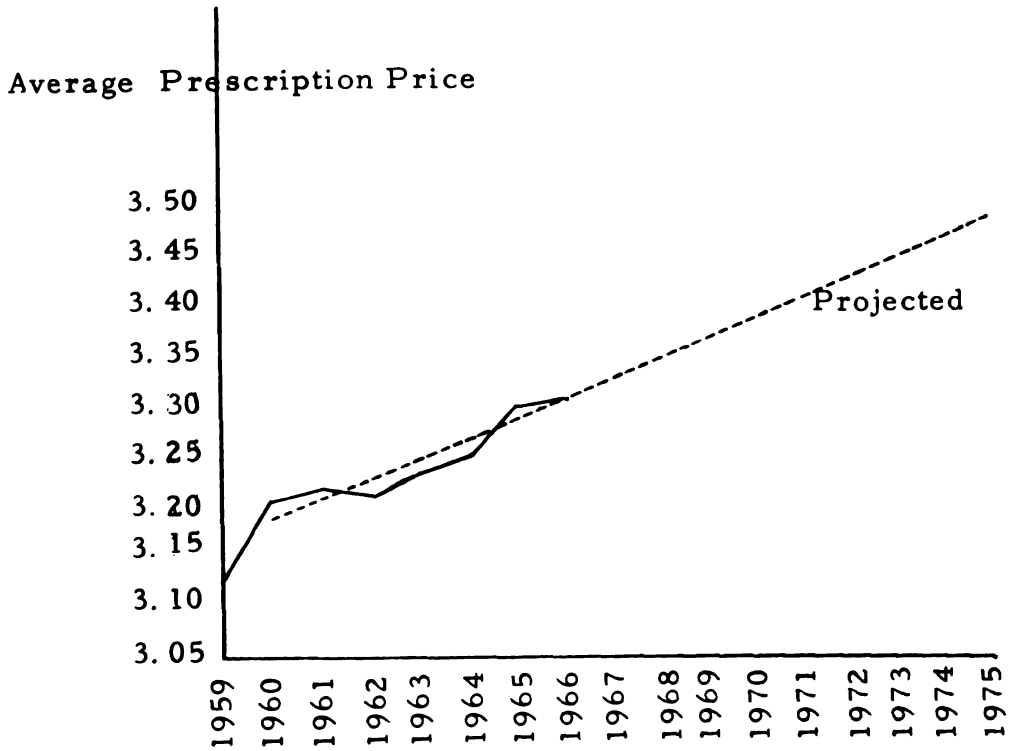
TOTAL AND PER CAPITA PRESCRIPTION DRUG EXPENDITURES, NUMBER OF PRESCRIPTIONS PER CAPITA, AND AVERAGE PRESCRIPTION PRICE, 1959 - 1966

Year	Total Consumer Expenditure (in billions)	Per Capita Expenditure	Number of Prescriptions per capita	"Current" Average Price Per Prescription	"Real" Average Price Per Prescription		Projected "Real" Average Price Per Prescription
1959	$2.0	$11.12	3.54	$3.14	$3.13	1967	$3.32
1960	2.0	11.33	3.52	3.22	3.21	1968	3.34
1961	2.1	11.75	3.65	3.22	3.22	1969	3.36
1962	2.3	12.30	3.83	3.21	3.21	1970	3.38
1963	3.4	12.37	3.83	3.23	3.23	1971	3.40
1964	2.6	13.33	4.09	3.26	3.25	1972	3.42
1965	2.8	14.37	4.29	3.35	3.30	1973	3.44
1966	3.1	15.47	4.51	3.43	3.31	1974	3.46
						1975	3.48

Source: Agnes W. Brewster, Testimony, before the Sub-Committee on Monopoly of the Select Committee on Small Business, United States Senate on Present Status of Competition in the Pharmaceutical Industry, (Washington: U.S. Government Printing Office, 1967) p. 1427.

FIGURE 2

REAL AVERAGE PRESCRIPTION PRICES 1959 - 1975



Source: Agnes W. Brewster, Testimony, before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate on Present Status of Competition in the Pharmaceutical Industry, (Washington: U.S. Government Printing Office, 1967), p. 1427.

Figure 2 shows real average price per prescription from 1959 to 1966, and an estimate of these projected to 1975. The time period selected as the basis for projection is 1960 to 1966. [1] During this time a relatively steady pattern of growth, unmarked by substantial breaks in the trend was evident.

Real average prices per prescription from 1960 to 1966 can be adequately characterized by a straight line. The least squares line is $Y_c = 3.19 + .0193X$, where X represents the time period of one year, and Y_c is the trend value for period X.

The least squared projections to 1975 are shown in Table 3.

R, the coefficient of correlation is .99, and the proportion of total variation explained by the least squares line is $r^2 = .99$.

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[1] Latest available data.

the Drug Act Amendment of 1962, with no substantial change in this trend being discernible after 1962. Finally, although their usefulness in describing price changes is limited, average prescription prices have actually risen from 1959 to 1966. From the foregoing evidence, it is concluded that H_3 is supported.

Effects on Pricing of New Product Introductions

The process of determining the "right" price for a new product is difficult. Reactions of competitors and responses of consumers to new products are largely unknown. A base commonly used in the Pharmaceutical Industry is the price of an average daily dose of competing products. The final price however, is based on the consideration of such additional factors, as costs, and the relative merits of the new product compared with those already on the market. Thus, it is not surprising to find a great similarity in pricing patterns of introductory prices within homogeneous therapeutic categories over time.

Comparison of introductory prices of similar types of products between the periods 1954 to 1962 and 1963 to 1967 provides another useful indication of the effects of the Investigation on pricing. Prior to 1962 a remarkable similarity in such introductory prices was common. Perhaps changes in

e relatively established pricing patterns for new products
oduced after the Investigation will reflect its influences more
changes in prices of those already on the market.

A study of introductory prices was undertaken. Seven
r product categories were selected on the basis of their
apeutic importance and the relative similarity of action
n each category.[1] Drug prices from the following
apeutic categories were studied: cardiovasculars, psycho-
ulants, anti-obesity, diabetic, antibiotics, ataraxics and
tics. Tables 4 through 10 show the wholesale prices of an
age daily dose of each product when introduced.

Within each category, the mean introductory price
calculated for the periods 1953 to 1962, and 1963 to 1967.
a limited number of observations were available in the latter
d because of the shorter interval and decline in new product
ductions, a comparison of introductory average daily dosage
s clearly shows that increases, rather than decreases
red in most categories after 1962 (see Tables 4 - 10).

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[1] The number of therapeutic categories can be broken down
ious ways. One list divides them into fifteen classes: analgesics,
otics, anti-histamines, anti-infectives, anti-obesity, anti-
nodics, ataraxics, cardiovasculars, common cold, dermatologics,
ones, psychostimulants, sedatives, anti-hypnotics and oxytoxics.
W, Brewster, Testimony, before the Sub-Committee on Monopoly
Select Committee on Small Business, United States Senate on
nt Status of Competition in the Pharmaceutical Industry,
ington: U.S. Government Printing Office, 1967) p. 1427.

The mean introductory dosage prices of four categories increased between 35 per cent and 188 per cent (see Table 11) after the Investigation. One category showed an increase of 0.5 per cent, and two decreased 5 per cent and 59 per cent respectively. But closer analysis of the decline shown by one category (diabetic therapy) revealed the initial average daily dose price decreased in 1959 (see Table 7). Therefore, the actual decrease occurred before the Investigation.

In summary, these findings show that introductory average daily dosage prices of six out of seven therapeutic categories increased after the Kefauver Investigation. Lower prices are therefore not associated with the results of the Investigation. Consequently, the hypothesis that after the Investigation, the introductory prices of newly released drugs were not substantially lower than those of similar drugs introduced prior to the Investigation, is confirmed.

TABLE 4

INTRODUCTORY PRICES

COMPARISON OF WHOLESALE DRUG PRICES BASED ON AVERAGE DAILY DOSAGE
(IN DOLLARS)

Cardiovascular Preparations

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
CARDIOTONICS, DIGITALIS															
Acylanid (acetyldigitoxin)		.014													
HYPOTENSIVES															
Dibenzyline (phenoxybenzamine HCl)	.08														
Ansolysen (pentolinum tartrate)		.05													
Ecolid Chloride (chlorisondamine chloride)				.084											
Inversine (mecamylamine HCl)				.048											
Ismelin Sulfate (guanethidine sulfate)								.079							
Capla (mebutamate)									.056						

TABLE 4 -- Continued
Cardiovascular Preparations -- Continued

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Aldomet Tablets (methyldopa)											.144				
Eutonyl (pangline HCl)											.108				
HYPOTENSIVES-Alkaloids (Rauwolfia and Veratrum)															
Rauwiloid (alzeroxylon)	.054														
Veralba (protoveratrines A & B)	.033														
Serpasil (reserpine)	.086														
Unitensen Tannate (cryptensmine tannate)		.113													
Moderil (rescinnamine)				.118											
Harmonyl (deserpidine)					.065										
Protalba (protoveratrine A)						.072									
Singoserp (syrosingopine)						.077									

TABLE 4 -- Continued
Cardiovascular Preparations -- Continued

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Raudixin (rauwolfia serpentina)	.090														
VASODILATORS - Coronary															
Athemol (theobromine magnesium oleate)				.152											
Isordil (isosprbide dinitrate)							.104								
Persantin (dipyridamole)									.262						
VASODILATORS - Microcirculatory															
Serc (betahistine HCl															.135
VASODILATORS - Peripheral															
Ididar Phosphate (azapetine phosphate)		.069													
Arlidin (nylidrin HCl)			.123												

Year of Introduction

Cyclospasmol (cyclandelate)	.156	
Vasodilan (isoxsuprine HCl)	.153	
Hexanicotol (inositol Niacinate)		.495*
OTHERS		
Cardioquin (quinidine Polygalacturonate)	.287	
	Mean .101	Mean .220

*Included in post-Kefauver mean because events affecting prices had already occurred.

Source: - Prices taken from Drug Topics Red Book of prices for appropriate years.
- New products from Paul deHaen, "Compilation of New Drugs, 1940 thru 1966; American Professional Pharmacist, November 1967, pp. 25 - 62.
- Average Daily Dose based on Physician's Desk Reference, and confidential Industry sources.

TABLE 5

INTRODUCTORY PRICES

COMPARISON OF WHOLESALE DRUG PRICES BASED ON AVERAGE DAILY DOSAGE
(IN DOLLARS)

Psychostimulants

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Meratran HCl (pipradol HCl)			.135												
Ritalin HCl (methyl-phenidate HCl)				.062											
Deaner (deanol acetamidobenzoate)						.165									
Tofranil (imi-pramine HCl)							.081								
Marplan (isocarboxazid)							.165								
Niamid (nialamide)							.184								
Nardil (phenelzine sulfate)							.097								
Elavil (amitrip-tyline HCl)								.209							
Parnate (tranyl-cypromine sulfate)								.147							

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Norpramin (desipramine HC1)												.256			
Aventyl HC1 (nortriptyline HC1)													.230		
						Mean .138						Mean .243			

Source: - Prices taken from Drug Topics Red Book of prices for appropriate years.
- New products from Paul deHaen, "Compilation of New Drugs, 1940 thru 1966"; American Professional Pharmacist, November 1967, pp. 25 - 62.
- Average Daily Dose based on Physician's Desk Reference, and confidential Industry sources.

TABLE 6

INTRODUCTORY PRICES

COMPARISON OF WHOLESALE DRUG PRICES BASED ON AVERAGE DAILY DOSAGE
(IN DOLLARS)

Anti-Obesity Preparations

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Preludin (phenmetrazine HCl)				.099											
Levonor (levo-amphetamine alginate)					.069										
Tenaute (diethylpropion HCl							.043								
Tepanil Ionamin (HCl							.043								
Ionamin (phentermine resin)							.112								
Didrex (benz-phetamine)								.051							
Cydril (levamphet-amine succinate)									.056						
Plegine (phen-dimetrazine tartrate)									.156						
Wilpo (phentermine HCl)									.105						

	Year of Introduction

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Pre-Sate (chlorphentermine HC1)															.115
						Mean .081					Mean .115				

Source: - Prices taken from Drug Topics Red Book of prices for appropriate years.
- New products from Paul deHaen, "Compilation of New Drugs, 1940 thru 1966"; American Professional Pharmacist, November 1967, pp. 25 - 62.
- Average Daily Dose based on Physician's Desk Reference, and confidential Industry sources.

COMPARISON OF WHOLESALE DRUG PRICES BASED ON AVERAGE DAILY DOSAGE
(IN DOLLARS)

Diabetic Therapy

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Orinase (tolbutamide)		.420													
Diabinese (chlorpropamide)						.540									
DBI (phenformin HC1)							.085								
Dymelor (acetophexamide)												.110			
Tolinase (tolazamide)														.176	
						Mean .348						Mean .143			

Source: - Prices taken from Drug Topics Red Book of prices for appropriate years.
- New products from Paul deHaen, "Compilation of New Drugs, 1940 thru 1966"; American Professional Pharmacist, November 1957, pp. 25 - 62.
- Average Daily Dose based on Physician's Desk Reference, and confidential Industry sources.

Antibiotics - Broad and Medium Spectrum

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Tetracyn (tetracycline)		1.152													
Sodium Cathamycin / Sodium Sodium Albamycin \ novobiocin				1.153 1.336											
Tetrex (tetracycline phosphate complex)				1.152											
Ilosone (erythromycin estolate)						1.185									
TAO (triacetyloleandomycin)						1.154									
Declomycin (demythylchlortetracy cline HC1)							1.152								
Lincocin (lincomycin HC1)														.896	
Rondomycin (methacycline HC1)															2.313
					Mean 1.183						Mean 1.60				

Source: - Prices taken from Drug Topics Red Book of prices for appropriate years.
- New products from Paul deHaen, "Compilation of New Drugs, 1940 thru 1966" . American Professional Pharmacist, November 1967, pp. 25 - 62.
- Average Daily Dose based on Physician's Desk Reference, and confidential Industry sources.

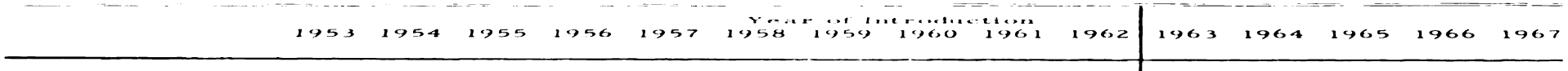
TABLE 9

INTRODUCTORY PRICES

COMPARISON OF WHOLESALE DRUG PRICES BASED ON AVERAGE DAILY DOSAGE
(IN DOLLARS)

Ataraxics

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Thorazine (chlorpromaxine HCl)		.199													
Miltown (meprobamate)			.156												
Atarax (hydroxyzine HCl)				.246											
Compazine (prochlorperazine)				.218											
Sparine (promaxine HCl)				.238											
Suavitil (benactyzine HCl)					.135										
Pacatal (mepazine HCl)					.180										
Trilafon (perphenazine)					.266										
Ultran (phenaglycodol)					.251										


Year of Introduction
1953 1954 1955 1956 1957 1958 1959 1960 1961 1962 1963 1964 1965 1966 1967

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Dartal (thiopropazate HCl)					.168										
Vesprin (trifluprom azine HCl)					.165										
Suvren (captodiamine HCl)						.159									
Vistaril (hydroxyzine pamoate)						.310									
Quiactin (oxanamide)						.156									
Stelazine (trifluoperazine HCl)						.181									
Permitil (fluphenazine							.180								
Prolixin (							.078								
Mellaril (thioridazine HCl)							.240								
Librium (chlordiazepoxide HCl)								.210							
Striatran (emylcamate)								.178							

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Tindal (aceto-phenazine dimaleate)									.109						
Listica (hydroxyphenamate)									.280						
Trepidone (mephenoxalone)									.261						
Proketazine (carphenazine maleate)										.132					
Taractan (chlorprothixene)										.191					
Valium (diazepam)												.232			
Serax (oxazepam)														.168	
Solacen (tybamate)														.272	
						Mean . 198					Mean . 199				

Source: - Prices taken from Drug Topics Red Book of prices for appropriate years.
- New products from Paul deHaen, "Compilation of New Drugs, 1940 thru 1966"; American Professional Pharmacist, November 1967, pp. 25 - 62.
- Average Daily Dose based on Physician's Desk Reference, and confidential Industry sources.

TABLE 10

INTRODUCTORY PRICES

COMPARISON OF WHOLESALE DRUG PRICES BASED ON AVERAGE DAILY DOSAGE
(IN DOLLARS)

Diuretics

	Year of Introduction													
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
BENZOTHIAZIDES															
Diuril (chlorothiazide)					.072										
Naturetin (bendroflumethiazide)							.070								
HydoDiuril (hydrochlorothiazide)							.066								
Esidrix (hydrochlorothiazide)							.072								
Saluron (hydroflumethiazide)							.066								
NaClex (now Exna) (benzthiazide)								.060							
Enduron (methyclothiazide)								.072							
Naqua (trichlormethiazide)								.067							
Renese (polythiazide)									.069						
Anhydron (cyclothiazide)											.055				

	Year of Introduction														
	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
MERCURIALS AND OTHERS															
Diamox (acetazolamide)	.147														
Rolicton (amisometradine)					.090										
Cardrase (ethoxzolamide)						.111									
Aldactone (spironolactone)							1.540*								
Hygroton (chlorthalidone)								.066							
Hydromox (quinethazone)										.066					
Dyrenium (triamterene)											.078				
Lasix (furosemide)															.101
					Mean .079						Mean .075				

* Included in post-Kefauver mean because events affecting prices had already occurred.

Source: - Prices taken from Drug Topics Red Book of prices for appropriate years.
- New products from Paul deHaen, "Compilation of New Drugs, 1940 thru 1966"; American Professional Pharmacist, November 1967, pp. 25 - 62.
- Average Daily Dose based on Physician's Desk Reference, and confidential Industry sources.

TABLE 11

MEAN COSTS OF AVERAGE DAILY DOSAGES OF

NEW PRODUCT INTRODUCTIONS

Therapeutic Category	Mean 1953 - 62	Mean 1963 - 67	Percentage Change
Cardiovascular	$ .101	$ .220	+ 188%
Psychostimulants	.138	.243	+ 76%
Antiobesity	.081	.115	+ 42%
Diabetic	.348	.143	- 59%*
Antibiotics	1.183	1.60	+ 35%
Ataraxics	.198	.199	+ 0.5%
Diuretics	.079	.075	- 5%

*Table 7 indicates that the cost structure had fallen by 1959, before the Kefauver Investigation.

Because of the limited number of products and relatively short time after the Investigation, the number of items included in the mean in the post-Investigation period for some categories is small. However, the upward trends in most introductory prices support the conclusion that no decline in prices can be associated with the Investigation.

PART III

EFFECTS ON PROMOTIONAL ACTIVITY

This section presents findings concerning the following hypothesis:

H_4 The relative cost of promoting a product in the ethical drug industry increased after 1962; and the increased costs can be associated with the Kefauver Investigation and Drug Act Amendments of 1962.

To consider the effects of the Investigation on promotional activity the following data are presented:

1. A survey of changes of advertising space used for government-required information before and after the Investigation.
2. A discussion of findings from the field survey concerning the impact of new regulations on advertising in individual firms.
3. A summary of government enforcement actions, and some public pronouncements of FDA officials concerning Pharmaceutical Industry advertising.

The Kefauver hearing exposed some undesirable advertising practices of the Pharmaceutical Industry. In some instances all good features about a drug were presented dramatically, but side effects, contraindications, warnings and limitations on the usefulness of a drug were omitted. Sometimes sweeping superlatives were used to describe the effectiveness of "just-another-drug" in the assortment available to the physician.

The investigators and some physicians complained about the volume of direct mail, samples, journal advertising and frequency of salesmen's calls. The possibility of excesses in the latter areas are great, because doctors are relatively few in number and easily identified. While some charges against Industry advertising practices were enlarged or distroted, there was some truth in many.

Change in Space Required for Journal Advertisements

The advertising legislation in the Drug Act Amendments of 1962 affected medical journal advertisements most significantly. New regulations require that advertisements include not only the merits of a product, but also a brief, but thorough summary of warnings, side effects and contraindications. Furthermore,

product claims and disadvantages must be presented in "fair balance".

To comply with these new regulations, companies often find it necessary to purchase additional advertising space in medical journals to include the expanded message. Direct mail advertisements have the same requirements, but the increased space costs are not great. Extra stock and type setting is the main cost.

A survey of medical journal advertisements before and after the new regulations came into effect [1] was made. A group of advertisements were selected at random from 1963 editions of a popular medical journal. [2] When available advertisements for the same products from the 1966 editions [3] were compared for space devoted to government-required information, the findings show a gradual, but definite change to the use of additional space for government-required information. Table 1 shows

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[1] The advertising regulations became effective January 1964.

[2] M. D. Medical News Magazine (New York: M. D. Publications Ltd.) various issues from 1963 and 1966.

[3] It took approximately two years before advertisers began to comply with the regulations to a significant degree. Changes occurred gradually because the wording and intent of the regulations were somewhat ambiguous (e. g. what is "fair balance"?) Furthermore, companies seemed unwilling to co-operate fully until the FDA began to enforce and clarify the regulations in late 1965.

Before Jan. 1963*	Space Used in 1966* for Precautions	Description	Actual Additional

TABLE 1

INCREASE IN ADVERTISING SPACE RESULTING FROM DRUG ACT AMENDMENT REGULATIONS

Product	Before Jan. 1963* Space Used for Precautions, Description, Contraindications and Dosage	Space Used in 1966* for Precautions, Description Contraindications and Dosage ("required summary")	Actual Additional Space Purchased for "required summary"
Appetrol	8 lines (long) 1/18 page	1/3 page	1/3 page
Capla	3 lines (med.) 1/18 page	1/3 page	1/3 page
Mysteclin F	8 lines (short) 1/12 page	1/4 page	--
Miltown	14 lines (short) 1/18 page	1/3 page	1/3 page
Serapes	1/3 page	1 page	1 page
Orinase	2/9 page	1/3 page	--
Declomycin	17 words	1 page	1 page
Terramycin	1/6 page	1/3 page	--
Penalba	1/6 page	1/4 page	1/4 page
Peritrate	24 words	2/3 page	2/3 page
Cyclex	1/8 page	1/2 page	1/2 page
Vistaril	80 words 1/18 page	1/3 page	1/3 page
Deprol	1/18 page	1/3 page	1/3 page

*The Drug Act Amendment was passed in the fall of 1962, but the full regulations concerning advertising did not come into effect until Jan. 10, 1964. "It was still about 18 months before the Food and Drug Administration began to actively enforce the regulations." James L. Goddard, statement before the Sub-Committee on Intergovernmental Relations of the House Committee on Government Operations, May 25, 1966, reported in Compendium of Medical Advertising (FDA Publication No. 40, June 1967) pp. 34 - 40.

Source: MD Medical News Magazine, various months, 1963 to 1966

that out of thirteen cases for which advertisements were found in 1963 and 1966, more space was purchased in ten, resulting in a cost increase per product ranging from 25 per cent to 100 per cent[1] of the amount spent prior to the new regulations.

Since journal advertising expenditures are usually second only to personal selling expenditures in a company's promotional mix, these increased costs are important. For example, total promotion costs account for approximately 25 per cent of sales[2] or $25 million in a firm with sales of $100 million. In 1968 the one-time page rate for a two color advertisement in the Journal of the American Medical Association was $2,320. A half page two color advertisement cost $1,650.[3] Assuming only one hundred product advertisements per year in five medical journals and one half page extra per advertisement purchased to carry required information, the added cost (based on an additional $1,650 per ad) would be $825,000. The hypothesis that the Kefauver Investigation can be associated with expanding promotion costs is, therefore, substantiated by these findings.

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[1] Volume discounts are not considered here for the sake of simplicity.

[2] Standard and Poors Corporation, Basic Analysis, March 1966, p. D 12.

[3] Standard Rate and Data, 1968.

Field Survey Findings

In the previous section, it was observed that pharmaceutical advertisers were required to modify the format of advertisements, and to conform to new advertising standards. Case histories from the field survey will be presented to illustrate the impact of legislation and regulations on individual companies.

Advertising Space and Cost

Has the cost of advertising increased for the companies surveyed? Five out of the seven companies interviewed reported higher expenditures per product for additional advertising space in medical journals to include government-required information. Increased space for full disclosure also raised the Physicians Desk Reference [1] advertising costs. For example, Company B felt obliged to include fifteen fewer products in the book because of these costs. This created problems of reducing the availability of general information about some products, thereby decreasing the usefulness of this reference book.

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[1] Physicians Desk Reference is a reference manual containing essential prescription information on major pharmaceutical specialties in a convenient reference form. Manufacturers specify and pay for the products to be included, and write the product description.

Preparation of Advertisements

All companies find development of required advertising information arduous, largely because of ambiguous requirements. The FDA uses "fair balance", "adequate summary", and similar general terms to state the requirements for preparing advertisements. It is difficult for them to be more accurate in specifying the regulations because medicine is not a precise science--nor is the practice of advertising. Often there is a difference of opinion between company and FDA medical experts as to what is sufficient and appropriate. The copywriter, advertising manager, product manager, legal and medical departments are all involved, and spend much time attempting to satisfy vague regulations. One company formed a "compliance panel" composed of two lawyers, two medical doctors, and one other individual to pass on all advertisements. Despite this, they were still subject to FDA disciplinary action.

The degree of government surveillance and control is exemplified by an advertisement that stated a certain action had not been "proven" concerning a product. The FDA felt this was inadequate, and forced the firm to write a letter (known in the trade as a "Dear Dr. letter") to all physicians saying their advertisement was incomplete, and should have said the drug action was neither "proven nor disproven". In addition to the

administrative time involved, such a mailing is costly.

Advertising Claims

The field survey showed that the new regulations restrict advertising claims unequally. When releasing a drug for sale, the FDA now approves it for specific therapeutic indications. For example, an antiobiotic may be approved for genito-urinary infections only. Although this drug is similar to other antibiotics in its range of actions, the company is not allowed to advertise or even discuss its use in indications not formally approved. Drugs currently on the market could suffer similar disadvantages.

> . . . for example, a tranquilizer produced by 28 different firms, may be advocated in the advertising for minor psychiatric illnesses, tension states, anxiety - almost anything that tranquilizers are good for. Another company may come along and do some entirely different research which shows that children who have, let us say, enuresis, benefit by the use of tranquilizers. That would be the only firm that could make a claim of enuresis relief in that advertising, despite the fact that the other 28 in the market have the same chemical compound. That is another irrationality. [1]

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[1] James L. Goddard, Former Commissioner of the Food and Drug Administration, Testimony before the Subcommittee on Monopoly of the Select Committee on Small Business, (Washington: U. S. Government Printing Office, 1967), Part 2, p. 762.

Such differences in claims allowed by government for similar products, can lead to significant competitive disadvantages.

Government Regulatory Actions

The previous discussions described some of the difficulties in understanding and obeying the new advertising regulations. Yet in 1965, the FDA began to enforce the regulations with some vigor. Two main methods of action were employed. One was to seize the product in its normal trade channel, often with subsequent criminal suits. The other required that the offending company send "Dear Doctor Letters" clarifying the record. The contents of each letter was negotiated with the FDA. These severe measures were sometimes imposed for a relatively minor offense.[1] Examples of other regulatory actions are given in Table 3 which provides a partial listing of the FDA regulatory actions since 1965.

The nature and extent of government activity in advertising has evolved to the point where officials even pass judgements on the methodology and strategy of advertising. The following comments by Theodore O. Crom, Assistant Commissioner for Education and Information, FDA, illustrate this point.[2]

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[1] See p. 72.

[2] Compendium of Medical Advertising, FDA publication No. 40 (June 1967), p. 49.

I would like to illustrate these remarks with a recent entry, the advertising for Lasix, or furosemide. These slides were made from the Lasix presentation in Medical World News, September 30, 1966.

Here is the first spread (dramatic picture of astronaut in space) * Very dramatic for a diuretic, but it is somewhat misleading, since the manufacturer is actually not interested primarily in the astronaut market.

* Parenthetic comments added.

Now we see what it's all about. Lasix is after the whole diuretic market. Its headline and stress is on all edemas - "from the easy-to-control to the severe edema". However, in one of the references listed by the company itself, the investigator states, "If the low toxicity of furosemide is confirmed by more extensive studies, it will probably replace thiazides as the first choice diuretic in the treatment of severe edema".

It would seem that the thrust for the top spot in the diuretic market is being made too vigorously. The attack on Diuril and other leading diuretics is perhaps too strong. Is it necessary to move so hard so fast for market leadership? We would tend to say no, particularly when we see this kind of ad as the instrument.

In this speech the government official took time to criticize publicly a harmless attention-getting device (picture of an astronaut). Next he criticized the advertiser for apparently attempting to capture a major share of the market for this type of product--a strategy normally expected of a firm having a promising product.

TABLE 2

PARTIAL LISTING OF FDA ADVERTISING REGULATING ACTIONS SINCE 1965

The following are some of the regulatory actions taken by the FDA because of advertising "violations" since 1965.

September, 1965:	Wallace was cited in a criminal case for lack of an adequate brief summary in a Pree MT ad run in June, 1964. The product had been removed from the market in April, 1965.
February, 1966	Warner Chilcott's Peritrate SA was seized in a token move because of misleading journal advertising claims.
May, 1966:	Wyeth's Serax suffered a token seizure because its journal ads lacked fair balance.
September, 1966:	A criminal suit was filed against Upjohn for incomplete Orinase disclosure in the 1965 PDR. [1]
September, 1966:	A criminal suit was filed against Abbott for incomplete Eutonyl disclosure in the 1965 PDR.
September, 1966:	Four suits were filed against CIBA for Esidrix advertising involving mail, journal and PDR ads.
October, 1966:	Upjohn's Lincocin was seized for lack of fair balance in a journal ad.
November, 1966:	Hoechst's Lasix was seized for journal ad misrepresentations.
March, 1967:	Roche was required to send out a Dear Doctor letter covering changes in the brief summary in its Librium advertising.

[1] Physician's Desk Reference

TABLE 2--continued

March, 1967:	Wallace's Deprol was the subject of a Dear Doctor Letter stating that some of the studies cited in its ads might be misleading.
April, 1967:	Abbott's Enduron and Enduronyl were cited in a Dear Doctor Letter for misleading comparisons and a revised brief summary in their journal ads.
April, 1967:	Ohio Chemical and Surgical Equipment Company's Indoklon was seized in a token move because its ads lacked information on side effects and contraindications.
May, 1967:	Pfizer's Renese and Rondomycin were the subject of a Dear Doctor Letter because of inadequate brief summaries in their ads.
June, 1967:	Mead Johnson's Oracon comparative advertising claims were called unfounded in a Dear Doctor Letter.
October, 1967:	Squibb's Mysteclin-F received a Dear Doctor Letter treatment for overexpanding its therapeutic indications in its advertising. There was also an enlarged brief summary.
November, 1967:	Massengill expanded its contraindications for several steroids listed in the PDR with a Dear Doctor Letter.
November, 1967:	Lakeside's Norpramin also showed PDR contraindication revision with a Dear Doctor Letter.
January, 1968:	Parke Davis sent out a Dear Doctor Letter on Ponstel because of lack of information on potency as well as other problems with its advertising.

Source: FDC Reports, various issues, 1965 - 1968.

The advertising regulations of the Drug Act Amendments have nothing to say concerning the points of criticism, yet a government official feels relatively free to comment on areas not covered by legislation.

Government officials now take the liberty of publicly pre-judging the motives of an advertiser before his advertisement is even published. The following quote illustrates the degree of power assumed by the FDA since the enactment of the Drug Act Amendments of 1962.

> . . . But since I was asked to clarify my remarks, let us see the next slide. This was published by Mead Johnson & Co. in Bride's, Parents' Magazine, and Today's Health, and may still be on those schedules. It is a lovely ad, with four-color photography of a fine-looking blonde dressed in lace with flowers and a gown and what all. The copy speaks of "conception control" and "family planning" and letting "your doctor" recommend the right method for you, and so on.
>
> There is nothing in the world wrong with this ad. Next slide, please. It even has a baby, which shows me that the company is really quite open-minded. There is nothing wrong with this ad, but it does bother me. No product name is mentioned; in fact, the closest we come to what's behind this thing is the tag line under the MJ logo: "Symbol of service in medicine".
>
> What will be the next advertisement by Mead Johnson? What is the next step in what has undoubtedly been thought to be an excellent public

> service by a company that is a responsible member of the business community? But what will the next ad in this series be, if indeed it is part of a series? [1]

The foregoing examples provide some indication of the degree to which advertising practices are now scrutinized by the FDA. In the space of five years since the Investigation, pharmaceutical companies find that instead of advertising relatively free of formal constraints, they are being warned publicly against advertising activities not yet undertaken.

Industry Response to the Criticisms and Regulations

After the Investigation, what did the Industry do about criticisms and proposed regulations? A few improvements in advertising practices were undertaken by the Industry, but it was not until January 1964 when the regulations took effect, that substantial improvement was noted. [2]

> An increasing number of drug ads began to contain a prominent section on indications for use, side effects, contraindications, and warnings . . . there was improvement in both the style and content of medical advertising. [3]

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[1] Ibid., p. 50.

[2] James L. Goddard, Ibid., p. 38.

[3] Ibid.

The FDA noted inadequacies in advertisements and in November 1964 a release was issued detailing the kinds of abuses found:

1. Extension or distortion of the claims for usefulness beyond that approved in the product's final printed labelling.

2. A quote from a study used to imply improperly that the study is representative of much larger and general experience with the drug.

3. The selection of poor-quality research papers that are favorable to the product and the omission of contrary evidence from much better research.

4. Quotation out of context of a seemingly favorable statement by an authoritative figure, but omission of unpleasing data from the very same article.

5. A favorable quote from an obviously authoritative source but no quote from other differing experts in the same field.

6. Data from papers that report no side effects while other papers reporting side effects exist but are not quoted.

7. Ads constructed from data previously valid but rendered obsolete or false by more recent research. [1]

Apparently these problems were not readily resolved. In 1967, the FDA was making similar complaints, and indicated practices

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[1] Ibid.

were no better.[1] With respect to complaints about sampling and frequency of sales calls, the field survey found little change in sampling practices, and all companies except one maintained or increased sales call frequency.

Apparently the Pharmaceutical Industry has remained relatively insensitive to public criticism. Although some changes have been made voluntarily, it seems that the Industry maintains current practices until forced to change. Even with knowledge of what was generally expected of it in 1963 when the new regulations were published, limited efforts were made to modify practices until the regulations took effect. Then the new standards were not fully adhered to. Granted there are ambiguities in the FDA standard, however, it is questionable whether the Industry is doing its best to meet those standards which are clear.

Society does not accept a laissez faire concept of government-business relationships. As an industry fails to heed warnings and public criticism, government regulation is imposed, with the consequent complexities described in the preceding pages.

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[1] "Medical Advertising: State of the Craft and of Regulations" FDA Papers, (Washington: Food and Drug Administration), February 1967, pp. 5 - 8.

Recommendations

Company advertising is used to present a product or service in the best possible light. Consequently, the temptation is great to maximize product claims while minimizing disadvantages. The Pharmaceutical advertisers have a serious responsibility; pharmaceutical products directly affect human life, and improper usage of drugs can result in untoward effects.

Since the enactment of the Drug Act Amendments of 1962, the Food and Drug Administration has a responsibility to insure that drug advertisements present information fairly on advantages and disadvantages of a product. This seemingly is the main intent of the advertising section of the Amendments; additional control of advertising is unwarranted.

Previous evidence showed that pharmaceutical advertisers have been slow to conform with some public demands and government standards.[1] It is essential that in every advertisement pharmaceutical firms provide true representation and full disclosure of pertinent information concerning each product advertised.

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[1]See p. 80 infra.

Industry Recommendations: To meet these standards it is recommended that each company in the Pharmaceutical Industry should:

1. Develop attitudes within the organization which hold that providing full information is paramount to all other advertising activities. The first purpose of an advertisement should be to provide information; persuasion should be the second. This must start with top executives in each organization.
2. Analyze previous promotional activities which precipitated past government regulatory actions and insure that these actions are not duplicated.
3. Insure that published FDA advertising guidelines are adhered to. While some FDA requirements are not specific or precise[1] others such as the list on page 80 provide some clear rules. For example, this list indicates proper usage of authoritative quotations in an advertisement, yet by 1966 companies were still not adhering to these guidelines.

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[1] For example, regulations concerning "fair balance" and "brief summary".

[2] See Table 3.

4. Check with FDA in cases where doubt or uncertainty as to proper procedure still exists.

FDA Recommendations: It is recommended that the FDA aid the process of complete information disclosure, and establish better relations with the Industry by:

1. Making certain that regulations and their interpretations are specific and precise.
2. Providing prompt, reasonable answers to Industry requests for information and clarification. This should encourage Industry to seek information when in doubt.
3. Regulating and controlling only important factors concerning product safety and effects. Government officials should show self restraint in judging advertising methodology [1] or prejudging advertisers' motives. [2]

Joint Recommendations: It is further recommended that a permanent liaison committee comprised of approximately three representatives

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[1] See p. 74 infra.

[2] See p. 78 infra.

each from the FDA and the PMA be established. The objectives of the committee should be:

1. To clarify ambiguous FDA standards concerning promotion of drugs. Clarifications should be based on the intent of the Drug Act Amendments of 1962.
2. To consider specific Industry and FDA complaints concerning the other's actions and/or rulings in the area of promotion. The committee should make recommendations concerning the merit of each complaint, and suggest guidelines for future action.

Conclusions

New regulations requiring that journal advertisements include a summary of warnings and side effects of a product resulted in allocation of a substantial portion of space in an advertisement for this purpose. Out of thirteen company product advertisements surveyed, ten firms purchased between 25 per cent and 100 per cent more space than before the regulations became effective to carry the required information. Consequently,

higher costs of advertising a product can be associated with the Investigation.

Preparation of advertisements also became more complex. Advertisers were strictly controlled with respect to product claims but the performance standards set by the FDA were imprecise.

An additional impact of the inquiry was the exposure of some undesirable advertising practices, and establishment of higher advertising standards. These standards resulted in more informative and accurate advertisements.

PART IV

EFFECTS ON PUBLIC RELATIONS ACTIVITY

Company Survey of Public Relations Activities and Attitudes

Public relations is an important function which evaluates public and government attitudes, identifies the policies and procedures of an organization of industry with the public interest, and executes a program of action to earn public and government understanding and acceptance. [1] Findings from the field survey provide an opportunity to describe and evaluate the public relations activities and attitudes of several different sizes of pharmaceutical firms.

Previous discussions (Chapter II) indicates a lack of Public Relations consciousness on the part of the Pharmaceutical Industry in the two decades prior to 1959. I felt that public pressures induced by the Investigation would spur the Industry into substantial public relations activity. My expectation was that this PR activity would increase after 1961 while the memory of the Investigation was fresh and then diminish gradually.

Specifically, the following two hypotheses were formulated:

H_5 Since the Investigation, the public posture of the Industry changed from a rather insular

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[1] Canfield, Public Relations, p. 4.

attitude toward public opinion and information disclosing activities to a positive attitude, as demonstrated by increased activity and expenditure on public relations.

H_6 The public relations effort of the Industry decreased substantially from the post-Investigation peak to 1966.

The material relevant to this section is organized around three main subject areas:

1. A discussion of joint company public relations advertising activities. [1]
2. A report of findings concerning public relations activities and attitudes of individual companies interviewed.
3. A description of the present status of public relations in the Pharmaceutical Industry.

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[1]Public Relations advertising is defined as the communication of public relations messages through general advertising media. See Bertrand R. Canfield, Public Relations, (Homewood, Illinois, Richard D. Irwin, Inc. 1964) p. 493.

Joint Company Public Relations Advertising

Only one group public relations advertising effort was undertaken after the Investigation. Between 1963 and 1964, five companies undertook a joint advertising campaign in general magazines, such as the Saturday Evening Post. The initiators tried unsuccessfully to persuade other companies to participate. Finally, they proposed that the Pharmaceutical Manufacturers Association sponsor the campaign, thereby involving all members. Rejection of the proposal marked the end of all joint PR advertising. Until 1967 the Pharmaceutical Manufacturers Association did no public relations advertising.

Individual pharmaceutical companies did not fill this advertising void. The few firms advertising to the general public did so as a continuing program started before the Kefauver Investigation. Thus, with the exception of one brief campaign, the Pharmaceutical Industry did not respond to the Investigation by expanding public relations advertising. [1]

Thus H_5 is not supported. The Industry did not respond to the Investigation by increasing PR advertising. But other public relations activities should be considered before final conclusions can be drawn.

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[1] Interviews with sample of Industry and Pharmaceutical Manufacturers Association.

Types of Public Relations Activities Undertaken

Are pharmaceutical companies active in the area of public relations? Five out of eight companies surveyed have a relatively active public relations program. Two of them advertise directly to the public through general magazines. Two have each established an office in Washington where a full time representative works closely with legislators and government officers to explain company and Industry viewpoints. Three firms expend a substantial proportion of their efforts preparing to counter and prevent public criticism by politicians. Current political activities are assessed, and statements are prepared for immediate rebuttal of likely charges against the Industry. This is an attempt to overcome the type of advantage attained by Kefauver in gaining damaging headlines in advance of Industry response. For example, when Senator Nelson undertook hearings on the Drug Industry in 1967, the first specific public charges against the Industry were expected the first morning of the hearings. However, an individual from Company C was awakened at 6:00 a.m. by a local editor asking for his comments to Nelson's charges which had been released to UPI [1] at 1:30 a.m. In this instance Company

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[1] United Press International Wire Service.

C had anticipated the nature of Senator Nelson's statements, and their previously prepared rebuttal appeared with his claims in the same edition of many newspapers.

The five firms active in PR have substantial programs aimed at professionals -- physicians and pharmacists. Two firms have projects to help the underprivileged in their own community. Table 1 summarizes the PR activities of the eight companies surveyed.

Public Relations Orientation

The Pharmaceutical Industry as a whole, rather than a single company, is criticized and subject to legislation. Part of the study therefore endeavoured to determine whether pharmaceutical companies undertook company-oriented public relations only, or also included the entire Industry in their approach. Findings showed the primary orientation of all firms with PR programs was toward enhancing their own image. Only two out of eight even attempted to develop the image of the Industry. If this is representative, it is not surprising that the Industry is criticized and misunderstood.

After the Kefauver Investigation three of the eight companies surveyed reported that they increased PR efforts substantially in response to it. For example, one of the companies increased the public relations staff from two to ten managerial people. The PR

TABLE 1

TYPES OF PR ACTIVITIES UNDERTAKEN

Company	Activities
A	professional orientation primarily
	prepare answers for political attack
	usual press releases
B	advertising to public
	Washington office
	community help
	usual press releases
C	anticipate and rebut political attacks
	Washington office
	"education" of newspaper editors
	community help
	usual press releases
D	advertising to public
	varied professional programs
	usual press releases
E	usual press releases

TABLE 1 -- Continued

Company	Activities
F	professionally oriented advertisements in general magazines usual press releases
G	usual press releases
H	no activities

budget was raised proportionately. The other five firms, however, have made few changes in the past ten years. None of the firms studied anticipates any substantial changes in PR programs in 1969.

Company attitudes toward public relations are evidenced in the previously described activities and comments made during the interviews further clarify these attitudes. Two companies which have active PR advertising programs, indicated willingness to expand them. Doubt was expressed, however, whether they could mount an advertising program to change indifferent or negative public attitudes. This point was also expressed by Company C which did not advertise to the general public.

Two other firms believed that Industry defense could best be achieved by contacting politicians, government officials and opinion leaders directly. One company said the company itself should undertake more public relations, but did not anticipate doing so.

The other companies looked to the Pharmaceutical Manufacturers Association to carry the public relations program for all. Three firms felt the PMA should be more active in this area. It was not until the end of 1967 however, that the PMA undertook their first PR advertising campaign to the public at large.

Considering their activities, the firms surveyed apparently have limited confidence in orienting public relations to the general public. Only two companies have an active program aimed at the general public, and these are admittedly not maximum efforts. The firms undertaking PR activities seem geared mainly for defense -- to have appropriate answers when public criticism comes.

Table 2 summarizes the foregoing research findings. For each firm studied it lists the PR activities undertaken and their orientation, significant changes in the past ten years, future PR plans and attitudes toward public relations.

COMPANIES SURVEYED

Company	PR Activities	Orientation of Activities	Changes in PR Activities	Future PR Plans	Attitudes Towards Public Relations
A	- Professional orientation - prepare answers for political attack - usual press releases	Talks of company only	- PR budget raised - 50% more staff, largely because of Kefauver Investigation - opened Washington office	Same as this year	Would spend more on PR advertising if it would work
B	- Washington office - general advertising to the public - community help - usual press releases	Talks of company only	- staff increased from 2 in 1959 to 10, largely because of Investigation	Steady growth. No change in plans for substantial change	Concentrate PR efforts at political level, and on doctors
C	- Washington office - anticipate & rebut - political attacks - "educate" newspaper editors - community help - usual press releases	Promotes image of both company and Industry	From time of Investigation developed into extensive program	Committed to total PR program at all levels except general advertising	Concentrate public relations efforts at political level, on doctors and opinion leaders. Have clear cut policies and actions

TABLE 2 -- Continued

Company	PR Activities	Orientation of Activities	Changes in PR Activities	Future PR Plans	Attitudes Towards Public Relations
D	- General advertising - professional program - local TV occasionally - usual press releases	Promotes image of both company and Industry	Same level for past ten years	Same level as this year	Would spend more on PR general advertising if it would work
E	- Usual press releases	Company only	Same level for past ten years	No change	Looked to PMA for action; said it should do more
F	- Professionally oriented general advertisements - usual press releases	Company only	Same level for past ten years	No change	Looked to PMA for action; said it should do more
G	- Usual press released	Company only	Increased 400% in 1964 because of new product developments	No change	Looked to PMA for action
H	- No activities	None exhibited	None	None	Looked to PMA for action; said it should do more; said company should do more

Present Status of Public Relations in the Industry

In 1966, the Pharmaceutical Manufacturers Association conducted a study of public relations activities in the Pharmaceutical Industry. Some of their findings, while representing only a portion of the Industry, are nevertheless useful in the evaluation of H_5 and H_6.

A mail survey was sent to all 136 member firms of the Pharmaceutical Manufacturers Association. The report is based on answers from the 36 firms which responded. Responses came in equal numbers from firms in each of three annual sales categories set up for the survey:

Group A - sales under $20 million.

Group B - $20 million to $80 million

Group C - over $80 million.

Time Spent on Public Relations -- When asked how much time was spent on PR by the executive responsible for the function, respondents from Group A indicated they spent no more than 5 per cent. Three firms in Group B had full time public relations men; in two others, 40 per cent of the PR officer's time was spent on PR. The remaining responses in the same category indicated an

average of 20 per cent of their time was involved.

Eight (75 per cent) of the larger Group C firms' PR men spent 100 per cent of their time on PR. One spent 90 per cent, another spent 30 per cent, and two were unspecified.

Allocation of the Public Relations Function -- Where is the PR function allocated within the firm? In Group A firms one allocated the PR function to the promotion department. Another firm allocated the PR function between personnel, administration, and sales; another between the PR division and the President; one used an outside PR agency, and in one case, the sales department also managed public relations. Half of the firms in Group A did not answer this question.

In Group B, one firm each reported the PR function was included with the sales, marketing and legal departments, and another indicated that it was divided between personnel, administration and publications. Eight Group B companies, however, did not answer the question concerning allocation of the PR function within the firms.

Six Group C companies did not answer the aforementioned question. Three firms from Group C indicated the PR function operated as a distinct entity, reporting to top management. In

three other firms the function was located in the administration, marketing, or personnel departments respectively. It is noteworthy that even some large companies apparently do not consider the PR function important enough to report to top management.

From these results it would appear that communicating with the public at large is not considered to be one of the more important functions. By depending on other departments for public relations service, public relations often gets secondary consideration and does not function effectively.

Evaluation of Public Attitudes -- Two firms in Group B and six in Group C occasionally conducted opinion surveys to gauge reaction of the general public to the company. One Group B company did so regularly. One Group C firm conducted opinion surveys to gauge press reactions to the company. Consequently, 78 per cent of firms responding to the survey had little knowledge of what the public thought of their company, and therefore could find it difficult to direct intelligently communications to the public.

Relationships with Elected Legislators -- Companies giving specific attention to developing and maintaining relationships with

elected legislators are indicated below:

a. With village or city representatives:
A-2; B-5; C-8.

b. With State representatives:
A-2; B-5; C-8.

c. With National representatives:
A-3; B-6; C-7.

It is evident that few took time to maintain relationships with elected legislators. Less than 45 per cent of the firms responding were so involved. This important activity was even ignored by over 40 per cent of the large pharmaceutical companies.

In summary, executives responsible for PR spent less than 40 per cent of their time on PR activities in twenty out of thirty-four firms studied by PMA. Public relations was relegated to a secondary role through according it low organizational status in thirteen of sixteen responding firms. But lack of attention to this important function allows public misunderstanding, criticism, and resentment of the Pharmaceutical Industry to grow virtually unchecked.

Recommendations

On the basis of findings in this section it is recommended:

1. That the Pharmaceutical Industry both collectively (perhaps through the Pharmaceutical

Manufacturers Association) and individually undertake a program of public relations advertising to the public through general magazines.[1] It is important that the final consumer have an understanding of the benefits, services and operations of the Industry.

2. That a study of general public attitudes towards, and images of, the Pharmaceutical Industry be undertaken by the PMA. This will determine both public conceptions and misconceptions and indicate information which should be communicated by advertising. The findings should be made available to all members of the PMA.

3. That the major goal of the PR programs be to develop an informed public concerning the benefits, services and operations of the Pharmaceutical Industry rather than to create public pressure against investigation. It is unrealistic to attempt to create public sentiment which will

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[1] In late 1967 and early 1968 the PMA undertook a PR advertising campaign consisting of four inserts in the Readers' Digest.

act to deter those undertaking Industry investigations. Unless the Industry explains and justifies its actions, however, it is likely to be misunderstood and criticized by the public.

4. That believable facts, and reasonable ideas be used in public relations efforts. Emotional appeals should constitute a secondary emphasis. Also, the source of the PR message should be clearly identified.

5. That companies, if they have not done so already, should organize a public relations program. Those responsible for public relations can convey and interpret information about public attitudes and reactions to management, and help the public to understand and appreciate what a corporation is doing for the public welfare.

6. That the public relations director should report to top management. In small firms where it is not feasible to establish a full time PR position, top management should provide a

communication channel between the PR executive and top management. Since every action and policy of management affects corporate public relations, public relations should be in a position to advise management on the probable public response to policies and actions, and to inspire policies in the public interest.

7. That company and Industry public relations activities with publics other than the consumer, such as legislators, opinion leaders, and the press, be continued.

Conclusions

The hypothesis that since the Investigation, the Industry changed from a rather insular attitude toward public opinion and information disclosing activities to a positive attitude has not been supported. The majority of the Pharmaceutical Industry is not active or effective in the area of public relations. Only three out of the eight firms surveyed for this study have exhibited a substantial positive change in both PR attitudes and activities

since the Kefauver Investigation. These firms and two others undertook some PR programs prior to the Investigation.

The hypothesis that the public relations efforts of the Industry decreased substantially from the post-Investigation peak to 1966 was not supported. There was only one indication ot retrenchment of public relations efforts since the Kefauver Investigation. This specific PR program was sponsored by five companies and lasted less than two years. Other measurable PR activities undertaken since the Investigation have continued. They have primarily involved addition of permanent staff.

More importantly, a majority of the companies studied were never substantially involved in public relations efforts. Consequently, the issue is not one of decreasing activities subsequent to the Investigation as hypothesized, but a serious lack of initial involvement.

PART V

INDUSTRY CONCENTRATION

Increased complexities and costs of doing business are associated with the Kefauver Investigation and subsequent Drug Act Amendments. What impact will they have on corporate organization? One conjecture is that small firms will fail or will be forced to merge. Therefore the following hypothesis was tested:

H_6 The Investigation and Drug Act Amendments of 1962 can be associated with a substantial increase in concentration in the Pharmaceutical Industry since 1962.

Industry concentration is measured mainly by the degree to which the market is controlled by the top firms: the percentage of total Industry sales accounted for by the top four, eight, or twenty firms in an industry. Another measure of concentration in the Pharmaceutical Industry is by a comparison of the share of prescriptions held by the top firms. Both of these measures will be considered in the following evaluation of H_6.

The findings of this study indicate that the hypothesis is not supported. The concentration in sales of the top four, eight and twenty companies actually declined steadily from 1958 to 1966 [1] as is shown

[1] Latest available data.

by the data in Table 1. The Investigation had no apparent effect on this declining trend in concentration of sales which has continued since 1958. [1] The concentration of sales of the top fifty firms decreased since 1964. Because of the break in the data between 1963 and 1964 [2] it is not possible to determine when the decrease for this group began. However, the data in Table 2 indicates a decline in concentration for the top fifty firms since 1962.

Industry concentration was also analyzed by comparing the share of prescriptions held by the largest five, ten, twenty and fifty companies. [3] The data are presented in Table 2 and substantiate the conclusions drawn from Table 1. Industry concentration, as measured by share of prescriptions held, has not increased since 1962. In fact, there was a slight decline from 1962 to 1965, [4] in the

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[1] See p. 65 infra for a discussion of possible reasons for this.

[2] See footnote a, Table 1.

[3] The grouping of firms is slightly different than in Table 1 because the only data available were in different presentations.

[4] Latest data available.

TABLE 1

PHARMACEUTICAL INDUSTRY CONCENTRATION

	Percentage of value of shipments accounted for by the:			
	4 largest companies	8 largest companies	20 largest companies	50 largest companies
1966 [a]	24.1	41.2	72.1	91.3
1965 [a]	24.1	43.1	73.3	92.1
1964 [a]	25.2 [a]	45.8 [a]	76.2 [a]	96.2 [a]
1963	22.0	38.0	72.0	89.0
1958	27.0	45.0	73.0	87.0
1954	25.0	44.0	68.0	NA
1947	28.0	44.0	64.0	NA

Source: Statistic abstract of the United States, 1967 (Washington: U.S. Government Printing Office, 1967), p. 751.

[a]Concentration ratios from 1947 to 1963 were obtained from census figures which include shipments for all sales activity of the Pharmaceutical Industry. Thus Veterinary products, perfumes, and other chemicals would be included. Similar figures were not available to compute precisely comparable concentration ratios for the years 1964 to 1966. For the latter years, domestic ethical pharmaceutical sales were obtained from confidential sources and related to U.S. Department of Commerce current Industrial Reports for the same categories. The resulting concentration ratios for the years 1964 to 1966 are consequently slightly different. However, both show similar continuing decreasing trends in Industry concentration.

TABLE 2

COMPETITION FOR NEW PRESCRIPTIONS

(SHARE OF PRESCRIPTIONS HELD)

	Cumulative Percent			
	1962	1963	1964	1965*
5 largest companies	32.9	33.1	33.0	32.4
10 largest companies	53.1	53.1	52.9	52.6
20 largest companies	78.1	77.8	77.3	76.9
50 largest companies	96.0	96.2	96.1	95.6
All companies	100.0	100.0	100.0	100.0

Source: Pharmaceutical Manufacturers Association, Prescription Drug Industry Fact Book (Washington: PMA 1967), p. 17.

* Latest data available.

share held by each group. Consequently, both indicators used to measure Industry concentration indicate that the hypothesis that the Investigation and Drug Act Amendments of 1962 can be associated with a substantial increase in Industry concentration since 1962, is not supported.

Why has Industry concentration continued to decline despite the increased complexities and costs of doing business associated with the Investigation? First, the added requirements and costs overcame the resources and skills of a relatively small number of firms. Although large firms had research and promotional programs which were substantially affected, they also had enough resources to adjust and absorb the additional costs. Small firms with no research programs experienced few increased costs resulting from the new Government regulations and requirements. Consequently, the regulations would have greatest proportional effect on the relatively few smaller firms with limited resources which were struggling to maintain basic and developmental research programs. Even if a few of them were forced out of business, or had to merge with other firms to survive, the effect on Industry concentration would be small.

Ironically, it has become more difficult to enter the major portion of the ethical pharmaceutical market which is largely dependent on continuing research and development of new products. Government requirements and regulations have made the possession of substantial resources to develop new products and compete in the ethical pharmaceutical market more important than ever.

Second, Industry concentration did not increase because of the rapid increase in sales experienced by the Pharmaceutical Industry since 1962. This sales growth was conducive to continued operation of growth of many smaller companies. Industry sales continued unabated after 1962 and surpassed the rate of growth of gross national product. From 1959 to 1962 sales increased 18.8 per cent; however, from 1963 to 1966 the increase was 29.4 per cent. Small companies shared in this expansion. [1]

Third, many small companies sold mostly generic products. These firms were relatively unaffected by the Investigation because sales of generic drugs expanded proportionately with sales of brand name products after the Investigation. Table 3 shows changes in sources of drugs for prescriptions from 1956 to 1965. Brand name

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[1] FDC, "The Pink Sheet Compilation" (Washington: FDC Reports, Inc.) 1966, p. 7.

manufacturers accounted for the same proportion of prescriptions in 1962 and 1965. Generic prescriptions increased slightly as a percentage of total Industry prescriptions moving from 5.6 per cent in 1962 to 6.2 per cent in 1965. Parenthetically, this shows that attempts by Senator Kefauver to increase substantially the amount of generic prescribing, were unsuccessful.

A fourth factor aided small companies: a relatively inexpensive channel of distribution was expanding. From 1954 to 1965 sales volume of pharmaceuticals to hospitals and the medical profession grew from 9.4 per cent to 19.8 per cent of Industry sales.[1] The majority of the increase involved sales to hospitals which increasingly turned towards a formulary system.[2] As they did, opportunities for direct sales expanded, thereby making it easier for smaller companies to maintain a share of the market.

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[1] PMA Fact Book, p. 12.

[2] A formulary is a standardized list of drugs, usually having no duplicates, adopted by an institution. A prescription for a specific brand of a certain type of product is filled with the one listed on the formulary. Products are often bought on a price rather than brand name basis. This provides opportunities for small companies which depend upon price appeals to gain sales.

TABLE 3

PRESCRIPTION COMPOUNDING

	Factory Compounded		
	Rx by brand or mfr. (%)	Rx by generic name only (%)	Pharmacist-Compounded (%)
1956	88.8	5.9	5.3
1959	91.2	4.8	4.0
1960	90.4	5.5	4.1
1961	90.9	5.5	3.6
1962	91.6	5.6	2.8
1963	92.3	5.3	2.4
1964	91.9	5.8	2.3
1965*	91.5	6.2	2.3

Source: Pharmaceutical Manufacturers Association, Prescription Drug Industry Fact Book (Washington: PMA, 1967), p. 63.

* Latest available data.

Implications for Competition

The findings of this study show that Industry concentration and tendencies toward aggressive promotion practices were not affected substantially by the Kefauver Investigation. The share of total ethical pharmaceutical prescriptions accounted for by the top five, ten and twenty pharmaceutical firms has been comparatively constant since 1962. The top five firms have maintained approximately 32.5 per cent of prescriptions since 1962 and the top ten and twenty companies have held approximately 53 and 77 per cent respectively.

Apparently most small firms have not been affected by the Investigation. Many do little or no basic or developmental research;[1] consequently, added research costs resulting from the Investigation made little difference to them. While larger firms were affected by such added costs, their resources and continued sales growth enabled them to continue to prosper.

Part III of this Chapter showed that large firms continued substantial promotional efforts despite criticism of the Investigators and the FDA. Consequently, competition through promotion is comparable to conditions before the Investigation. Large firms develop and patent products then promote them heavily, with prices reflecting these costs. Small firms cannot afford enough research

[1] Almost all research is accounted for by the 136 members of the Pharmaceutical Manufacturers Association, which has a few smaller firms as members.

and promotion expenditures [1] to make them fully competitive with the major firms. Furthermore, they do not have the backlog of experience or trained researchers to maintain a successful research program should funds be available. However, the prospect of continued growth of pharmaceutical sales, increased scrutiny of drug prices by legislators and government officials, and expiration of many product patents acquired in the early 1950's augur well for continuing success of small companies in selective markets. These companies must depend upon seizing opportunities afforded through other company or government research. The gap in size and methods of operation between large and small companies is unlikely to decrease.

Conclusion

H_7 stating that the Investigation and Drug Act Amendments of 1962 can be associated with a substantial increase in Pharmaceutical Industry concentration since 1962 was not supported. The gradual decline in Industry concentration which commenced in 1958 continued through to 1966. Sales in the Pharmaceutical Industry grew rapidly,

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[1] Research and promotion costs are even higher since the Investigation.

and the type of business traditionally obtained by smaller peripheral firms expanded proportionately to Industry sales. Effects of the Investigation and Drug Act Amendments on small companies previously attempting to undertake research is still largely unknown.

CHAPTER VI

SUMMARY AND CONCLUSIONS

Summary

One of the many ways government exerts control over business is through a Congressional investigation of business activity. The effects of such scrutiny and publicity, and the resulting legislation on industry can be substantial. Investigations have been used both to condemn business for some of its practices notably pricing policies and advertising claims and to aid industries in distress, as for example with the mining and railroads. The most prevalent form of investigation has sought to attack, change, or control business in some manner. Yet little is known of the impact of a government investigation on business practices. Therefore, a study of the effects of the Kefauver Investigation on the Pharmaceutical Industry was undertaken.

A broad mandate is given to members of Congress wishing to undertake an investigation. Congress may investigate all matters that will aid in determining the need for legislation, or its formulation. Unlike legal processes, there are few formalized rules to protect individuals or companies questioned during a Congressional Hearing. To investigate effectively, a Congressional committee must have virtually unrestrained delegation of the vast Congressional power. But great power, wielded by individuals, acting without formal restraint, may lead to abuse.

The Pharmaceutical Industry became the subject of an investigation in late 1959, at the peak of a phenomenal period of growth. From 1947 to 1966 it experienced a fourfold increase in sales. This was stimulated by a rapid proliferation of new products after World War II. During this period, Industry efforts were concentrated on the development of new products and expansion of market shares. Pharmaceutical firms vigorously promoted products and services to members of the health team, but virtually ignored relationships with the general public.

Although some drug prices seemed high to many consumers, the Industry made few efforts to explain the costs and work involved in bringing a pharmaceutical product to the market. To most of the public the Pharmaceutical Industry was a faceless entity, readily subject to political attack.

Skilful manipulation of headlines allowed Senator Kefauver to create much adverse publicity concerning the Drug Industry. When the conduct of the Kefauver Investigation was evaluated by ranking it with a list of operational criteria for the management of an investigation (Chapter III, p. 84) it was judged to be inferior in almost every respect.

The Drug Amendments of 1962 were a result of the Investigation. The final legislation was not as extensive nor as drastic as Senator Kefauver wished. The Amendments were primarily concerned with the power of the Food and Drug Administration. They provided more rigid controls for the development of new products, including tests for safety and efficacy; additional labeling requirements; new controls over advertising; and periodic registration and inspection of manufacturing plants.

This study examined the specific effects of the Kefauver Investigation on new product development, pricing, promotion, public relations, and Industry concentration. The methodology used was a case study of eight ethical pharmaceutical companies, plus a thorough analysis of government data, investigation testimony, and Industry statistics.

Conclusions and Recommendations

Effect on New Product Development

After the Investigation, many Industry sources claimed new regulations would decrease the number of new products developed. It is not possible to observe any association between the Investigation and the specific declining trends in the total number of new products, or new chemical entities. New drug applications and total new

product introductions declined steadily after reaching a peak in 1955, through to 1967. Introduction of new chemical entities declined steadily from the peak year 1959, to 1963, and remained at relatively low levels to 1967.

Changes in the rate of new product development were apparently influenced by several factors. First, product introductions may have declined because few additional developments from extant knowledge are possible and further understanding of basic causes of disease and biochemical techniques are needed. The great proliferation of new products from 1945 to 1959 was largely based on knowledge accumulated over the preceding fifty years. Second, it is also possible that few products are now being introduced because much attention was diverted from expanding basic research to the development of improved, but similar products during the past twenty years.

Although the specific trends in the decline in new product introductions cannot be associated with the Investigation, other associated negative effects on new product development are evident. Product development costs increased substantially from $8.8 to $16.7 million between 1962 and 1963, the year following the Drug Act Amendments, and they continued to increase through 1967.

The requirement of more extensive studies for new product development and subsequent increased costs of research caused six out of the seven firms surveyed, which were engaged in research, to reduce significantly the number of research areas. They also reported that high costs of new product development negatively affected the development and marketing of new products having limited sales potential. Consequently, the Investigation created conditions which probably decreased new product development and may continue to do so in the future.

Recommendations

Based on the foregoing findings on new product development it is recommended:

1. That the Pharmaceutical Industry increase the proportion of funds allocated to basic research. The decline in new product development is associated with a lack of basic knowledge, and an increased emphasis on basic research is needed. Pharmaceutical research firms should allocate more than the current sixteen per cent of research and development funds which is

channeled into basic research.[1] In other industries, firms known for their research accomplishments have found that the allocation of 30 per cent of their research and development budgets to basic research is a useful norm.

> Almost all of the larger corporations have independently found that about thirty per cent of their research funds should be budgeted to basic research to get maximum long-range profits . . .[2]

2. That firms select carefully basic research areas which will yield to investigation, and result in important subsequent applications. One way of accomplishing this is for company basic research scientists to participate actively in contemporary currents of scientific thought. Thus they can be aware of, and stimulated by worldwide activity in the sciences relevant to pharmaceutical development.

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[1] PMA Fact Book, p. 41.

[2] Augustus B. Kinzel, Vice President of Research, Union Carbide Corporation in National Science Foundation, Academic and Industrial Basic Research, p. 4.

3. That management recognize the marketing possibilities in longer product life cycles as the rate of new product introductions declines. The following strategies might be considered:

   a) For existing products, promotional efforts should be designed to protect and improve the present competitive position. After a product has been on the market for a period of years, consideration should be given to reviving interest and improving it through innovations such as new dosage forms, combination with other products and improved packaging.

   b) For new products, investment in promotional funds may be greater, because of the possibility of larger returns over a longer period. On the other hand, a gradually expanding campaign as market acceptance becomes known is also feasible.

c) For products with long life cycles, a gradually declining price pattern may be developed to discourage competitors from entering the market.

4. That the Industry and the FDA discuss ways to bring important, but limited-use products to the market.

a) One alternative might be a selective reduction of less essential FDA requirements such as chronic toxicological studies for products treating terminal diseases, and a co-operative approach by the FDA to expedite approval of such products.

b) Where it is impossible to ease costly requirements, government should subsidize the development of these products, since they are of benefit to society as a whole and not to the company or stockholders. In these cases, where commercial risks are reduced, a corresponding reduction in the risk-premium element of prices should follow.

5. That the FDA should not discourage the introduction of analogues as long as they meet established requirements for safety and efficacy. In this way, competition may be increased, prices may be lowered, and greater service and selection should be provided for the physician and his patient.

6. That processing of new drug applications be accelerated. This might be accomplished by making FDA approval decisions from carefully prepared summaries of Industry research. The total research findings on which the summaries are based should be submitted also, and random spot checks by FDA staff members could be made to verify that the summaries represent adequately all significant findings. The FDA and the Pharmaceutical Manufacturers Association should meet to work out procedures and requirements.

7. That the Federal government expand its support of basic research considered too risky by Industry. Since industrial firms must consider the possibilities of return on research funds expended, high-risk long-term research projects may not receive

adequate attention. The Federal government has an advantage in such cases because public resources can be committed to long-term projects necessary to solve fundamental problems.

Influences on Pricing

The high price of pharmaceuticals was stated as the major concern of the Kefauver Investigation, yet no decline in prices of existing products, or introductory prices from similar therapeutic categories, can be associated with the Investigation. Prices of the top five products in each of eight companies surveyed showed no substantial decline between the periods 1957 to 1962 and 1963 to 1966. Both the Bureau of Labor Statistics Index and the Prescription Specialties Producer Price Index showed that small but steady price declines began several years before the Drug Act Amendments of 1962. Since then no substantial change in this trend is discernible.

Comparison of introductory prices of similar types of products for the periods 1954 to 1962 and 1963 to 1967 provides another useful indication of the possible effects of the Investigation on pricing. Prior to 1962, a remarkable similarity in these

introductory prices within a therapeutic category was common. Perhaps changes in pricing patterns of new products introduced after the Investigation will reflect its influences more than changes in prices of those already on the market. Therefore, introductory wholesale prices from seven therapeutic categories of ethical drugs were studied. The mean average daily dosage costs increased in four categories after the Investigation and these increases ranged from 35 per cent to 188 per cent. Two other categories increased slightly, while the introductory costs in the seventh decreased 5 per cent. Apparently, there is a trend toward increasing prices of new products, despite the Investigation.

Effects on Promotional Activity

One significant legislative area in the Drug Act Amendments of 1962 affected medical journal advertisements. New regulations require that journal advertisements include not only the merits of a product, but also a brief, but thorough summary of warnings, side effects and contraindications. Furthermore, the law states that product claims and disadvantages must be presented in "fair balance".

To comply with these new regulations and include government-required messages, companies often find it necessary to purchase additional advertising space. A comparison of thirteen product advertisements in medical journals before and after the new regulations showed that advertisers purchased from 25 per cent to 100 per cent more space to carry the required information in ten advertisements. Thus the cost of advertising a product is higher since the Investigation.

Preparation of advertisements have also become more complex. It is difficult to know precisely what is required to achieve a "fair balance" between claims for and against a product and how to present a "brief summary" of contraindications as demanded in the regulations.

The Kefauver hearings exposed some undesirable advertising practices, such as the exaggeration of claims and the minimization of contraindications. The quantities of direct mail, samples and journal advertisements were also criticized. While some charges against Industry practices were enlarged or distorted, some were true. Despite this, the Industry made few changes until the new regulations became effective. Furthermore, this study reveals that some promotional practices such as unsolicited sampling which were criticized were still unchanged in 1968.

Recommendations

Company advertising is used to present a product or service in the best possible light. Consequently, the temptation is great to maximize product claims while minimizing disadvantages. The Pharmaceutical advertisers have a serious responsibility; pharmaceutical products directly affect human life, and improper usage of drugs can result in untoward effects.

Since the enactment of the Drug Act Amendments of 1962, the Food and Drug Administration has a responsibility to insure that drug advertisements present information fairly on advantages and disadvantages of a product. This seemingly is the main intent of the advertising section of the Amendments; additional control of advertising is unwarranted.

Previous evidence showed that pharmaceutical advertisers have been slow to conform with some public demands and government standards. [1] It is essential that in every advertisement pharmaceutical firms provide true representation and full disclosure of pertinent information concerning each product advertised.

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[1] See p. 80 infra.

Industry Recommendations-- To meet these standards it is recommended that each company in the Pharmaceutical Industry should:

1. Develop attitudes within the organization which hold that providing full information is paramount to all other advertising activities. The first purpose of an advertisement should be to provide information; persuasion should be the second. This must start with top executives in each organization.
2. Analyze previous promotional activities which precipitated past government regulatory actions and insure that these actions are not duplicated.
3. Insure that published FDA advertising guidelines are adhered to. While some FDA requirements are not specific or precise [1] others such as the list on page 80 provide some clear rules. For example, this list indicates proper usage of authoritative quotations in an advertisement, yet

[1] For example, regulations concerning "fair balance" and "brief summary".

by 1966 companies were still not adhering to these guidelines. [1]

4. Check with FDA in cases where doubt or uncertainty as to proper procedure still exists.

FDA Recommendations-- It is recommended that the FDA aid the process of complete information disclosure, and establish better relations with the Industry by:

1. Making certain that regulations and their interpretations are specific and precise.
2. Providing prompt, reasonable answers to Industry requests for information and clarification. This should encourage Industry to seek information when in doubt.
3. Regulating and controlling only important factors concerning product safety and effects. Government officials should show self restraint in judging advertising methodology [2] or pre-judging advertisers' motives. [3]

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[1] See Table 3.

[2] See p. 74 infra.

[3] See p. 78 infra.

Joint Recommendations--It is further recommended that a permanent liaison committee comprised of approximately three representatives each from the FDA and the PMA be established. The objectives of the committee should be:

1. To clarify ambiguous FDA standards concerning promotion of drugs. Clarifications should be based on the intent of the Drug Act Amendments of 1962.
2. To consider specific Industry and FDA complaints concerning the other's actions and/or rulings in the area of promotion. The committee should make recommendations concerning the merit of each complaint, and suggest guidelines for future action.

Effects on Public Relations Activity

A limited increase in public relations activities occurred after the Investigation. Group PR efforts, however, have been rare. Only one joint advertising program, lasting two years, was carried out during the period 1962 to 1966.

Although five of the eight companies surveyed undertake some public relations activities, only three exhibited substantial

positive changes in PR attitudes and activities since the Kefauver Investigation. In a study conducted by the Pharmaceutical Manufacturers Association a majority of respondents indicated that they do not have a substantial PR program. The Industry as a whole still is not very concerned with public relations.

Those companies increasing public relations activities after the Investigation have increased their PR staffs, and concentrated on influencing legislators, government officials, and opinion leaders. No substantial change in PR activities is anticipated by any of the companies in 1969.

Are pharmaceutical firms explaining their cause and contribution to the general public? Only two companies of the eight studied have an active PR program aimed at the general public. Even these, however, are, admittedly, not their maximum feasible efforts. Current PR activities seem to be geared mainly to provide a company and/or Industry defense -- to have appropriate answers when public criticism comes.

Even after the Investigation, remarkable indifference remains on the part of the Industry to the questions, criticisms, and fears of the public concerning Pharmaceutical Industry activities. Few, if any, of the firms surveyed appear prepared for significant

positive steps to clarify the issues, and develop respect and confidence in their Industry.

Recommendations concerning public relations

On the basis of findings in this section it is recommended:

1. That the Pharmaceutical Industry both collectively (perhaps through the Pharmaceutical Manufacturers Association) and individually undertake a program of public relations advertising to the public through general magazines. [1] It is important that the final consumer have a clear understanding of the benefits, services and operations of the Industry.
2. That a study of general public attitudes towards and images of the Pharmaceutical Industry be undertaken by the PMA. This will determine both public conceptions and misconceptions and indicate information which should be communicated by advertising. The findings should be made available to all members of the PMA.

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[1] In late 1967 and early 1968 the PMA undertook a PR advertising campaign consisting of four inserts in the Readers' Digest.

3. That the major goal of the PR programs be to develop an informed public concerning the benefits, services and operations of the Pharmaceutical Industry and not to create public pressure against investigation. It is unrealistic to attempt to create public sentiment which will act to deter those undertaking industry investigations. However, unless the Industry explains and justifies its actions, it is likely to be misunderstood and criticized by the public.

4. That believable facts, and reasonable ideas be used in public relations efforts. Emotional appeals should constitute a secondary emphasis. Also, the source of the PR message should be clearly identified.

5. That companies which have not done so should organize a public relations program. Those responsible for public relations can convey and interpret information about public attitudes and reactions to management, and help the public to

understand and appreciate what a corporation is doing for the public welfare.

6. That the public relations director should report to top management. In small firms where this is not feasible, top management should provide a communication channel between the PR executive and top management. As every action and policy of management affects corporate public relations, public relations should be in a position to advise management on the probable public response to policies and actions, and to inspire policies in the public interest.

7. That company and Industry public relations activities with publics other than the consumer, such as legislators, opinion leaders and the press, be continued.

Industry Concentration

Increased costs and greater complexities were associated with the effects of the Investigation. Consequently, it was expected that small firms would find it difficult to continue operations, resulting in a substantial number of failures or mergers and increased concen-

tration in the Pharmaceutical Industry. However, this did not prove to be so.

Industry concentration, measured by share of Industry sales accounted for by the top four, eight, and twenty companies declined steadily from 1958 to 1966. When concentration was measured by share of prescriptions held, there was also a slight decline from 1962 to 1965.

The expected large number of failures and mergers of smaller companies did not materialize because:

1. The rapid increase in sales experienced by the Pharmaceutical Industry since 1962 provided opportunities for survival and growth of smaller companies.
2. The sales of generic products increased proportionately to Industry sales, providing continued growth opportunities for many small companies specializing in generics. Such firms were least affected by the new regulations.
3. The adoption of formularies increased sales opportunities for smaller companies in the relatively inexpensive direct channel of distribution to hospitals.

Implications for competition

The prospect of continued growth in pharmaceutical sales, increased scrutiny of drug prices by government officials and legislators, and expiration of many product patents acquired in the early 1950's augur well for continuing success of small companies. However, the realities of high costs of new product development almost preclude the small company from competing through new product introductions. These companies must depend upon seizing the aforementioned opportunities and obtaining products through other company or government research. Consequently, the differences in size between large and small companies are unlikely to decrease.

Summary: The Hypotheses and Conclusions Concerning Them

H_1 -- There is a positive association between the substantial reduction in the number of new ethical pharmaceutical products and the Kefauver Investigation and subsequent Drug Act Amendments of 1962.

Conclusion -- The hypothesis is not supported. The Investigation and Amendments are not associated with any observable effects on specific trends in new product introductions in the short run (1963 - 1967). However, the Amendments created

conditions which will decrease new product development in the long run.

The Investigation is associated with the adoption of practices which increase the probabilities that new products will be somewhat safer than those introduced to the market prior to the Investigation.

H_2 -- No substantial decline in prices of ethical pharmaceutical products can be associated with the Investigation and Drug Act Amendments of 1962.

Conclusion -- The hypothesis is supported. No price decreases were found after 1962 for the majority of products in the study.

H_3 -- After the Investigation, the introductory prices of newly released drugs (for corresponding categories) were not substantially lower than those of similar drugs introduced prior to the Investigation.

Conclusion -- The hypothesis is supported. The Investigation is not associated with decreases in prices of newly introduced products. In fact, prices of drugs introduced after 1962 were generally higher than those for similar indications from 1954 to 1962.

H_4 -- The relative cost of promoting a product in the ethical drug industry increased after 1962, and the increased costs can be associated with the Investigation and Drug Act Amendments of 1962.

Conclusion -- The hypothesis is supported. Increased costs and complexities in undertaking advertising and selling are associated with the Investigation. However, the Investigation is also associated with the assurance of more accurate drug promotion.

H_5 -- Since the Investigation, the public posture of the Industry changed from a rather insular attitude toward public opinion and information disclosing activities to a positive attitude, as demonstrated by increased activity and expenditure on public relations.

Conclusion -- The hypothesis is not supported. A majority of the Industry still undertakes little or no public relations. Most existing PR activities have been aimed at professionals, or legislators, not the general public.

H_6 -- The public relations effort of the Industry decreased substantially from the post-Investigation peak to 1966.

Conclusion - The hypothesis is not supported since a substantial increase in PR efforts did not materialize.

H_7 -- The Investigation and Drug Act Amendments of 1962 can be associated with a substantial increase in concentration in the Pharmaceutical Industry since 1962.

Conclusion -- The hypothesis is not supported. Concentration of the top four, eight and twenty firms in the Pharmaceutical Industry decreased steadily since 1958.

Suggestions for Further Research

1. This study has presented some findings on the effects of one investigation on one industry. Further studies of other industry investigations are needed in order to develop ultimately a list of useful generalizations concerning investigations. The studies should include both an evaluation of the conduct of the investigation, and investigation effects on marketing practices. Perhaps the list of criteria developed in Chapter I could be used for the former purpose.

2. Because of the small sample size, it was not possible to study thoroughly the role of the small company with sales of less than $3 million on the Pharmaceutical Industry. These firms

should be subjected to special scrutiny for there are nearly 1200 of them. An examination of their product development and marketing practices would be a valuable contribution to the understanding of the small pharmaceutical manufacturer.

3. The study showed that the number of new products has declined steadily since the mid-1950's. Improvement in the rate of new product development is desirable. Research should be undertaken to determine whether any firms have been able to maintain relatively better productivity, and reasons for this. New product output of all pharmaceutical research firms might be determined; then a comparison of research methods of those with highest and lowest productivities made. More fruitful new product research procedures might be isolated in this way.

APPENDIX A

Operational Criteria for an Investigation, as proposed by Members of Congress, Attorneys, and Others

1. Any person who believes that testimony or other evidence given in a public hearing before any committee tends to defame him or otherwise adversely affect his reputation may file with the committee a sworn statement, concerning such testimony, which shall be made a part of the record of such hearing.

2. Aggrieved persons may testify in own behalf, secure and examine not more than four favorable witnesses, and cross-examine hostile witnesses, one hour each, personally or by counsel.

3. Petition to invoke safeguard No. 2 must be filed within thirty days and acted on within thirty days thereafter. Petitioner must swear his purpose is not delay or obstruct committee.

4. Right to be accompanied by counsel at public or private hearing as observer, but not as participant, or adviser while on stand, unless committee consents.

5. Evidence shall be relevant to subject of hearing.

6. Witness may have stenographic transcript of his testimony.

7. Committee shall not publish or file any report, interim or final, unless and until a meeting of the committee has been called upon proper notice and such report has been approved by a majority of those voting.

8. No committee or employee thereof shall publish or file any statement or report alleging misconduct by, or otherwise adversely commenting on, any person unless and until such person has been advised of the alleged misconduct or adverse comment and has been given a reasonable opportunity to present to the committee a sworn statement with respect thereto.

9. No committeeman or employee shall speak, lecture, or write about the committee for compensation.

10. No. 9 supra is to apply to standing, select and joint committees and subcommittees thereof.

11. Subpoenas shall not issue unless approved by majority of committee in writing.

12. Hearings shall be public or secret as majority of committee rules to be in public interest.

13. Secret testimony requires presence of two committeemen, plus interrogator.

14. Accurate stenographic record must be kept of all testimony at public hearings.

15. All witnesses, at hearings, public or secret, shall be entitled to full and fair presentation of matter under investigation, to aid and advice of counsel, and such other assistance as may be necessary to protect their rights.

16. All witnesses at hearings of the committee, whether public or secret, shall be advised of their constitutional right against self-incrimination and their right not to divulge confidential communications protected by law.

17. Any person who claims a privilege not to appear or who, having appeared, claims a privilege not to answer a question, shall be entitled to present through counsel a written motion and oral argument presenting the claimed privilege to the committee.

18. Any witness at a hearing, public or secret, may question another witness who comments upon his testimony, via a written question handed to the chairman, who in his discretion may refuse to use part or all of it.

19. No witness shall be in contempt of the committee for refusing to obey a subpoena, unless and until the committee has, upon notice to all its members, met and considered the alleged contempt, and by a majority of those present voted such witness in contempt.

20. No adverse statement or report shall be publicly released until the committee, upon due notice, has met and approved such release by quorum of whole committee.

21. No photographs, moving pictures, television or radio broadcasts shall be made during hearings.

22. No major investigation shall be initiated without unanimous approval of subcommittee or majority approval of full committee.

23. All testimony taken in executive hearings shall be secret and not released or used in public hearings without approval of majority of committee.

24. A clear statement should be made of the subject of any investigation.

25. Any witness giving testimony in open hearing which reflects adversely on character or reputation of another person shall disclose his sources of information, unless his answer would threaten the national security.

26. No report or statement, interim or final, shall be filed, published or released that reflects adversely on any person's character or reputation unless based on evidence presented at an open hearing.

27. There shall be created by law a civil penalty for false testimony before a congressional committee, the penalty to be the right of any injured person to collect damages in a federal court action against the false witness. Such damage actions to be placed at top of court calendars and expedited.

28. Every witness who testifies in a hearing shall have a right at the conclusion of his testimony either to make a sworn statement or at his option to file a sworn statement which shall be made part of the record of such hearing, but such oral or written statement shall be relevant to the subject of the hearing.

29. Except at his own request, no reporter, editor, or publisher shall be called to testify before a committee to be questioned concerning any publication by him, unless upon vote of a majority of the committee or subcommittee before whom he is called to testify. In such case the committee or subcommittee must have at least five members.

30. Counsel for the committee must be a lawyer.

31. A person who is under the committee's scrutiny should be fully apprised of the matters as to which the committee proposes to inquire.

32. The committee should identify the witnesses upon whose testimony it has relied in commencing the hearing.

33. Investigations should be conducted by groups within the regular standing committees of the House or Senate and not by special committees.

34. No legislator who is an interested party or who is in a position to shake down potential witnesses should be permitted to serve as head of an investigating subcommittee.

35. Investigations should be confined to important matters of public concern, as distinguished from party interests, and should be conducted in a non-partisan manner.

36. Investigations should be conducted in the open.

37. No witness should be cited for contempt of Congress for refusal to answer questions as to his religious or political beliefs.

38. Every investigating committee should be supplied with expert counsel and staff investigators especially trained in the art of fact-finding by democratic methods.

39. No transcript of testimony taken under oath at either a public hearing or an executive session shall be altered or edited.

40. No summary of a report or prediction of the contents of a report of a statement of his conclusions concerning an investigation may be made by a member prior to the issuance of a duly approved report. Any member violating this provision shall, on the vote of the majority of a quorum of the committee, be denied the right to take part in the formulation of or vote upon the committee report with respect to such investigation.

41. All of the testimony on which a report is based shall be released concurrently with the report.

Originators of Proposed Codes From Which The Foregoing List Was Developed [1]

1. Lucas Bill, Sen. Con. Res. 2, 81st Cong. 2d Sess. (1948)

2. Holifield Bill, H. R. 74, 81st Cong. 1st Sess. (1949)

3. Buchanan Bill, H. R. 824, 81st Cong. 1st Sess. (1949)

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[1] George B. Galloway, "Congressional Investigations: Proposed Reforms", The University of Chicago Law Review, Vol. 18, Spring 1951, No. 3, pp. 499 - 502, for a cross-comparison of each proposal with Galloway's list.

4. Javits Bill, H J. Res. 20, 81st Cong. 1st Sess. (1949)

5. Douglas Bill, H. R. 4564, 80th Cong. 1st Sess. (1947)

6. Klein Bill, H. R. 3443, 81st Cong. 2d Sess. (1950)

7. Statement by Forty-five Law School Professors.

8. Proposal of Judge Wyzanski .

9. Proposal by the New York City Bar Association.

10. Proposal by Henry H. Glassie and Thomas M. Cooley.

11. Proposed by Arnold, Fortas and Porter.

12. Proposal by Prof. Stanley Surrey.

13. Proposal by the American Civil Liberties Union.

14. Proposal by The Washington Post (a series of twelve editorials entitled "Turning on the Light").

Source: George G. Galloway, "Congressional Investigations: Proposed Reforms", The University of Chicago Law Review, Vol. 18 Spring 1951, No. 3, pp. 496 - 502.

APPENDIX B

INTERVIEW SCHEDULE

PART I

Interview with Marketing Manager

1. Have there been any significant changes in your detailing (or selling) program since 1957:

   e. g. - number of men increasing or decreasing?

   - selling emphasis (e. g. "hard sell" vs. scientific approach)

   - call frequency.

   a. If yes, what were they?

   b. When did they occur?

   c. Why did each occur?

   d. Would you please rate these in order of importance.

   e. How much was the change (percentage)?

2. Have there been any significant changes in your sampling program since 1957?

   a. If yes, what were they?

   b. When did they occur?

   c. Why did each occur?

   d. Would you please rate these in order of importance.

   e. How much was the change (percentage)?

3. Have there been any significant change in your advertising program since 1957?

   a. If yes, what were they?

   b. When did they occur?

   c. Why did each occur?

   d. Would you please rate them in order of importance.

   e. How much was the change (percentage)?

   f. If yes, how did the factors that were mentioned affect:

      - general company policies toward advertising

      - use of advertising space

      - size of advertising budgets over the past ten years.

      - allocation of advertising funds (concentrated on a few or spread over more products)

      - preparation of advertisements

      - specific examples

4. Taking into consideration the previous three promotional elements - detailing, advertising and sampling - have there been any significant changes in the relative use of these elements in your total Marketing program since 1957?

   a. If yes, what were they?

   b. When did they occur?

   c. Why did each occur?

d. Would you please rate these in order of importance.

e. How much was the change (percentage)?

5. How do you think the public at large views ethical drug prices?

- What is your attitude toward these viewpoints?

6. Do you think any major changes in pricing policies are in the offing for the pharmaceutical industry? Please elaborate.

7. What public relations activities does your company undertake?

8. What emphasis, or copy approach does your company use in its public relations advertising?

e. g. - the contribution of your company

- the contribution of the pharmaceutical industry

- etc.

9. Last year did you undertake more, less, or about the same public relations activities:

- as compared to this year?

- as compared to two years ago?

a. approximately how much percentage change for each case?

10. Next year do you expect to be undertaking more, less, or about the same public relations activities as compared to this year? Why?

a. approximately how much percentage change.

11. (If the Kefauver Investigation and Drug Amendments have not yet been mentioned, ask the following questions):

Did the Kefauver Investigation and subsequent Drug Act Amendments of 1962 induce any significant changes in your advertising?

If yes, ask for comments on the sub-parts of question 3 (a - f)

12. In addition to the factors we have already discussed, I would appreciate your general comments on the effects of:

a) The Kefauver Investigation -

- Has it been better or worse for the industry?
- Did it change your method of operation in any (other) areas? How, and in what way?
- Why do you think the Kefauver Investigation was undertaken? Any other reasons?
- Do you think that the point of view of the pharmaceutical industry was expounded adequately? Please elaborate.
- In your opinion, has the industry reacted properly to the Investigation? Please elaborate.

b) The subsequent Drug Act Amendments

- Has it been better or worse for the Industry?
- Did it change your method of operation in any (other) areas? How, and in what way?

- In your opinion, has the Industry reacted properly to the regulations arising out of the Drug Act Amendments?

NAME _____

POSITION _____

COMPANY _____

PART II

Interview with Research Director

1. Have there been any significant changes in the direction or thrust of your research program since 1957?

   If so, please elaborate, including dates.

   Why did they occur?

   - any changes in emphasis on basic or developmental research? Reasons? Date?
   - have steps been taken to either concentrate research in specific areas or to broaden it? If so please elaborate, including dates.
   - have there been any changes in number of projects since 1957 (complete chart at end of questionnaire)

2. Have you made any significant changes in research expenditures since 1957?

   - If so, would you please elaborate on the reasons, and dates when these changes occurred.

3. If changes in research expenditures have occurred, what have been the approximate percentage changes per year?

4. What would typical developmental research costs be for a product in each year since 1957?

5. What are your policies concerning developing products with limited market potential?

   - Have they always been thus?

   If there has been a change, why? When?

6. (If the Kefauver Investigation and Drug Amendments have not yet been mentioned, ask the following question):

   Did the Kefauver Investigation and subsequent Drug Act Amendments of 1962 induce any significant changes in your advertising?

   If yes, ask for comments.

7. In addition to the factors we have already discussed, I would appreciate your general comments on the effects of:

   a) The Kefauver Investigation

      - Has it been better or worse for the industry?
      - Did it change your method of operation in any (other) areas? How, and in what way?
      - Why do you think the Kefauver Investigation was undertaken? Any other reasons?
      - Do you think that the point of view of the pharmaceutical industry was expounded adequately?

      Please elaborate.

- In your opinion, has the industry reacted properly to the Investigation? Please elaborate.

b) The subsequent Drug Act Amendments

- Has it been better or worse for the Industry?
- Did it change your method of operation in any (other) areas? How, and in what way?
- In your opinion, has the Industry reacted properly to the regulations arising out of the Drug Act Amendments?

NAME _____

POSITION _____

COMPANY _____

QUESTION 1: NEW PRODUCT DEVELOPMENT

	1957	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967
Number of NDA's											
Number of new drugs approved											
Average time(days) for NDA to be approved											
Average cost of research for a new drug.											

APPENDIX C

Letter Requesting Interview

MICHIGAN STATE UNIVERSITY

March, 1968

President,
X Y Z Co.

Dear Mr. ____ :

I am a doctoral candidate at the Graduate School of Business, here at Michigan State University, and am writing a thesis concerning changes in the pharmaceutical industry. Specifically, I am studying changes which have taken place in the Marketing, and Product Research and Development areas during the past ten years. A great deal of information is available from already published materials, however, it is important to discuss a few aspects with a representative group of pharmaceutical firms.

I would greatly appreciate the privilege of separately interviewing your Marketing Manager, and Director of Research to discuss the changes experienced by your company. Each interview should not be longer than one or one and a half hours.

Both the names of companies and individuals will remain confidential, and if necessary, information will be disguised in the report to assure anonymity.

I have discussed the study with the Pharmaceutical Manufacturers Association and have a letter of introduction from Mr. Howard Binkley, Vice President, Administration and Planning. He concludes his letter:

> "Very little responsible study has been made of the subjects Mr. Beckman's thesis will examine. It is therefore my hope that you will extend to him whatever co-operation you can, in order to help him complete this important project."

As time before graduation is short, I would like to complete these interviews in the next week or two. Consequently, I will 'phone you on _____ to answer any further questions you might have, and to see if a visit with your company will be possible. If you are agreeable to the idea, may I suggest the possibility of the morning of _____? Or would another date be more convenient?

I have been deeply interested and involved in the pharmaceutical industry for a number of years, and am appreciative of its accomplishments. I believe this study will make a contribution to the industry and business in general.

The co-operation of interested pharmaceutical companies is an essential part of this thesis. If you can help, I will be very grateful for this significant contribution.

Thank you for your interest and consideration.

Sincerely,

M. Dale Beckman

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