Pharmaceutical Marketing

Strategy and Cases

Mickey Smith, PhD

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Dedicated to the memory
of Dr. Charles W. Hartman;
thinker, teacher, friend.

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Preface

When *Principles of Pharmaceutical Marketing* was first published in 1968, it was intended as an undergraduate textbook, primarily for Pharmacy students. Over the years and through two subsequent editions, pharmacy, pharmaceutical education and the pharmaceutical industry have undergone fascinating and dramatic changes. All of these have led to a new approach and a modified title in the present book, although it is certainly the "great grandson" of the original *Principles*.

This book is still a textbook (we hope), but aimed consciously at those who would or do practice pharmaceutical marketing. It is hoped that it will provide an understanding of the functions of pharmaceutical marketing for non-practitioners as well.

Acknowledgement is due to the contributors who are named in the pages that follow. My friends Max Ferm and Ted Klein have for many years directly and indirectly influenced what I have put in all the editions. Lea and Febiger published the earlier works and I enjoyed fully my relationship with them as I now do with Haworth.

The pharmaceutical industry is fortunate to be served by a fine internal press. "*The Pink Sheet*," *Medical Marketing and Media*, *Pharmaceutical Executive*, and *Medical Advertising News* are "must" reading for pharmaceutical marketers and I have made heavy use of materials published in these media.

Finally, I must thank Mary Ann Iverson for typing draft after draft of the manuscript and my wife for supporting my yellow legal pad and brown pen habit.

Mickey C. Smith

Contributions

Some material in this text is adapted from work published in the Third Edition of *Principles of Pharmaceutical Marketing*. It is so identified when it appears. The contributions of the following individuals are gratefully acknowledged.

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Chapter 1

Definitions and Approaches to Pharmaceutical Marketing

It is well at the outset to establish that this book deals with the marketing of both prescription and nonprescription *medications* and that this is done from the position that *good* marketing and good medicines are not only compatible, they are inseparable.

THE SOCIAL POSITION OF PHARMACEUTICAL MARKETING

Drugs affect and alter health. By their very nature they play a prominent role in society. The drug industry consequently also plays a prominent role. The president of one of the largest pharmaceutical manufacturers has defined this role to include the following:

1. Discovery and development of new drugs;
2. Rapid and safe development of these drugs into useful therapeutic tools; and
3. Production and distribution of safe and efficient existing drugs.

This role is admirably fulfilled by most members of the pharmaceutical industry (at all levels). Nevertheless, the health field is ripe for exploitation. Those who are ill have notoriously been prey to all manner of quacks, counterfeiters, and outright crooks. The vulnerability of the sick has led to the development of an extensive network of regulatory devices, self-imposed by the industry and enacted by governmental agencies, for the protection of the public.

Although the term has been used almost generically, there is an "ethical" pharmaceutical industry which jealously guards the reputation of its members, both individually and collectively, by adherence to industry-wide codes of ethics. The unethical and the unscrupulous are controlled by

the most extensive set of laws and regulations imposed on any industry, ranging from restrictions on the content of the advertising of the manufacturers to the requirement that the distribution of prescription drugs at the community level be limited to licensed health professionals.

The efforts of marketing practitioners to match as closely as possible the marketing mix of their companies with the needs of the consumer has led to the development of a way of thinking known as the "marketing concept." The marketing concept states what seems obvious now, but was not always practiced, that it is easier to change the products and activities of the individual manufacturer to fit the market than it is to convince the entire market to use the products and services as the individual marketer prefers them. The marketing concept further requires that all of the resources of the firm be organized into a total system aimed at meeting the needs of the customer. Those firms which once prided themselves on their production expertise now find that marketing know-how is perhaps more important.

Marketing plays a key role, influencing or directing activities from the manufacturer to the patient. And the patient, it should be noted, stands at the peak of the marketing pyramid. It is his characteristics which determine which goods will be sold or, more correctly, which goods will be produced. Any firm that wishes adequately to serve its market would therefore strive to direct marketing activities so the right product is sold in the right quantity at the right place at the right price at the right time. As the products with which we are dealing in this industry affect patients' health, some of these factors assume even greater importance than that attached to the stimulation of sales.

The Right Product

Few industries feel so keenly the need to have their products meet such rigid specifications as the drug industry. A few micrograms difference in the composition of the active ingredients of a tablet may not only injure the sales curve but the patient as well.

One of the most desirable developments in recent years in the pharmaceutical industry has been the increased role played by the marketing department in the development of the right product. The specific subdivision of marketing which bears the major responsibility for aiding in this development is marketing research. This functional area is charged with the determination not only of the therapeutic activity needed in diseases with an incidence (which also must be determined), but also the dosage form and package which is likely to be most acceptable to both physician and patient.

Current practice in modern pharmaceutical companies finds medical research working hand-in-hand with marketing research in selecting product characteristics that best suit patient characteristics. It is a tribute to the production technology of the industry that neither of these research efforts often finds itself faced with the roadblock of inability to produce that which is needed.

The Right Quantity

The quantity characteristics of pharmaceutical products are closely related to the packaging. In certain situations the packaging of the drug can determine its effectiveness. At other times the packaging can be so unique as to serve as a form of promotion. The quantity and type of packaging for an analgesic, for example, may range from the bottle of 100 tablets sent to the community pharmacy to the drum of 5000 individually wrapped tablets designed for unit-dose dispensing in the hospital. Again, the right quantity is an important marketing characteristic of a product, but it has parallel value to the public health.

The Right Place

For prescription drugs the problem of place would seem to be an easy one. Prescription drugs must be dispensed by physician or pharmacist, therefore the place is pre-chosen. It is not that simple, however. Efforts toward fulfilling the requirements to distribute prescription drugs as efficiently as possible have been the reason for the development of the complex distribution channels that include wholesalers, retailers, hospitals, clinics, and government installations. These establishments are influenced by both the needs and desires of the patient. Further, the location of the patients and the establishments in the channels of distribution will affect plant location, warehousing, development of sales territories, and transportation of the product.

A further responsibility of marketing in the consideration of the problems of "place" is the maintenance of good business relations with the other elements of the channels of distribution. Thus, retailers, wholesalers, and hospitals all must be familiar with the distribution policies of the manufacturer. Extremely important in maintaining good trade relations is the nature of the return-goods policy of the manufacturer, efficiency of invoicing and issuance of credit, and good communications regarding the availability and nature of all of the company's products. Most drug manufacturers have a Director of Trade Relations or Director of Distribution in their marketing departments whose job it is to see that the

establishments on whom the manufacturer must depend for distribution understand and in general agree with their distribution policies.

The Right Price

Price is an integral part of the marketing mix, even though needed drugs will probably be purchased regardless of price, within limits. Insofar as there are other products that are substitutable, a product that bears an excessive price tag may find itself without a market.

As we shall see throughout this text, one of the many unique characteristics of the drug industry is the undesirability of its products, i.e., with few exceptions patients would prefer not to purchase a prescribed drug. They would prefer to purchase a new dress, a ticket to a movie, a dinner in a fine restaurant. Further, they are usually ill when the prescription is necessary. These factors combine to make prescription drugs unpopular and their prices even more unpopular. As a consequence, the prices of drugs are regularly publicly criticized. Sometimes the community pharmacist receives the complaint. At other times the industry as a whole is criticized. In this context there is no right price—only a "too high" price.

Obviously, if drugs are to continue to be produced by private industry there will have to be a charge for them. Regardless of whether they are paid for by the patient, by an insurance company, or by a government agency, it is part of the task of the marketing department to determine what that charge should be. In practice, not one price, but several prices will be set for a given product. The price per capsule for a given antibiotic might differ:

1. As sold in varying quantities;
2. As sold to the retailers;
3. As sold to the wholesaler;
4. As sold to hospitals;
5. As sold to physicians;
6. When sold in foreign countries.

There are many business reasons, some more valid than others, that go into the determination of the price. The marketing department would want to know, among other things:

1. Expected sales of the product;
2. Price of competing products;
3. Cost of research and development;
4. Nature of the market.

The Right Time

Availability of the drug product when it is needed is a further responsibility of marketing management, and is closely related to the place function. The injection must be available in the hospital emergency room when the patient is there, not several hours later.

There is another dimension to the timing problem that is also the responsibility of marketing. This is the determination of the optimal timing for the introduction of a new pharmaceutical product. Obviously, the time for the introduction of a safe, effective cure for any life-threatening condition is immediately. For other types of drugs the decision may not be so clear cut. The introduction of the oral contraceptive, for example, required a special social atmosphere which did not exist even ten years previously. A new product for the treatment of frostbite would not logically be presented during the summer months.

Spreading the Word

Even though marketing succeeds in its basic task, which we defined to include right product, quantity, place, price and time, it is still theoretically possible for the product to fail as a marketable item. The potential area of failure could be described broadly as communications. The part of the marketing communications process which may be most familiar to us is advertising. This is the most visible and perhaps most exciting form of communication. However, if marketing is performing efficiently, communication will be a two-way process.

The minimum amount of information that must be communicated by the manufacturer is the availability of a product. Obviously one does not purchase a product that he does not know exists. The physician is engaged in what the late Wroe Alderson called a "vicarious search," i.e., with a knowledge of the needs of his patient, he searches the characteristics of available products for the patient (who is not equipped to judge) for that which most closely approximates the answer to the patient's problem. Even though the physician is engaged in this relatively active and educated search process, there is a strong possibility that he will not become aware of a given product unless someone (usually, but not always, the manufacturer) has made a formal effort to communicate to him its availability.

We would not expect the producer of an expensively produced new product to limit his communication to a terse—"Utopiotic is now being marketed by Rhemstrand Pharmaceuticals." The marketer will wish to tell the doctor what it is that makes it worth his prescription. He will wish

to explain its proper use. For the patient's good, he will wish to point out the inherent dangers in the use of the product. Drugs have been described as a two-edged sword, with the benefits of therapy always offset to some degree by risk. No manufacturer should wish so strongly to sell his product that he might try to conceal the potential side effects of a drug.

Marketing and the Marketing Mix

We have now stated implicitly the components of pharmaceutical marketing as we see them. The explicit definition of marketing as adopted by The Board of Directors of the American Marketing Association is as follows:

"Marketing is the process of planning and executing the conception, pricing, promotion, and distribution of ideas, goods, and services to create exchanges that satisfy individual and organizational objectives" (*Marketing News*, 19:1, March 1, 1985).

Approaches to the explanation and study of marketing are varied. One such is that shown in Figure 1-1 which shows the flow of steps in the process used by IMS International in its first level training program in pharmaceutical marketing. Another is that provided by Pathak.

*MARKETING AS AN ACTUALIZING PROCESS**

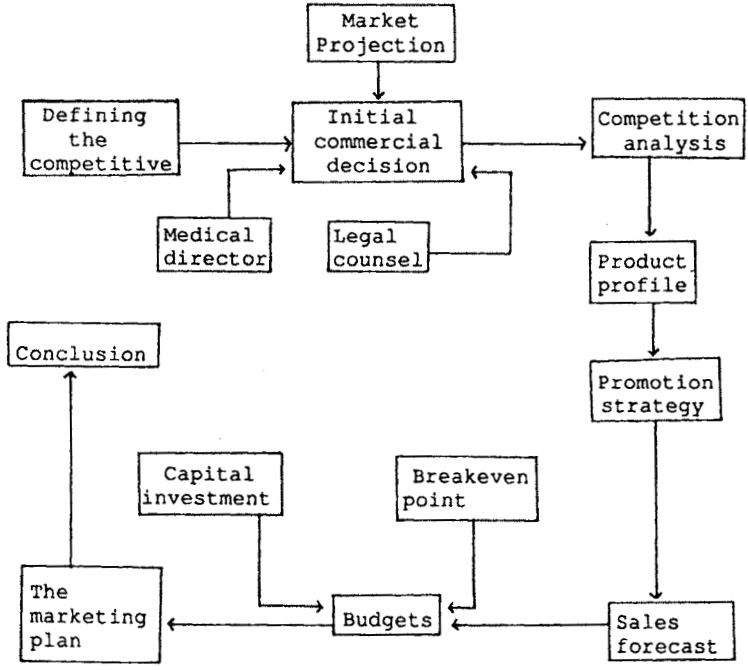
Pathak illuminates the discussion of marketing from the perspective that marketing is a process by which markets are actualized. Because markets may be viewed as gaps that separate parties interested in an exchange, marketing as a discipline is a study of how various gaps or separations between parties interested in an exchange are anticipated and removed. Consequently, the process of market actualization (Fig. 1-2) requires that various activities (called marketing activities) remove the gaps between parties interested in an exchange. Some of these points require careful examination.

The essence of marketing is exchange. The existence of a market is the foundation for an exchange and not a substitute for it. Every exchange requires that (1) there are two or more parties who (2) are interested in satisfying their unfulfilled desires, (3) have something of value to offer to each other, and (4) are capable of communication and delivery.

The process of market actualization may be initiated by either party

*This section adapted from materials written by Dr. Dev Pathak for *Principles of Pharmaceutical Marketing*, Third Edition.

FIGURE 1-1. A systematic approach to the marketing of ethical pharmaceutical products

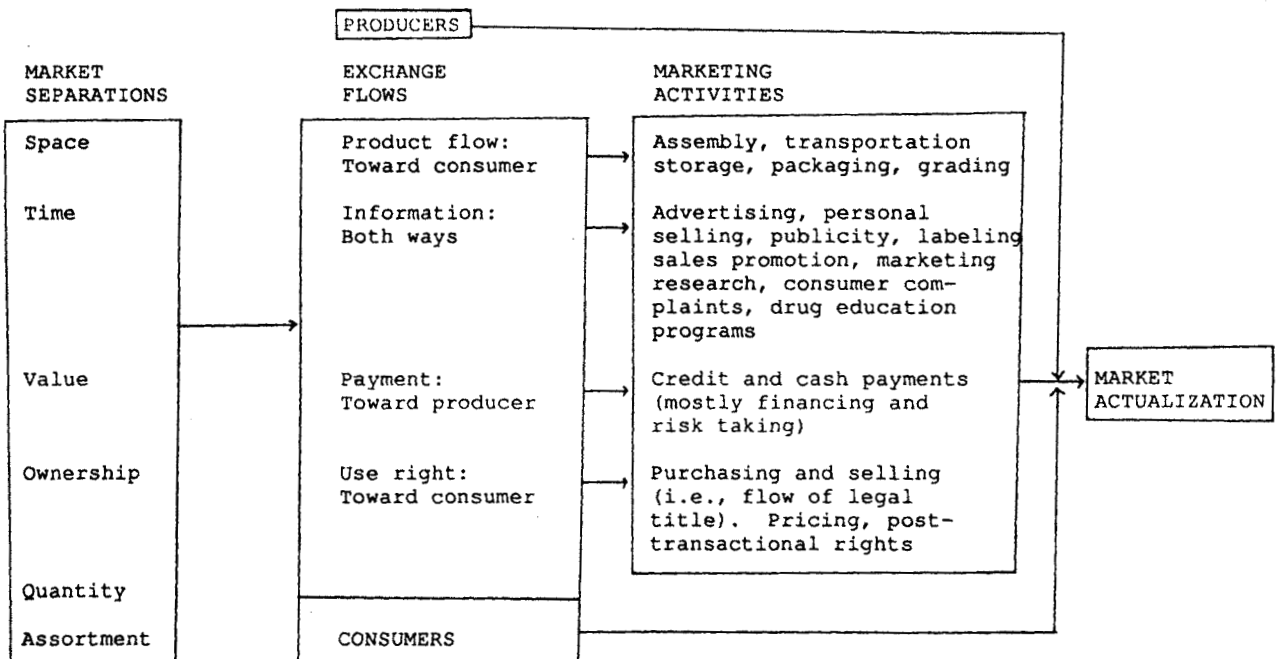


Source: Adapted from promotional brochure, System 100, IMS International, Management Development Systems.

interested in an exchange. In the normal economic sense, the party with goods is called a producer and the party with money is called a consumer. This is why markets, as defined from the producer's view, are viewed as people with money (purchasing power) and felt or quiescent need.

If the party interested in providing goods or services is labeled as a producer or seller, and the party interested in receiving and consuming goods or services is labeled as a buyer or consumer, we find that four major exchange flows (Fig. 1-2) occur in the process of market actualization: product flow, information flow, payment flow, and use right flow. Although the direction of product flow and use right flow is normally from producer to consumer, the direction of payment flow is toward the producer, and information flows both ways. Various activities, such as advertising, pricing, transportation, and marketing research, which are under-

FIGURE 1-2. The process of market actualization



Adapted from McInnis, W.: "A Conceptual Approach to Marketing, in *Theory in Marketing*, edited by R. Cox, W. Alderson, and S. J. Shapiro. Homewood, IL: Richard D. Irwin, 1964, p. 51; McCarthy, E. J.: *Basic Marketing*, 7th Ed., Homewood, IL: Richard D. Irwin, 1981, p. 20.

taken to identify the gaps between parties interested in an exchange and to facilitate the exchange are called marketing activities. Marketers are those individuals and institutions involved in anticipating and removing separations between parties interested in an exchange. Marketing activities may be undertaken by any party involved in the process of market actualization; one does not have to be a manufacturer to be involved in marketing.

Although most definitions of exchange and marketing revolve around dyadic or restricted exchanges (two-party reciprocal relationships), exchange relationships in modern society are becoming more complicated because of specialization due to division of labor, the use of money as a medium of exchange, and the increasing number of participants. Complex exchanges (a system of mutual relationships between at least three parties) and interactive exchanges are more commonplace in today's society, especially in the pharmaceutical marketplace. Figure 1-3 illustrates various types of exchanges in the pharmaceutical market. It is important to realize that while separations (gaps) between parties interested in exchanges are getting larger, the need for exchange makes them dependent on each other.

Pharmaceutical marketing, as a subspecialty of marketing, can be defined as a process by which market for pharmaceutical care is actualized. It encompasses all the activities carried out by various individuals or organizations to actualize markets for pharmaceutical care. Let us examine this definition closely.

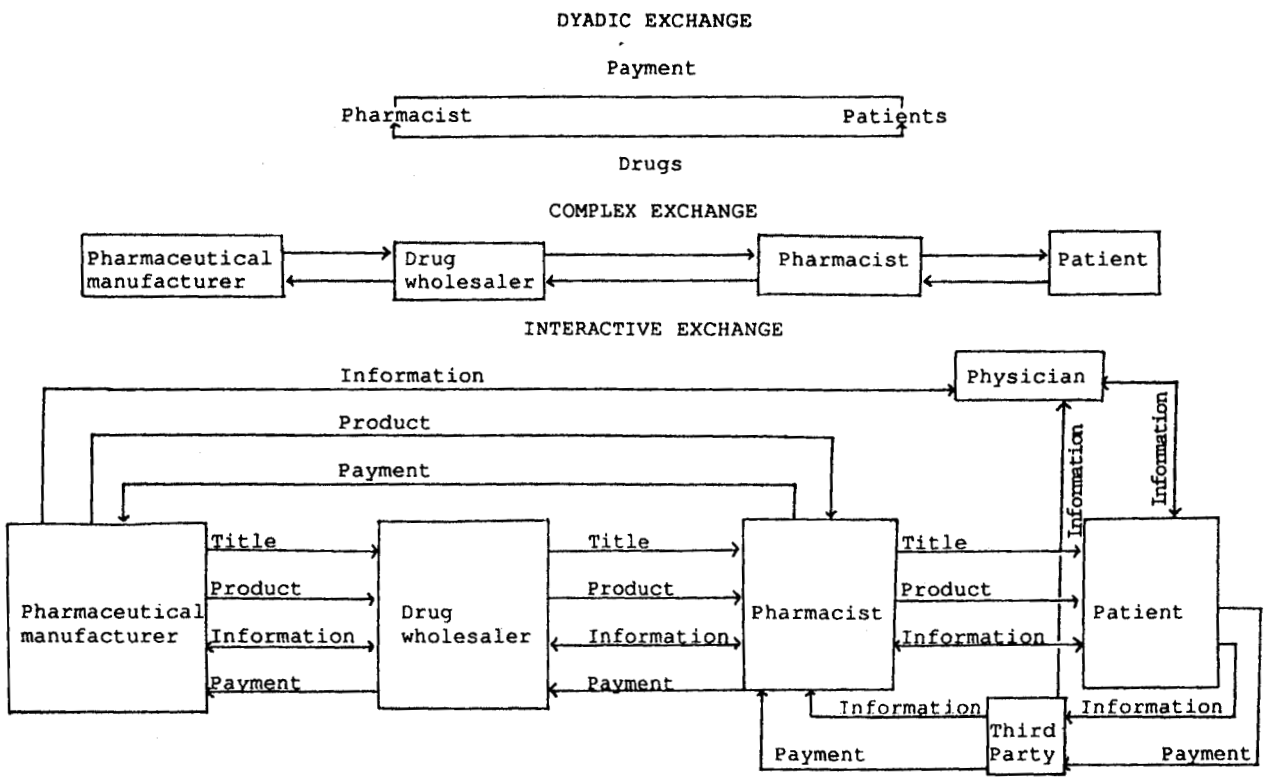
The emphasis in pharmaceutical marketing is on pharmaceutical care, and not just on drugs. Any article, service, or idea needed to anticipate and to remove gaps in pharmaceutical care should be included in the discussion of pharmaceutical marketing. The marketing of many clinical pharmaceutical services and programs is as much a part of pharmaceutical marketing as is the marketing of drug products. In other words, pharmaceutical marketing is not synonymous with, and is significantly broader than, the marketing of pharmaceuticals.

The emphasis in this definition is on pharmaceutical care, indicating that the justification for the existence of pharmaceutical marketing is the patient, and not the manufacturer or the pharmacist.

Any party interested in the exchange for pharmaceutical care may undertake pharmaceutical marketing activities. Hospital pharmacies, community pharmacies, third-party insurance companies, consulting pharmacies, and many other organizations and individuals, in addition to pharmaceutical manufacturers and drug wholesalers, are involved in pharmaceutical marketing.

Pharmaceutical marketing, as a field of investigation, is amoral or goal-

FIGURE 1-3. Examples of types of exchanges in the pharmaceutical market



free. The definition does not indicate any other goal than the process involved in completing the exchange for pharmaceutical care. Value judgments regarding efficiency or effectiveness of the pharmaceutical marketing system or any of its activities are not an inherent part of the study of the field.

The actualization of markets for pharmaceutical care indicates that all activities involved in anticipating, enlarging, facilitating, and completing or removing gaps in pharmaceutical care are within the scope of the field of pharmaceutical marketing. In other words, pharmaceutical marketing is not a static passive process but a dynamic active process.

If pharmaceutical marketing is viewed as a part of the health-care marketing system, it can be depicted as a simplified network of relationships between various institutions and their attributes, leading to actualization of markets for pharmaceutical care through exchange flows and marketing functions within the bounds established by external systems. This is depicted in Figure 1-4.

APPROACH USED IN THIS TEXT

In this book we will combine approaches to the discussion of pharmaceutical marketing, primarily from the producer's point of view. Following the presentation of some of the structural characteristics of the pharmaceutical industry, we will construct a marketing strategy structure on a framework consisting of the traditional "Four-P's" of marketing as well as a fifth "P" – Positioning.

The definitions we will use for the Marketing Mix components are as follow.

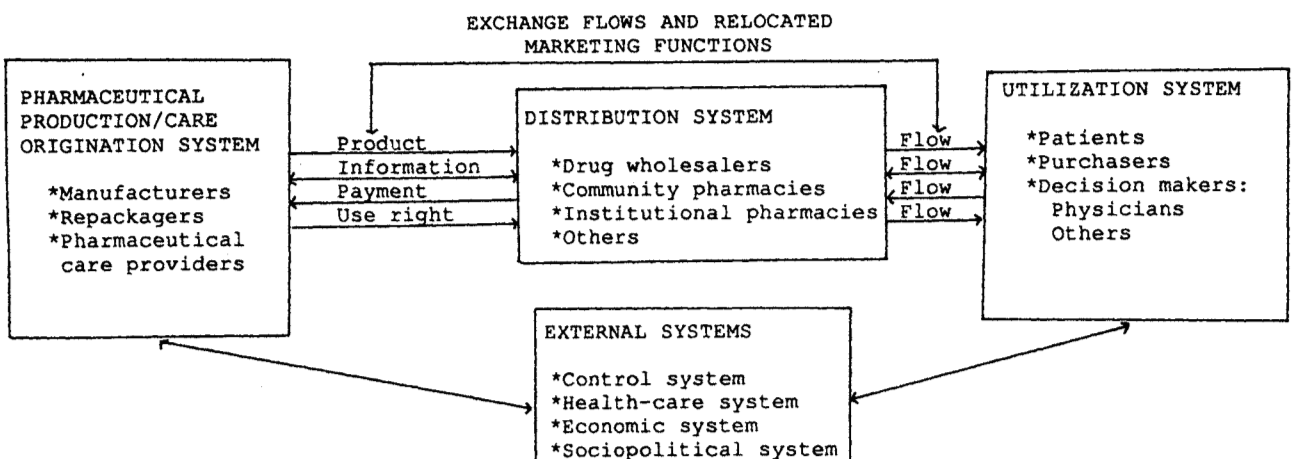
Product

The *benefits* or positive *results* that markets derive out of doing business with the company using the products you offer in the way you offer them.

Place

The distribution channels and physical distribution practices that make it possible, easy or difficult for markets to use the product.

FIGURE 1-4. Pharmaceutical marketing system



Price

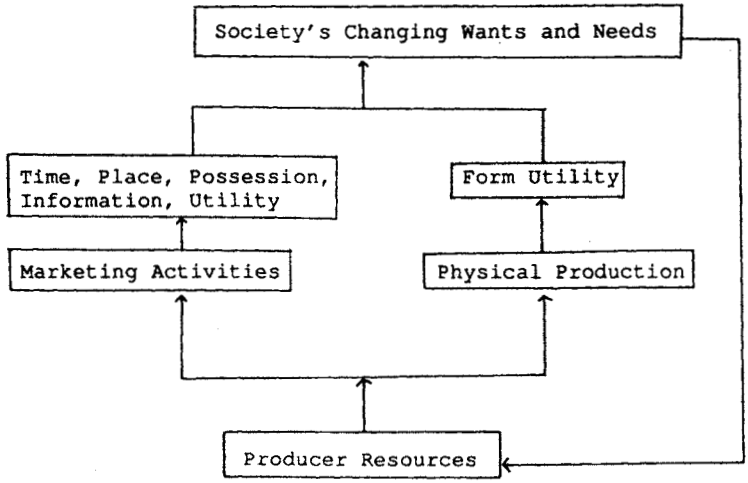
The total cost components that markets must bear in order to use the products offered.

Promotion

What and how markets are informed of the firm's product, place, price.

The interaction of these components makes up the marketing mix (Figure 1-5) and results in utilities for the consumer.

FIGURE 1-5. Meeting society's wants and needs through the marketing mix



Chapter 2

The Environment of Pharmaceutical Marketing

Organizations (and people) are creatures of their environment. Survival and all of its perspectives/resources, problems, and opportunities are generated and conditioned by the environment. Thus, it is important for an organization to monitor and predict the relevant changes taking place in the environment surrounding the organization and to formulate strategies to adapt to these changes.

But what is meant by environment? An international example is provided in a study by Maclayton and Smith (*Medical Marketing and Media*, February, 1981) who surveyed nearly 150 U.S.-based health care producers in an effort to identify environmental factors in decisions to enter foreign markets. Using factor analysis techniques to analyze responses from company executives, they identified five clusters of national environmental characteristics that were seriously considered prior to an international marketing decision. The authors named the factors:

- Market and Marketing Opportunity
- Legal Barriers and Their Economic Objectives
- Cultural Unity and Physiographic Barriers
- Political Stability
- Economic Development and Performance

Each of the factors consisted of anywhere from seven to thirteen statistics which grouped to form a related cluster for consideration. An example is the Economic Development and Performance Factor, which consists of the following items:

- Level of GNP
- Gross private domestic investment as percent of GNP
- Total energy consumption per capita
- Exports plus imports as percent of GNP

- Raw materials as percent of total exports
- Currency reserves (in U.S. dollars)
- Five-year trend in balance of payments.

Obviously, a company already operating in its home country (e.g., U.S.) does not have an option of deciding whether to enter that market. Nevertheless, these same kinds of environmental factors on the domestic front are critically important. (Indeed, the U.S. market might not fare too well on some of the measures listed).

Business derives its existence from the environment. Thus, it should monitor its environment constructively. To do so the business should scan the environment and incorporate the impact of environmental trends on the organization by reviewing the corporate strategy on a continual basis.

In this chapter environmental scanning includes six areas: technological, political, economic, social, and legal/regulatory. These are helpful divisions but it should be pointed out that they are not separate and unrelated. Social change typically leads to political and regulatory change. Political developments have economic sequelae. Technological revolutions may require changes in the delivery system. (See Figure 2-1).

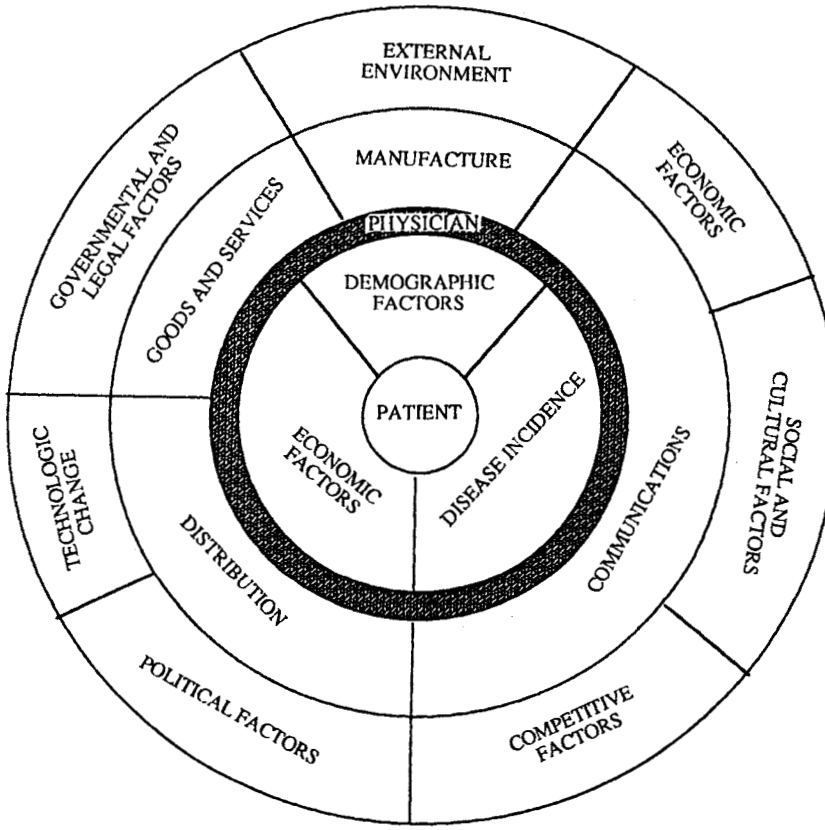
TECHNOLOGY ENVIRONMENT

The pharmaceutical industry lives and thrives because of technological advances in therapy. That is well understood. What should also be understood is that changes in technology outside the industry can and often do have a significant impact on pharmaceutical marketing practices. An example is the Medicare Outpatient Drug Program in the U.S., which, as proposed, would have been impossible without the computer technology to allow immediate verification of eligibility, deductible status, etc. The success of cable television made it possible to utilize a new sales/educational tool by bringing pharmaceutical programs into the physician's office or home.

Sometimes with and sometimes without the contributions of an industry, technology evolves which at least influences and at times transforms the character of that industry. Clearly, the pharmaceutical industry is technology based and it would be folly to attempt future planning without careful scanning of the environment and attempts to identify incipient technological developments.

As the pharmaceutical industry looks toward the twenty-first century there are some rather clear technological portents. In Bezold's *Pharmaceuticals in the Year 2000* (Institute for Alternative Futures, Washington,

FIGURE 2-1. The environment of pharmaceutical marketing



D.C., 1983) a number of important technologic possibilities were identified. They included the following.

- "Targeted" drugs which may not require liver metabolism or digestion
- Drug manufacture in space
- Breakthroughs in understanding of the immune system, probably accelerated by AIDS-related research
- Identification of greater numbers of neuropeptides with the potential effect of developing a new class of compounds to mimic natural brain chemicals

- Revolutions in contraception—perhaps a safe and effective pill for men—certainly improvements in predicting or isolating actual ovulation time
- Expansion of the use of monoclonal antibodies as treatment agents and as conveyors of drugs
- Innovations in drug delivery systems. Second- and third-generation patch technology, long term (weeks, months) release of chronic medications from implants and other devices
- Better understanding of dictating factors in the development and mediation of disease processes

It must be emphasized that the technologic environment is much broader than that within the drug industry itself. Consider, for example, the rapid growth, and the even greater potential, of laser technology in non-invasive surgery. Given the widespread use of antibiotics in the prophylaxis and treatment of surgery-related infection, what would be the effects of a rapid expansion of this kind of surgical procedure?

The marketing planner must mount a systematic technology scanning program to identify both potential problems and opportunities. In Bezold's book, James Turner advises the pharmaceutical industry to ask itself whether its business is chemicals or health. The answer will determine the relevance of some of the technologic environment. Spilker (*Multinational Drug Companies*, Raven Press, 1989) has elaborated on this issue, identifying nearly twenty potential businesses related to ethical pharmaceuticals:

- Cosmetics
- Contract Manufacture
- Pharmaceutical Distribution
- Specialty Chemicals
- Exercise Equipment
- Surgical Supplies
- Medical Devices
- Medical Supplies
- Health Foods
- Generic Drugs
- Over-the-Counter Drugs
- Diagnostics
- Pesticides
- Other Drug Products
- Bulk Chemicals, Dyes, and Pigments
- Animal Products
- Agricultural Products
- Bio-technology Products

POLITICAL ENVIRONMENT

In stable governments the political trends may not be as important as in countries where governments are weak. Yet even in stable countries political trends may have a significant impact on business. For example, in the

United States one can usually expect greater emphasis on social programs and an increase in government spending when Democrats are in power in the White House. The same is true for liberal governments in the United Kingdom.

More important, however, are the political trends overseas because the U.S. economy is intimately connected with the global economy. Therefore, what goes on in the political spheres of other countries (both free-market and state-controlled economies) may be significant for U.S. corporations, particularly the multinational corporations.

The following are examples of political trends and events affecting business planning and strategy:

1. The increase of geopolitical federations
   a. Economic interests: resource countries vs. consumer countries
   b. Political interests: third world vs. the rest
2. Rising nationalism vs. world federalism
   a. Failure of the United Nations
   b. Trend toward world government or world law system
3. Limited wars: Middle East, Russia-China; international conflict
4. Increase in political terrorism; revolutions
5. Third-party gains in the United States; rise of socialism
6. Decline of the major powers; rise of emerging nations (e.g., Brazil), shifting of power (e.g., Japan)
7. Rise in senior-citizen power in developed nations
8. Political turmoil threatening world oil supplies and peace in the Middle East
9. Revolutionary change in South Africa, limiting Western access to important minerals and threatening huge capital losses to the economies of Great Britain, the United States, and West Germany
10. Instability in other places where the economic consequences could be important, including Mexico, Turkey, Zaire, Nigeria, South Korea, Brazil, Chile, and the People's Republic of China. While the chances of any particular crisis occurring may be small, the odds that at least one or two shocks will occur may be rather high.

The marketing strategist needs to study both domestic and foreign political happenings, reviewing selected published information to keep in touch with political trends and interpret the information as it relates to the particular company. The types of information a multinational corporation may find useful to gather and review with reference to the political environment identified in the Maclayton/Smith study cited above were:

- Political stability of central government
- Type of government (dictatorship or parliamentary)
- Number of years since independence
- Existence of antibusiness pressure groups
- Direction of dominant political party
- Military or civilian government
- Major riots or insurrections in the past five years.

ECONOMIC ENVIRONMENT

Examples of economic trends and events affecting businesses include the following possibilities:

- Depression; worldwide economic collapse
- Increasing foreign ownership of U.S. economy
- Increasing regulation and management of national economies
- Several developing nations become superpowers (e.g., Brazil, China)
- World food production: Famine relief vs. holistic management
- Decline in real world growth; or stable growth
- Collapse of world monetary system
- Continuing high inflation
- Significant employee-union ownership of U.S. businesses
- Worldwide free trade

It is not unrealistic to say that all companies, small or large, engaged in strategic planning examine the economic environment. Relevant published information is usually gathered, analyzed, and interpreted for use in planning. In some corporations the entire process of dealing with economic information may be manual and intuitive. But several pharmaceutical companies have established full-blown pharmaceutical economics study groups.

An example of the response of pharmaceutical marketers to a major economic development is provided by the passage, in the U.S., of the 1983 Diagnosis Related Groups (DRG) Regulations, which limited the amount of reimbursement to hospitals by diagnosis. What would be the "trickle down" effect on the drug industry of this economic pressure on the hospitals?

According to a report in *Pharmaceutical Executive* (May, 1984), the leading firms set out to gather more information:

- They surveyed hospital administrators
- They tracked interval company sales data
- They conducted focus groups with hospital pharmacists
- They purchased syndicated market research studies

As a result of these information gathering (environment scanning) efforts, a variety of new or modified marketing practices emerged.

- New marketing targets (e.g., pharmacists) were identified.
- Sales training to prepare for group selling was initiated.
- Cost-effectiveness, cost-benefit studies were begun to support other promotional efforts on behalf of company products.
- New promotional materials emphasizing economic benefits were prepared.

CASES IN POINT

Medicare Outpatient Drugs

The Medicare outpatient drug benefit moved through Congress in 1987-1988 at the legislative equivalent of the speed of light. As a visible benefit for the elderly in an election year, it quickly got the support of the Democratic leadership. The Republicans, in turn, were not inclined to a protracted fight on the bill, providing the Democrats with a ready-made election issue. One of the prime Capitol proponents of the bill, in fact, was a Republican.

Although the ultimate legislative action on Medicare outpatient coverage was rapid, the process leading up to it was much slower. The final act can be viewed as the progeny of previous health care entitlements and prescription drug legislation.

The concept of adding an outpatient prescription drug benefit to the Medicare program goes back to 1967, when the Johnson Administration set up a task force to study the issue. That group issued a report supporting the addition of a drug benefit, a recommendation which was then seconded by a nongovernmental commission established to review the task force's work.

In the early 1970's Congress increased its focus on the drug industry. Senator Kennedy held a series of hearings which focused on drug prices to argue that the price differential between brand name drugs and generic products was not justified by quality concerns.

In this atmosphere, the Department of Health and Human Services began to look at ways to reduce costs, and the prescription drug reimburse-

ment system was one area singled out for reform. The result was the Maximum Allowable Cost/Estimated Acquisition Cost (MAC) program, which incorporated the basic ideas contained in the task force report prepared for HEW in the late 1960's. The basic cost control element of the program was reimbursement limits for individual drugs, encouraging the dispensing of lower cost generic equivalents in place of brand name products.

A major change in the pharmaceutical environment since the advent of MAC in 1977 has been the explosive growth in the availability of generic products. That change was brought about legislatively in 1984 with the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984. (See below.)

The Waxman/Hatch Act, as it is known in recognition of the two principle sponsors, contained two major sections which together represented the most significant piece of legislation affecting the drug industry since the 1962 effectiveness amendments were added to the FD&C Act.

Under Title I of the Waxman/Hatch Act, Congress established a procedure to extend the patent terms for pharmaceutical products meeting specified eligibility criteria. The purpose of extending the patents of some new pharmaceutical products beyond the standard 17 year period was to compensate research based firms for the patent time lost during premarket approval process at FDA.

The second section of the Waxman/Hatch Act is more significant in relation to the coverage of outpatient drugs under Medicare. In Title II of the Waxman/Hatch Act, Congress authorized procedures for FDA for the first time to review and approve generic versions of prescription drugs first approved after 1962 when the effectiveness amendments were added to the FD&C Act.

Title II of the Waxman-Hatch Act immediately and dramatically expanded the multi-source drug marketplace so that it now includes many of the most commonly prescribed drugs. In some ways, the inclusion of a Medicare outpatient drug reimbursement system is merely an extension of the Waxman Act. Federal reimbursement of outpatient drugs on a scale proposed by the Medicare Catastrophic coverage Act would simply be unaffordable without the existence of the large pool of multisource drugs which developed as a result of the Waxman-Hatch Act.

Source: *F-D-C Reports* (By early 1989, only a few months after the election, many members of Congress were "discovering" that they had voted for the Bill without a full appreciation for its potential cost.)

Mifepristone

Mifepristone is an antiprogesterone abortifacient with an interesting story.

First the compound was approved for marketing in France. Then the company announced it would not market the drug because of intense pressure from French anti-abortion groups. Finally, the French government ordered Roussel to market the compound, thereby calling attention to the government's power to withdraw one company's product license and offer it to another.

So Roussel capitulated, and the company's vice president, Pierre Joly, declared, "We have thrown off what for us had become a moral burden . . . It was not up to us to come between those who are in favor of abortion and those who are against." In short, he welcomed the government's action in solving the company's ethical and political dilemma. During the few years of a compound's existence, U.S. companies have shown a conspicuous lack of interest in bringing mifepristone onto the American market. An important ramification of the controversy is that manufacturers have no incentive to investigate applications of RU 486 that are not related to abortion. Any attempt by a company to market the drug for an alternate indication would still draw the same response from right-to-life groups.

Although its ability to terminate pregnancy has received the most attention, RU 486 has other potential important indications. Studies on the use of RU 486 as a contraceptive have shown it to inhibit ovulation and prevent implantation, two well-described mechanisms of steroid agonist contraceptives. It has been shown to inhibit in vitro the growth of progesterone-dependent tumor cells from the breast and pituitary gland.

The usefulness of this drug in the therapy of minor gynecological and obstetric problems is just now starting to be explored. It may be helpful in the treatment of premenstrual symptoms, postmenopausal symptoms, and delayed lactation after delivery. Ironically, RU 486 has even shown promise in the treatment of endometriosis – the third leading cause of infertility in the United States.

The opponents of RU 486 in the U.S. have succeeded in suppressing manufacturer interest in and media coverage of this first member of a new pharmacological class of drugs.

Source: *Pharmaceutical Executive*, January, 1989 and *American Journal of Hospital Pharmacy*, January, 1989.

LEGAL/REGULATORY ENVIRONMENT

The Thalidomide tragedy of the early 1960's may have been the single most important event in the history of the pharmaceutical industry insofar as the legal/regulatory environment is concerned. Certainly, it played a key role in the subsequent strengthening of the F.D.A. regulatory powers in the U.S. and definitely was the most important factor leading to the passage of the 1962 Drug Amendments.

The *indirect* effects of the Thalidomide incident may have been even greater. It served to remind the world public of the dangers associated with medication after the heady atmosphere of the therapeutic explosion of the 1950's. It also brought into public view the courtroom battles over company liability . . . and kept the light of publicity there for years. There had been drug liability headlines before (Chloromycetin, MER-29), but nothing as protracted and widespread. Finally, the Thalidomide situation attracted the attention of primalistic muckrakers and self-appointed industry watch dogs who have since been unrelenting in their scrutiny and criticism of drug industry practices.

The legal and regulatory issues, perhaps as much as or more than any of the other environmental factors must be assessed as part of the strategic marketing process.

In the United States, as in many countries, the legislation is often only the beginning of the control process, with the regulations becoming the rule book of day-to-day operations. Drug law and regulation in the U.S. began in 1848 with the Import Drugs Act, the first federal statute to ensure the quality of drugs, in this case the quinine used by American troops in Mexico.

Modern day legislation and regulation (supported and modified by court decisions) can be traced from the 1938 Federal Food, Drug and Cosmetics Act (FDCA) which contained the following provisions.

- Extended coverage to cosmetics and devices.
- Required redistribution clearance for safety of new drugs that an approved New Drug Application (NDA) was mandated before a manufacturer could commercially distribute a new drug.
- Eliminated Shirley Amendment requirement to prove intent to defraud in drug misbranding cases.
- Provided for tolerances for unavoidable poisonous substances.
- Authorized standards of identity, quality, and fill of container for foods.

- Authorized factory inspections.
- Added the remedy of court injunction to previous remedies of seizure and prosecution.

Other important legal/regulatory milestones since that legislation are presented below.

1943

The U.S. Supreme Court ruled that the FDCA authorized the Administrator to use his judgment, based on "substantial evidence," to promulgate definitions and standards of identity for certain products where truthful labeling is not adequate to maintain their integrity.

1945

The FDCA was amended on June 6th to require certification of the safety and efficacy of penicillin because of the uncertainties in production technologies experienced by the early penicillin manufacturers. Subsequent amendments which became effective in 1963 extended certification to any other antibiotic drug or any derivative thereof.

1950

The U.S. Court of Appeals held that the directions for use on a drug label must include the purpose for which the drug is offered. Therefore, a worthless remedy cannot escape the FDC Act by not stating the condition the drug is supposed to treat.

1951

The Durham-Humphrey Amendment to the FDCA specifically required that drugs which cannot be safely used without medical supervision must be dispensed only by prescription of a licensed practitioner, and prohibits refills of prescriptions without the express consent of the prescriber.

1962

News reports on the role of Dr. Frances O. Kelsey, FDA Medical Officer, in keeping thalidomide off the American market aroused public inter-

est in drug regulation. The drug had been associated with the birth of thousands of malformed babies (phocomelia) in western Europe.

The Kefauver-Harris Drug Amendment to the FDCA passed October 10th to assure a greater degree of safety and to strengthen new drug clearance procedures. For the first time, drug manufacturers were required to prove to FDA the effectiveness of their products before marketing them. In addition, the Amendments:

- Transferred jurisdiction over medical advertising of prescription products from the FTC to FDA;
- Extended FDA's inspection authority over establishments in which Rx drugs are manufactured, processed, packed, or held to include records, files, papers, controls, and facilities;
- Required that facilities, methods, and control procedures used by manufacturers to conform to "current good manufacturing practices";
- Established "full disclosure" under which the most vital, up-to-date and reliable information about an Rx drug was required in its labeling, in the form of a package insert;
- Added more extensive control for clinical investigations by strengthening FDA's authority governing human testing of new drugs.

1965

The Drug Abuse Control Amendments were enacted to deal with problems caused by abuse of three groups of dangerous drugs: depressants, stimulants, and hallucinogens.

1966

FDA contracted with the National Academy of Sciences/National Research Council to evaluate the effectiveness of 4,000 drugs approved on the basis of safety alone between 1938 and 1962.

1968

FDA Bureau of Drug Abuse Control was transferred to the new Bureau of Narcotics and Dangerous Drugs (BNDD) in Department of Justice, to consolidate policing of illegal drug traffic.

1970

The U.S. Court of Appeals made possible the enforcement of the 1962 Drug Effectiveness Amendments by holding that commercial success of a drug alone does not constitute substantial evidence of safety and efficacy, and that hearings will be held only if issues of fact exist.

The Drug Abuse Control Amendments of 1965 were repealed with the enactment of the Comprehensive Drug Abuse Prevention and Control Act of 1970. BNDD became the Drug Enforcement Administration (DEA).

The Poison Prevention Packaging Act became effective December 30th. Its basic purpose was to provide special packaging to protect children from serious personal injury or illness that could result from handling, using, or ingesting certain toxic or harmful household substances and certain OTC and Rx drug products.

1972

FDA embarked on a long-range regulatory program to apply the Drug Efficacy Amendments to drugs sold over-the-counter (OTC Drug Review).

1973

The Supreme Court upheld FDA in four drug effectiveness cases and gave the FDA a new charter to control entire classes of products by regulations rather than through time-consuming litigation. The Court held that enforcement limited to acting case-by-case against individual products is "inherently unfair because it requires compliance by one manufacturer while his competitors marketing similar products remain free to violate the Act."

1983

The Orphan Drug Act amended the FDCA to provide incentives for manufacturers to develop and market drugs or biological products intended for a rare disease or medical condition occurring in the United States. Products are termed "orphans" because commercial markets sufficient to cover the cost of development do not exist.

The Federal Anti-Tampering Act amended the U.S. Code to establish

penalties for threatening to tamper or tampering with an article subject to the FDCA in a manner to create a risk of death or bodily injury.

1984

The Drug Price Competition and Patent Act (Waxman-Hatch Amendments) was signed into law on September 24th. There are two titles which concern new drugs. Title I, which amended Section 505 of the Federal Food, Drug, and Cosmetic Act, codifies FDA's authority to accept abbreviated new drug applications (ANDAs) for generic versions of drug products first approved after 1962. Prior to Title I, ANDAs were only permitted under FDA regulations for generic versions of drug products first approved between 1938 and 1962. (The FDA can approve ANDAs for drugs without the submission of safety and effectiveness data if they are generically equivalent to brand name drugs already proved to be safe and effective.) Title II requires FDA's involvement in the process to allow holders of patents for drugs, biologics, medical devices, food, and color additives to obtain up to five years of patent life lost during FDA's regulatory review of a product. (Patent protection ordinarily lasts 17 years, but some of this time is often lost while products are evaluated prior to approval. Title II permits up to five years of this time to be restored but limits the total time to no more than 14 years.)

The chronicle just presented reflects an ever-changing legal/regulatory environment, which, in turn, reflects changes in social, economic, technological, and political environments. This comment having been made, it may be well to examine the interaction between two environmental sectors.

ECONOMIC EFFECTS OF REGULATION

An excellent example of the interaction of environmental factors is that between the regulatory and the economic environments. Douglas Cocks, one of the pharmaceutical industry's most respected economists, has provided a cogent analysis of these relationships.*

*This section adapted from the Third Edition of *Principles of Pharmaceutical Marketing*. It was written by Douglas Cocks. References appear in the original version.

Supply Side Regulation

There are two main economic effects of regulation. One category can be described as the economic effects of supply side regulation. The studies that have considered this aspect attempted to determine the economic impact of the regulation associated with the Food and Drug Administration (FDA). There have been several studies that attempted to assess the effects of the 1962 Drug Amendments to the 1938 Federal Food, Drug, and Cosmetic Act. The general conclusion to be drawn from these studies is that the 1962 Drug Amendments had a significant negative impact on the research and development productivity of pharmaceutical firms.

The studies concentrated on pharmaceutical firms and the industry. Sam Peltzman attempted to assess the effects of FDA regulation—again primarily the 1962 Drug Amendments—on consumers. It has been estimated that the value of reduced innovation for consumers costs $300 million to $400 million annually.

Duke University Professors of Economics Henry G. Grabowski and John M. Vernon have provided further analyses of the impact of regulation on the economics of the industry. A principal finding of their research is that the generation of innovative new products is becoming more highly concentrated in large multinational pharmaceutical firms. Grabowski has also found evidence that new drugs are generally introduced in foreign markets much sooner than they are in the United States. This is known as the "drug lag" which was first identified and measured by Louis Lasagna and William Wardell.

An important reason for these phenomena is the sheer cost of introducing new drug innovations—new single chemical entities. Hansen estimated that the cost of innovating and developing a new single chemical entity was in excess of $50 million in 1976 dollars. This cost determination incorporates an assessment of direct dollar outlays, a normal return on investment, and inflation. In 1987 a PMA report estimated this cost to be around $125 million.

In addition to the supply side regulation associated with the FDA, there are other regulatory agencies that affect the operation of pharmaceutical firms. An important economic aspect of this type of regulation is its social opportunity cost—that is, what society gives up for the kinds of regulation that are in effect. Something that may be given up is productivity improvement, as concluded by a large United States pharmaceutical firm. It was determined that, if the excessive regulation from just seven federal agencies could have been eliminated in one year, that firm's rate of productivity improvement in that year would have been twice what it was. Of

course, the FDA was by far the major contributor to this negative productivity effect.

It is important to note that this assessment of regulatory impact was not based on the elimination of the goals of regulation, but rather was based on the assumption that the goals could be achieved differently from the way mandated by the federal agencies. It was assumed that firms could achieve these goals if left to their own devices.

Another manifestation of supply side drug regulation is the impact on effective patent lives. United States patent law grants a 17-year period of exclusivity to unduplicated pharmaceutical agents. With pharmaceuticals, a patent is generally applied for when the compound is discovered. Subsequent to this, the compound must be tested and must adhere to all the FDA regulatory requirements contained in the IND (investigational new drug) and NDA (new drug application) processes. Because the FDA regulatory process must be completed before a new drug can be marketed, the effective patent life is shortened. The longer the regulatory process, the shorter the patent life. Some relief has been achieved from the Waxman-Hatch Act.

Demand Side Regulation

The study of the effects of demand side regulation has not been as comprehensive as that of the supply side, both because the effects of such regulation are much more subtle and because the data to study demand side consequences are not as readily available. In order to address the effects of demand side regulation, it is necessary to put into context the way in which this type of regulation may affect pharmaceutical firms, especially research and development-intensive firms. The overall context in which to view this type of regulation is how it affects the cash flows and the expectations of cash flows of firms. Because the major source of funds for research and development-intensive pharmaceutical firms is from internally generated cash flows, this type of regulation is very important.

Demand side regulation is not as monolithic as supply side regulation in that it is not as focused on one agency or activity, such as the FDA. Examples of demand side regulations include the efforts to repeal states' antisubstitution laws, policies to limit reimbursement under public assistance programs (the Maximum Allowable Cost program for Medicaid is an example), formularies, and the various efforts to increase use of generic drugs.

These types of regulation are demand side regulation because they are public policies designed to constrain the use of certain manufacturers' products and the prices that can be charged for these products. There is a

direct logic chain from increased regulation to increased costs for firms to a reduction in new innovations. To understand the impact of demand side regulation it is necessary to understand the implications of the internal markets that were discussed previously, as well as the importance of cash flows as the primary source of pharmaceutical research and development funding.

John Virts has identified one of the most significant aspects of demand side regulation in the pharmaceutical industry, the fact that many of the effects of this type of regulation are long run in nature. It may be possible to show short-term benefits from these policies but, when the long-term effects are taken into account, the policies may not be beneficial. The primary long-term effect would be the reduction in innovation. The logic flow here is that a reduction in cash flows reduces the amount of funds available for research and development, and reduced research and development lead to fewer new single chemical entities, thus reducing the potential for price competition.

CASE IN POINT

The United States, as well as Germany (FRG) and Canada, are the few remaining major states that retain a free market environment. However, Canada's compulsory licensing policy has in reality mooted free pricing. When dealing with a free market economy the regulatory strategies aimed at achieving expeditious approval will probably be most productive in returning the R&D investment. For most countries of the developed world technical regulatory approval is followed by pricing approval and/or incorporation into a reimbursement list (either a positive or negative list). In these countries the regulatory strategy should include emphasis on demonstrating an advantage over existing therapies to support a higher price. In Scandinavian countries, Norway most notably, even technical approval may be dependent on a demonstration of increased benefit of the NCE over existing therapies. This could be either improved therapeutic benefit or increased cost-effectiveness of the new medicine. In other European states the negotiation of a reimbursement price for an NCE will be dependent on demonstration of its relative therapeutic benefit to current medications, its cost-effectiveness, and in some cases the timing of price negotiation (relative to pricing in another state or entry to market of a new competitor). To avoid manipulation of price based on costs, a draft European Commission Directive on Pricing transparency would authorize member states to know the cost basis for products made in one state and passed on to another.

Source: William H. Hubregs, *Drug Information Journal*, (Vol. 22, #3, 1988).

SOCIAL ENVIRONMENT

The ultimate test of a business is its social relevance. As we saw in the previous chapter, the drug industry is as socially relevant as any, but social relevance is especially significant from a marketing point of view when a society's survival needs have already been met. While much of the activity of the pharmaceutical industry continues to focus on survival, even in the most developed countries, some prescription drugs (Rogaine, oral contraceptives) have appeared which go beyond survival needs.

It behooves the strategic planner to be familiar with emerging social trends and concerns. The relevance of the social environment to a particular business will of course vary depending on the nature of the business. For a medical products company, however, the impact of the social environment cannot be overemphasized.

An important aspect of the business environment is the values people hold. In recent years changes in these values have stimulated massive regulations, deep criticisms, new demands, and challenges of the very foundation on which business rests. For example, a substantial percentage of people in the United States are less and less willing to accept the impartial operation of the market mechanism as the best way to allocate resources. They expect government to intervene in their behalf. Equality had meant that conditions should permit individuals, whatever their origins, to make a life on the basis of ability and character. It was believed that everyone should have an equal place at the starting line. More recently the emphasis has shifted to the finish line, a guarantee of an equal outcome for all—all of this is a part of the continuing debate over the right to health care which continues in the U.S.

Information on social trends may be derived from published sources. The impact of social trends on a particular business can be studied in-house or with the help of outside consultants. Books such as *Megatrends* help in a general way but specific applications to the company and its products are essential. Simply rereading and analyzing news reports can help.

In an article in *Pharmaceutical Executive* (May, 1988) Jeff Larsen and Dee Miller Prince described the way the better educated consumer would result in expansion of opportunities in the OTC marketplace. They projected this progression:

PAST	↓ Passive Patient
	↓ Active Consumer
	↓ Consumer Attitudes Toward Health
FUTURE	↓ Competitive Activities/New Entrants
	↓ Social Policy Realities
	↓ Regulatory Change
	↓ New Products
	↓ Increased Demand for OTC Products

Negative news items, too, can help interpret the environment. An example was reported in *Medical Advertising News* (November, 1988). It was a story with a "Halcion Madness" banner that was printed on the cover of *California* magazine. To help sell this September issue, the magazine's publisher took out ads in *The New York Times* and *Advertising Age*.

Entitled "Halcion Nightmare," the piece is intended to offer the "frightening truth" about America's favorite sleeping pill. The author, an independent writer, describes her continuing descent into anxiety, depression, and suicidal tendencies and tags Halcion as the cause. She cites (many cases and sources reporting adverse reactions caused by Halcion and intimates) that problems with the brand are much more common than Upjohn's literature indicates.

Even with the knowledge it was given unfair treatment, what Upjohn did (passively deny the problem) is about all any company can do, say the experts. Sometimes they are favorable stories, detailing the miracles of wonder drugs. When they are unfavorable stories, pointing to adverse reactions, company officials have the difficulty of deciding how to counter the negative publicity.

The key is whether or not company officials *know in advance* about the story. If they do, industry experts suggest that the company provide as much information as possible. Even if the story is going to be negative, the writer will have access to correct information – and may even view the drug more kindly, leading to fairer coverage.

According to public relations experts, this can happen to any company. In fact, the more popular the drug is, the better the chance for something sensational being printed or aired. It stands to reason that as more people take the drug, the higher the chances are of adverse reactions and unfavorable stories about them.

An interesting phenomenon with consumers is that even a negative article may bring favorable attention to a drug. People who may have never heard of the drug may go ask their doctors for it because they think this may be the one that finally works for them. Another interesting point made by the experts is that today's consumers are sophisticated; they may

have sympathy for the writer, but know that anybody can have an adverse reaction to anything.

CASES IN POINT

In 1988 Merck introduced its cholesterol-lowering agent, Mevacor, into the United States. The year before in an effort to show that high levels of cholesterol can be reduced without forfeiting taste, Merck hired seven prestigious New York chefs to prepare a low-cholesterol haute cuisine luncheon for the food press at The Pierre hotel in Manhattan. The spectacular dishes were cooked up by Brendan Walsh of Arizona 206, Gerard Pangaud of Aurora, Gary Coyle of La Cote Basque, Gilbert Le Coze of Le Bernardin, Andrea Da Merano of Palio, Georges Masraff of Tavern on the Green and Josefina Howard of Rosa Mexicano. Each dish averaged fewer than 50 milligrams of cholesterol, but the sumptuous array proved that sound nutrition needn't be tasteless. (Reported in Bon Appetit, October, 1987)

It would have been very difficult for Searle to gain social approval for the marketing of Enovid as a contraceptive ten years earlier. The "sexual revolution," Playboy, and other factors combined to make it feasible. By 1989 Lilly was well along in its clinical testing of a drug, quinelorane, for sexual dysfunction. Without the work of Masters/Johnson one wonders if Lilly would ever have been able to enroll 3,000 in clinical trials.

CONCLUSION

The impact of successful environmental scanning on marketing planning and strategy can hardly be overemphasized. The comparatively recent increase in importance of organized health plans in the U.S., particularly HMOs, has altered the environment of health care delivery, for example. This environmental change is, in turn, causing shifts in company marketing practices.

In the September, 1987 issue of *Pharmaceutical Executive*, Joel Tau listed some of the ways in which companies are altering their marketing practices to adapt to change.

- *Market research* is being asked to identify and describe new drug purchase decision makers.
- *Sales forces* are expected to decrease in size but increase in sophistication and specialization.

- *Pricing strategies* may require modification to respond to pressure from larger, more powerful buyers.
- *Cost-effectiveness and quality of life studies* will be needed to provide *non*-price competitive advantages.
- *Value added* in terms of such services as education materials may take on added importance.
- *Research and development* targets may change in response to evolving market needs.

There is no shortage of environmental signals to analyze.

- In 1988, for the first time in history, pharmaceuticals registered a negative balance of trade for the United States.
- Pharmaceutical trade and research and development exchange with the vast Soviet Union is being publicly discussed.
- The elderly population is growing in number, age, and political influence as well as drug use.
- Entire new classes of therapeutic agents are emerging.
- Therapeutic substitution grows in the hospitals.

The list could go on. Which are significant to the industry as a whole? Which are significant to an individual firm or product? The answers to such questions require macro market research and analysis.

Chapter 3

The Pharmaceutical Industry: Institutions and Characteristics

To outperform competitors and to grow despite them, a company must understand why competition prevails, why firms attack, and how firms respond. Insights into competitors' perspectives can be gained by undertaking two types of analysis: industry and competitive. Industry analysis assesses the attractiveness of a market based on its economic structure. Competitive analysis indicates how every firm in a particular market is likely to perform given the structure of the industry.

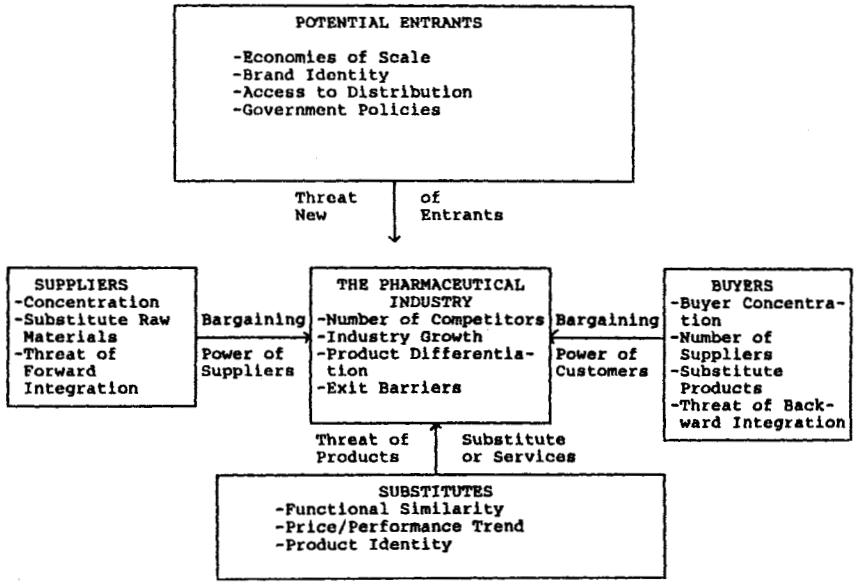
Every industry has a few peculiar characteristics. These characteristics are bound by time and thus are subject to change. We may call them the dynamics of the industry. No matter how hard a company tries, if it fails to fit into the dynamics of the industry, ultimate success may be difficult to achieve.

To formulate marketing strategy, a company should determine the relevance of each of the competitive factors in its industry and the position it occupies with respect to competitors. An attempt should be made to highlight the dynamics of the company in the industry environment.

There are many approaches to the analysis of an industry. One is Porter's "Five-Factor" model (Michael E. Porter, *Competitive Strategy*, New York, The Free Press, 1980). Although this model is not perfectly adaptable to the pharmaceutical industry, it does provide a convenient framework for a discussion of several pharmaceutical industry institutions and characteristics.

As shown in this model (Figure 3-1), the degree of rivalry among different firms is a function of the number of competitors, industry growth, product differentiation, and exit barriers. Among these variables, the number of competitors and industry growth are the most influential. Further, industries with high fixed costs tend to be more competitive since the competing firms are forced to cut price to enable them to operate at capacity. Differentiation, both real and perceived, among the competing offer-

FIGURE 3-1. Porter's Model of Competition (adapted)



ings, however, lessens rivalry. Finally, difficulty of exit from an industry intensifies competition.

Threat of entry into the industry by new firms is likely to enhance competition. There are, however, several barriers that make it difficult to seek entry into an industry. There are three cost-related entry barriers: economies of scale, absolute cost advantage, and research and development costs. Economies of scale require potential entrants either to establish high levels of production or to accept a cost disadvantage. Absolute cost advantage is enjoyed by firms with proprietary technology or favorable access to raw materials and by firms with production experience. In addition, high capital requirements, limited access to distribution channels, and government policy can act as entry barriers.

Substitute products that serve essentially the same function as the industry products are another source of competition. Since substitute products place a ceiling on the prices that firms can charge, they affect the industry potential. The threat posed by a substitute also depends on its long-term price/performance trend relative to the industry's product.

Bargaining power of buyers refers to the ability of the industry's customers to force the industry to reduce prices or increase features, thus

bidding away profits. Buyers gain power when they have choices—when their needs can be met by a substitute product or the same product offered by another supplier. In addition, high buyer concentration, the threat of backward integration, and low switching costs add to buyer power.

Bargaining power of suppliers is the degree to which suppliers of the industry's raw materials have the ability to force the industry to accept higher prices or reduced service, thus affecting the profits. The factors influencing supplier power are the same as those influencing buyer power. In this case, however, industry members act as buyers.

These five forces of competition interact to determine the characteristics and the attractiveness of an industry. The strongest forces become dominant in determining profitability and become the focal points of strategy formulation.

A firm should first diagnose the forces affecting competition in the industry and their underlying causes and then identify its own strengths and weaknesses relative to the industry. Finally, the firm should formulate its strategy, which amounts to taking offensive or defensive action in order to achieve a secure position against the five competitive forces. According to Porter this involves:

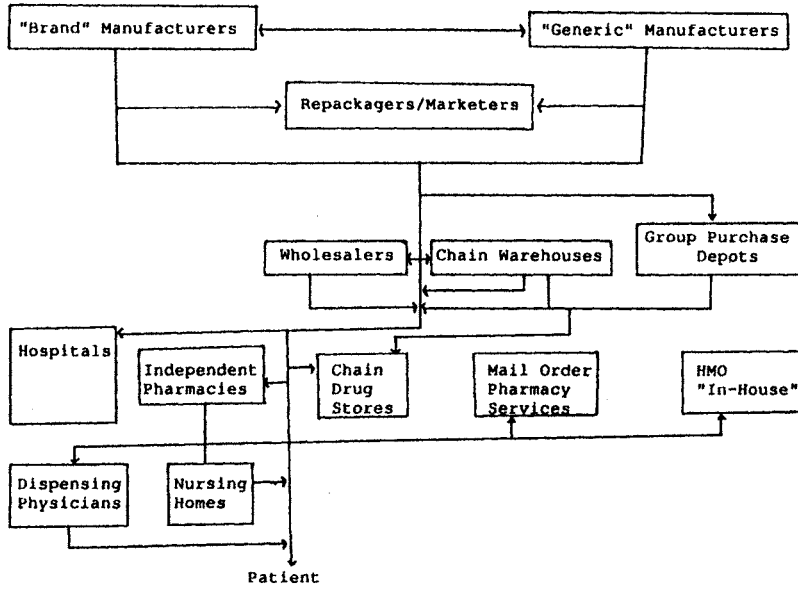
- Positioning the firm so that its capabilities provide the best defense against the existing array of competitive forces;
- Influencing the balance of forces through strategic moves, thereby improving the firm's relative position; or
- Anticipating shifts in the factors underlying the forces and responding to them, hopefully exploiting change by choosing a strategy appropriate to the new competitive balance before rivals recognize it.

As we review the institutions and activities within the pharmaceutical industry we will see that some components of the model exert much stronger influence than do others.

THE PHARMACEUTICAL INDUSTRY

Broadly speaking, the pharmaceutical industry would include all those institutions and agencies involved in the production and marketing of medications. For our purposes here, and because it fits Porter's Model, we will discuss the "pharmaceutical industry" in terms of those firms engaged in the manufacture of pharmaceuticals. Nevertheless, as Figure 3-2 illustrates, prescription drug distribution channels involve many different types of marketing institutions.

FIGURE 3-2. Prescription drug channels



Who are the drug manufacturers? We should note the following:

1. Companies engaged in the manufacture of pharmaceuticals constitute only a part of what the media likes to refer to as the "drug industry."
2. The manufacture of drugs is only part of the business of many corporations.
3. Many companies whose main business is the manufacture of drugs have many other businesses as well.
4. Many companies who market drugs do not manufacture them.

The U. S. Pharmaceutical Industry

Perhaps the best, although still incomplete, view of the U.S. prescription drug manufacturing industry can be obtained from statistics compiled by the Pharmaceutical Manufacturers Association (PMA). In this section we will present data dealing with the members of that association taken from PMA publications. Such publications are issued regularly, and the reader is urged to refer to current editions for updated information.

The Pharmaceutical Manufacturers Association is a nonprofit scientific,

professional, and trade organization. Its active membership is comprised of approximately 150 firms that are principally engaged in the manufacture of prescription pharmaceutical, medical device, and diagnostic products. The manufacturers promote these products primarily to health practitioners licensed by law to prescribe, administer, and dispense them.

Table 3-1 presents a picture of the sales pattern of ethical pharmaceuticals by the industry, both for the United States and worldwide. The picture is one of steady increases in both areas by a multibillion dollar industry. This industry is justly proud of the research and development base that makes such sales figures possible. Research and development figures are shown in Table 3-2.

Concentration and Competition

Concentration and degree of competition in the industry can be measured in several ways. One example is given in Table 3-3 which shows the degree to which the total prescription market is concentrated in the hands of industry leaders.

Another measure of industry concentration – the Herfindahl-Hirschman Index (HHI) – has been used to examine the effects of proposed mergers. This measure has been advocated as the appropriate market power measure for antitrust purposes. It is computed by squaring the market share for each firm, expressed in percent, and summing the result. This sum is then multiplied by 10,000 to express the HHI value in whole numbers.

Table 3-4 shows the HHI values computed for 1978 through 1986, using the same data upon which the concentration ratios of Table 3-3 were based. In examining the impact of merger activity, the critical value of the HHI that would trigger concern about a particular merger is not well-

TABLE 3-1. U.S. and foreign pharmaceutical sales by PMA member firms ($ Billions)

Year	Domestic	Foreign	Total
1989	33.8	17.7	51.5
1988	29.9	16.3	46.2
1987	26.6	15.1	41.6
1986	24.1	13.0	37.1
1985	21.1	10.9	32.0
1980	12.0	10.5	22.5
1975	6.9	4.8	11.7
1970	4.4	2.2	6.6
1965	3.0	1.1	4.1

TABLE 3-2. U.S. pharmaceutical companies R&D expenditures (PMA Members)

Year	Expenditure ($Billions)
1970	0.6
1975	1.1
1980	2.0
1985	4.1
1986	4.7
1987	5.5
1988	6.5
1989	7.3

Source: PMA Annual Surveys

established. However, a value of 1000 is generally viewed as being unlikely to be challenged. As Table 3-4 shows, the pharmaceutical industry HHI is less than half of this usually accepted value and in fact has declined by 23 percent since 1980.

U.S. leaders in the field of *non*-prescription drug sales are shown in Table 3-5 and the ten largest generic manufacturers are listed in Table 3-6.

The International Pharmaceutical Industry

The worldwide prescription drug industry is not as easily characterized nor identified as is that of a simple country such as the United States. There are helpful data available, however. The best source of such data is the British publisher, *Scrip*.

Scrip publishes its "League Tables" annually based on a survey of more than 200 companies worldwide who are engaged in the business of pharmaceuticals. They note the difficulty both in gathering and in interpreting the data.

> A second, more fundamental problem is that of defining "pharmaceutical" companies and "pharmaceutical" activities—true "pharmaceutical" companies are few and far between. "Pharmaceutical" companies can range from such giant chemical companies as Hoechst, where "pharmaceuticals" account for only 16.5 percent of total sales, or companies such as Astra where pharmaceuticals can be regarded as the company's sole activity. Nevertheless, Hoechst's 16.5 percent pharmaceutical turnover translates into $2,396 million (ranking it third in the world), whereas Astra's 100 percent pharmaceutical turnover translates into $516 m (ranking it 34th).

TABLE 3-3. Competition for new U.S. prescriptions measured in total prescription dollars, 1979-1987

	Percentage of New and Refill Prescription Dollars[a,b,c,d]								
Company Group	1979	1980	1981	1982	1983	1984	1985	1986	1987
Leading Company	10.1%	9.8%	9.2%	8.4%	8.3%	8.4%	7.5%	6.8%	7.2%
4 Largest	32.3	31.6	30.5	29.5	29.6	29.2	27.1	25.0	23.6
8 Largest	50.2	50.1	49.8	48.9	48.4	47.7	44.7	43.3	41.4
20 Largest	81.9	81.8	81.9	79.4	78.4	77.0	74.1	72.6	71.9
50 Largest	98.8	98.8	98.7	96.7	96.1	96.2	94.3	95.7	95.4
All Companies	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	

[a] "Unspecified" prescriptions not included in calculations for the years 1978-1981. The Unspecifieds accounted for 6.4 percent to 6.8 percent of total Rx dollars between 1978 and 1981.

[b] Pharmacy cost level.

[c] Data for 1982-1987 are for prescriptions as they were dispensed, not prescribed as was the case for earlier years.

[d] Sales of subsidiaries were combined with parent corporation sales in making calculations.

Source: National Prescription Audit, IMS America, Ltd.

The same applies to pharmaceutical activities. The report aims to compare companies' performance in the area of ethical pharmaceuticals. However, few companies can claim figures for pharmaceuticals representing strictly ethical drugs. Most large companies have pharmaceutical "divisions" which cover OTC drugs as well as ethicals, and many include their pharmaceutical figures under segment headings such as "medical" or "healthcare." The true, ethical pharmaceutical figures in such cases are often hidden amongst figures for hospital supplies, diagnostics and veterinary products.

Data problems notwithstanding, the *Scrip* League Tables are an invaluable asset in analysis of the international pharmaceutical industry. Tables 3-7 through 3-9 illustrate the character of the data contained in this rich resource.

THE BUYERS

As Figure 3-2 shows there are many "buyers" between the pharmaceutical manufacturer and the ultimate consumer of his products. In this section we will describe some of them prior to commentary on changes in the bargaining power of these drug industry customers. This discussion will be limited to the U.S. market.

TABLE 3-4. Pharmaceutical industry concentration Herfindahl-Hirschman Index values, 1978-1986

Year	Index Value
1978	440
1979	453
1980	446
1981	439
1982	414
1983	411
1984	394
1985	368
1986	342

Source: PMA calculations based on data from National Prescription Audit data, IMS, America

TABLE 3-5. Top OTC companies by sales

Rank	Company	1987 Sales ($ in millions)
1	Whitehall Laboratories	863.0
2	Warner-Lambert Consumer	783.0
3	Glenbrook Laboratories	610.0
4	McNeil Consumer Products	550.0
5	Bristol-Myers Products	470.0
6	Parke-Davis Consumer	412.0
7	Richardson-Vicks	280.0
8	Procter & Gamble	230.0
9	Miles Consumer	220.0
10	Smith Kline Consumer	185.0
11	Beecham Products	180.0
12	Thompson Medical	141.1
13	Carter Products	125.3
14	Norcliff Thayer	110.0
15	Squibb Mark	66.0
16	Commerce Drug	27.2
17	Chattem Consumer	14.1

Wholesalers

Wholesalers, as Table 3-10 shows, are the most important class of buyers from pharmaceutical manufacturers in the U.S. There is also a clear trend toward increasing the proportion of sales through this partner in the channel of distribution.

Key wholesale executives see continuing strength for the wholesaler.* This strength arises from the ability to meet the needs both of the retail/hospital customers and of the manufacturer/supplier.

The wholesale drug industry continues to make progress in spite of a long-term decline in its operating margins. It operates in a highly-competitive environment and must accommodate changing customer demands, new products and services, and emerging technologies that influence its overall performance. Drug wholesalers registered strong sales growth in

*John T. Fay, Jr. of Bergen Brunswig in the previous edition of this text and Bruce R. Siecker and Robin C. Emigh in the Spring, 1989 issue of the *Journal of Pharmaceutical Marketing and Management*.

TABLE 3-6. Top generic companies by sales

Rank	Company	1987 Sales ($ in millions)
1	LyphoMed	172.7
2	Bolar Pharmaceutical	95.4
3	Mylan Laboratories	95.1
4	Par Pharmaceutical	78.7
5	Squibb Mark	70.0
6	Barr Laboratories	60.1
7	Roxane Laboratories	57.0
8	Warner Chilcott Laboratories	54.0
9	Biocraft Laboratories	49.3
10	Duramed Pharmaceuticals	18.6

TABLE 3-7. Pharmaceutical industry leaders, 1988

Company Name	Sales in Millions of Dollars (Rank)	Per Cent Profit	Per Cent Spent on R&D
Merck and Co.	(1) 4,227	28.4	11.2
Hoechst	(2) 3,511	4.1	15.5
Glaxo	(3) 3,374	28.0	11.2
Ciba-Geigy	(4) 3,171	7.0	10.6
Bayer	(5) 2,961	4.0	6.2
American Home Products	(6) 2,926	16.8	4.9
Takeda	(7) 2,741	6.0	6.2
Sandoz	(8) 2,724	7.0	14.1
Eli Lilly and Co.	(9) 2,382	23.2	12.8
Abbot	(10) 2,333	14.4	8.2

Source: *Scrip,* Pharmaceutical Company League Tables, 1988.

TABLE 3-8. Concentration in the international pharmaceutical industry

Number of Companies	Sales in Millions of Dollars	Combined Per Cent of Total	Cumulative Sales	Cumulative Per Cent
1 - 10	30,350.5	28.5	30,350.5	28.5
11 - 20	20,704.9	19.4	51,055.4	47.9
21 - 30	15,080.5	14.2	66,135.9	62.1
31 - 40	9,956.0	9.3	76,091.9	71.4
41 - 50	7,490.6	7.0	83,582.5	78.4
51 - 60	5,371.0	5.0	88,953.5	83.4
61 - 70	3,451.1	3.2	92,404.6	86.6
71 - 80	2,734.0	2.6	95,138.6	89.2
81 - 90	2,254.2	2.1	97,392.8	91.3
91 - 100	1,896.1	1.8	99,288.9	93.1
Total 194 Companies	106,504.0	100%	106,504.0	100%

Source: *Scrip*, Pharmaceutical Company League Tables, 1988.

TABLE 3-9. International character of the pharmaceutical industry

Country	Company Sales Leader in Specified Country	World Ranking of Company	Per Cent of Sales of Company That are Foreign
Canada	Connaught	112	0
France	Rhone-Poulene	20	71.5
West Germany	Hoechst	2	75.0
Italy	Erbamont	46	62.0
Japan	Takeda	7	5.9
Switzerland	Ciba-Geigy	4	98.0
United Kingdom	Glaxo	3	86.5
United States	Merck and Co.	1	50.6

TABLE 3-10. Percentage distribution of U.S. ethical pharmaceutical sales by class of customer. Selected years 1972-1985

Class of Customer	1976	1978	1980	1982	1983	1985	1986
Wholesalers	48.5%	51.4%	57.3%	59.6%	61.7%	67.3%	68.3%
Retailers	26.4	22.8	20.8	18.0	17.2	16.0	15.5
Private Hospitals	14.8	16.0	12.7	13.7	12.6	8.8	8.0
State & Local Government Hospitals	4.5	4.2	4.1	3.8	3.5	2.5	2.3
Federal Hospitals	2.5	2.4	2.5	2.5	2.5	2.1	2.4
Other Federal Government	1.3	1.4	1.2	1.1	1.2	1.6	1.5
Practitioners	1.2	1.2	1.0	.8	.7	.7	1.0
Manufacturers, Repackagers, And Other Direct Sales	.8	.6	.4	.5	.6	1.0	1.0
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: PMA Annual Survey (various years)

1987—up 17.82 percent over 1986 and 126 percent over 1981—producing $19.46 billion in sales.

One of the major forces contributing to the industry's strong sales performance is its ability to increase market share. The latest industry surveys indicate that the wholesale drug industry is now handling almost 70 percent of total pharmaceutical products distribution. Drug wholesalers continue to capture a larger share of both hospital and retail accounts. Direct drug manufacturer shipments continue to decline. This is evidence of the wholesaler's unequaled operating efficiency and ability to fill unique local market needs most effectively.

Obviously, there will be some point where market share increases will begin to level off. But even in the absence of strong growth in market share, drug wholesaler sales increases are still very impressive and should continue as everyone searches for ways to contain costs in health care.

Table 3-11 presents an overview of the drug wholesaler's customer mix. The independent drug store continues its long-term decline as a percentage of the total customer mix, although dollar volume is still growing. Industry sales to independent pharmacies were 11.5 percent higher in 1987 than in 1986. Thus, the independent drug store is still the most important and expanding customer segment for drug wholesalers.

Sales to hospitals continued an unbroken record of dollar and market share growth in 1987, while chain drug stores slipped back a percentage point (while still producing an increase in dollar sales). Other sales—representing mass merchandisers, food stores, clinics, and nursing homes—are still less than 5 percent of the industry's overall customer mix.

Although National Wholesale Druggist Association members are all full-service, full-line distributors with a myriad of products, most of their 1987 product sales were pharmaceuticals. Almost four fifths (78.79 percent) of drug wholesalers' product sales were prescription items, with proprietary (OTC) drugs a distant second (12.15 percent). See Table 3-11.

For several reasons, wholesaler executive John Fay believes that wholesalers' market share can be expected to increase from the current 70 percent to 85 percent. In turn, an 85 percent share of the projected $95 billion market is $80 billion. That would leave a 15 percent share for direct sales by manufacturers.

Electronic data interchange (EDI) between manufacturers and wholesalers should yield a significant increase in wholesalers' market share. When wholesalers established electronic links with their customers through automated order entry, market share increased from 45 percent to 70 percent in 13 years. Among the more obvious benefits are speed, ease

TABLE 3-11. Customer mix (weighted average of gross sales and product sales mix)

	1981	1982	1983	1984	1985	1986	1987
Customers							
Independent D.S.	56.97%	56.10%	54.51%	53.45%	50.01%	47.66%	45.60%
Chain D.S.	26.09	25.71	25.05	24.40	27.92	28.78	27.74
Hospitals	14.10	15.64	17.43	18.61	19.47	20.13	22.23
Others	2.84	2.55	3.01	3.54	3.20	3.43	4.43
Products							
Pharma-ceuticals	64.74%	65.34%	68.17%	71.73%	75.75%	76.41%	78.79%
Proprietaries	17.61	15.53	14.94	13.15	12.50	12.52	12.15
Toiletries	9.29	9.51	9.14	8.42	5.92	4.48	3.95
Sundries	6.76	7.89	6.26	4.96	3.75	4.27	3.14
Other	1.60	1.73	1.50	1.76	2.09	2.32	1.97

of transmission, more efficient service levels, improved turnover rates, reduced cash investment, and balanced delivery schedules.

Although the buyer-seller relationship in distribution is generally better than ever before, a basic problem persists. As middlemen, should wholesalers be sales agents for manufacturers or should they be purchasing agents for their customers? To some degree, wholesalers must perform both functions, and the two forms of agency are not mutually exclusive. Current business experience, however, supports the movement toward expansion of the wholesaler's role as purchasing agent for the pharmacist. It is a strategy described by management consultants as "forward integration."

Pharmacists and their wholesalers are working together more closely. This change for the better comes during a period of unusual dynamism in the distribution industry. It is an important and integral part of the structural change now generally recognized by industry observers. The stability at the macro-wholesale level is misleading. At the micro-level, wholesaling is very dynamic. The channel structure depends upon the time-space-quantity-variety gap between the assortments of sellers and buyers. To the extent that this gap changes, the wholesaling task changes.

In simpler language: the closer you get to the action in wholesaling, the more interesting and innovative it is. The trend line for the wholesalers' market share of prescription sales clearly indicates a turnaround after a period of decline of 1973 and rapid growth since. Computerization and continued application of cost-effective technology are major factors in this growth.

Other factors involved in distribution dynamics include competitive intensity, a changing product-services mix, consolidation of the customer base, new efforts in managerial and marketing continuity, greatly improved productivity, and innovations in pricing strategy. The latter can be illustrated by the shift to cost-plus pricing that follows by several years the pharmacist's shift from markup to professional fee methods.

Retail Pharmacies

There are more than 50,000 retail pharmacies (drug stores) in the United States and they are divided into two rather different groups in terms of size and market power.

Independent drug stores represent about 60 percent of all retail pharmacy outlets, but their market power is reduced in two ways. First, independent pharmacists typically operate only a single (sometimes 2 to 4) outlets, so their overall market impact is small. Second, their volume per outlet is also comparatively small.

In recent years the independent drug store share of retail sales has slipped to below 40 percent of the total. This represents average annual sales in the $600,000 to $700,000 range per store. The independents have attempted to retain market influence through their trade association (National Association of Retail Druggists), by joining "voluntary chains" and buying groups, and through the franchise mechanism.

The chain industry share of the retail drug business has grown every year since the mid-1970's to more than 60 percent. The per outlet sales volume averages more than $2.5 million. Market power is quite concentrated in the chains as the data in Table 3-12 show. There were 49 companies in 1987 with sales above $50 million. It should be noted that the proportion of prescription drugs in the total sales of independents vs. chains and even between chains is often markedly different, so the market power can vary by drug type.

The growing power of retail chains, especially for nonprescription drugs, was highlighted in a 1989 report by *Marketing News* (Vol. 23, January 16, 1989).

> The relationship between supplier and retailer always has been a struggle for power: a tug-of-war pitting the supplier's need for shelf space and distribution against the retailer's need to remain competitive in its inventory assortments and one-stop category appeal to its consumers. . . .

TABLE 3-12. Leading retail drug chains, 1987

Company	Sales Volume In Millions (Rank)	Number of Outlets (Rank)
Walgreens	4,154 (1)	1,356 (4)
Osco	3,047 (2)	645 (7)
Eckerd	2,750 (3)	1,581 (3)
Rite Aid	2,486 (4)	2,070 (1)
Revco	2,317 (5)	2,051 (2)
Longs	1,772 (6)	229 (14)
Peoples	1,396 (7)	819 (5)
CVS	1,394 (8)	698 (8)
Thrifty	1,346 (9)	641 (8)
PayLess NW	1,280 (10)	254 (13)

Source: *Drug Store News*, 1988 Chain Drug Survey.

Among the factors cited for the power shift are those which follow.

Integration of information technologies. Virtually all of the major retailers began full item-data-capture, some with scanning devices, at their electronic point-of-sale terminals. Capture of that data, in some instances in real-time, for the first time gave retailers more information about particular items than the manufacturers. Retailers also found they could sell that information to their suppliers.

Implementation of direct product profitability analysis. DPP has helped lead to actual per-item profitability calculations and is affecting shelf-space allocation by influencing planograms.

An unending stream of new product introductions and line-extensions. As some consumer goods markets matured and convenience took over, manufacturers began a product assault on retailers, who, when faced with a multitude of similar items from a multitude of manufacturers, began to rebel.

Forward investment buying. As retailers emphasized just-in-time delivery to their stores and flow-through distribution has become a reality, more warehouse space has been freed for buying on deal. Moreover, technology and DPP have enabled retailers to calculate correctly the actual costs of inventory ownership. As a result, some retailers buy almost exclusively on deal, warehousing the items until needed at store level.

*Hospitals**

As late as the 1960s the marketing of pharmaceuticals to hospitals differed little from the approach taken with the office-based physician. The manufacturer's representative simply promoted drugs directly to the hospital-based physician for use with his hospital patients. The hospital market today and of the future represents a change as well as a major challenge to the pharmaceutical marketer. Factors such as drug selection, therapeutic substitution, purchasing, type of packaging required, the change to more clinically oriented services, and the movement of the practice to the hospital pharmacy in the direction of specialization have all increased the complexity of marketing to hospitals.

Other than retailers, hospitals are, by far, the largest dispensers of

*Some material in this section was written for the Third Edition of this text by Roger Becker, Russell Lehn, Phillip Zarlango, and David Kruger.

drugs. As they slowly evolve into combinations of inpatient treatment and outpatient centers for ambulatory health care, hospital outpatient pharmacies are becoming a significant source of drug dispensing.

The hospital market may be described in terms of ownership control by the number of hospitals and size, determined by number of beds. Most teaching hospitals are in the over-300 bed group, so the major hospital pharmaceutical marketing emphasis is directed to them.

The size of the market in terms of the number of hospitals and beds has declined, whereas the size of the market in terms of dollars has shown substantial growth. We will now discuss some of the factors that have an impact on the pharmaceutical marketing approach to this growth market.

The physician has traditionally been the orderer of drugs. Although he will probably continue to remain important in deciding whether or not a patient should receive medication, the choice of drug, source, and supplier are more frequently being decided by others.

Due to the decline in the number of significant new and patentable drugs and the increased number of sources of generic and nonpatented drugs, hospital pharmacists have expanded their role in the drug selection process. The expanded role and selection authority of the pharmacist has created what is termed "the hospital formulary." This is a list of drugs, classified both generically and therapeutically, which have been approved for use in the institution. Nearly all hospitals use such a system. Except in the case of a new and major single-entity drug, the formulary approval process represents a major challenge for the pharmaceutical marketer.

The efficient operation of a hospital is dependent on the cooperative efforts of many types of health-care professionals, such as physicians, nurses, pharmacists, and lab technicians, who have independent interests. As a result, many proposed changes are decided by the Pharmacy and Therapeutics (P&T) Committee. This committee has the responsibility of making formulary decisions. It is most commonly comprised of representatives from the various physician specialties, nursing, and pharmacy.

In their hospital promotional efforts pharmaceutical manufacturers will find it increasingly necessary to include or place more emphasis on decision makers other than physicians.

In order to be successful in obtaining drug formulary approval, pharmaceutical representatives must first identify members of the P&T Committee, and then must provide information necessary for a favorable decision. This is not a simple task. It challenges the selling skills of the representative as well as the marketing expertise of the representative's company.

Single-source products will continue to be promoted to the physician

for brand specification. This, too, presents a challenge to the sales representative, because full-time staff physicians in teaching hospitals are not readily accessible. Residents and interns also play varying roles on influencing and making decisions in teaching hospitals. These roles must be identified in each hospital in order for the pharmaceutical representative to be effective in generating product specification.

In the nonteaching hospital the medical staff is composed primarily of office-based physicians, a situation that provides a different challenge for the pharmaceutical representative. Promotional efforts and materials presented to the physician in the office are generally developed to generate prescriptions for the ambulatory nonhospitalized patient. Because the product benefits presented pertain to this type of patient, physicians may not carry their office-prescribing habits over into their hospital practice. (The reverse may also be true as the *Case in Point* demonstrates.) To generate hospital prescriptions by office detailing, the pharmaceutical representative must present product benefits as they apply to the physician, to the hospitalized patient, and to the overall clinical situation. Although formulary approval for a major new drug is not usually a problem, it is a process that must be completed. If the new, single source product is not considered to be a significant therapeutic advancement, formulary approval may be as difficult to obtain as with multisource drug equivalents. From a marketing standpoint, the appropriate contacts must be made and the necessary information must be communicated.

The classic free market forces that normally exist between buyer and seller do not function as distinctly in the purchase of hospital prescription drugs. In the typical model the physician orders the medication, the pharmacist dispenses it, a nurse administers it, a third-party financier pays the cost of it (for a high percentage of patients), and the patient consumes it. To further complicate this process, the pharmaceutical manufacturer is faced with increasingly complex systems of purchasing by hospitals as well as with a shift in the distribution channel for hospital purchases.

In today's era of cost containment, group purchasing organizations are becoming some of the most powerful players in the hospital purchasing arena and a necessary fact of life for both hospitals and suppliers. They have, in fact, turned into an entire new industry and have created a novel set of challenges for pharmaceutical executives.

In a review of the group purchase phenomena, Leavenworth (*Pharmaceutical Executive*, January 1989) has characterized four different types of hospital group purchase organizations.

- multiple-hospital systems, whether owned or managed, such as Humana, Hospital Corporation of America, American Medical International, National Medical Enterprises, and various Catholic, Lutheran, and other church-owned systems. These systems offer services and management programs beyond group purchasing.
- voluntary "diverse" alliances with diverse members or owners who voluntarily join an association, such as the Voluntary Hospitals of America (VHA), MedEcon, and Amerinet. Again, these alliances have been expanding to offer services to members beyond group purchasing.
- voluntary "related" alliances that are similar to voluntary diverse alliances but the members of which have something in common. Examples of such alliances and their unifying characteristics include Premier Hospitals Alliance, an association composed of medical centers; SunHealth, with all its members located in the southeastern U.S. region; and American Healthcare Systems, a system of "systems."
- group purchasing organizations that focus primarily on offering group purchasing discounts. As alliances have expanded their service offerings, however, groups focusing totally on purchasing are actually becoming obsolete.

> As many pharmaceutical companies have learned, these four types of organizations have all established themselves as new "gatekeepers" for their hospital members, adding a new layer of customers to the purchasing process. Initially, the emphasis of these organizations was heavily focused on group purchasing for volume discounts. Over time, however, many GPOs have begun to develop additional services and programs to respond to other needs of their members. Thus, in some situations group purchasing is just one of many services offered. . . .
>
> The difference between manufacturers that depend on GPOs and those with limited involvement results from a difference in the role of the GPO as gatekeeper compared to the relative influence of hospital end users. Exclusive, one-of-a-kind pharmaceutical products and "specialty" products that have few substitutes are highly driven by end-user preferences.

The hospital pharmacist's increased importance also presents a selling challenge to the pharmaceutical representative. The clinical pharmacist is exercising greater influence on formulary decisions and on physicians'

therapeutic decisions. The representative must be better educated and must possess the necessary clinical knowledge to communicate with the clinical pharmacist. The salesperson must also keep informed of current clinical articles and the latest medical advances. The marketing expertise of the company will be challenged to provide the representative with the technical service and data needed for clinical evaluation. Special packaging will be required to meet the needs of the unit-dose distribution systems, IV admixture services, and outpatient dispensing. Educational services will be increasingly important for in-service and student training. The representative and the company will be successful in this market only if they accept and meet these challenges.

Of special potential significance is the growth of therapeutic substitution in the hospital setting.

CASE IN POINT

Influence of Hospital Prescribing Habits on Outpatient Prescribing

A hospital-pharmacy-based program to decrease inappropriate prescribing of triazolam is described, and the program's effect on triasolam prescribing patterns for both hospitalized and nonhospitalized patients is reported.

Pharmacists developed criteria for the triazolam "target drug program" in cooperation with the pharmacy and therapeutics committee. Pharmacists contacted prescribers when bedtime triazolam doses were ordered that (1) exceeded 0.125 mg, (2) were for patients ≥ 60 years of age, and (3) were not to be given immediately before a surgical or diagnostic procedure. The pharmacists recommended to the prescribers that triazolam be started at a dosage of 0.125 mg in elderly or debilitated patients and that the dosage be adjusted according to the patient's response, with a repeat dose given if appropriate. Data were collected on triazolam use in the hospital before and after the pharmacist intervention program began. Data also were collected on sales of triazolam to community pharmacies near the hospital. The number of inpatient triazolam orders meeting the criteria for intervention decreased. The percentage of inpatient interventions that resulted in a dosage change also decreased, probably because prescribers' orders for higher triazolam dosages were more likely to be appropriate after the target drug program. Community

pharmacies purchased more 0.125 mg triazolam tablets and fewer tablets of greater strengths after the target drug program.

Intervention by hospital pharmacists caused a change in the inpatient prescribing pattern for triazolam and appeared to cause a parallel change in the community surrounding the hospital.

Source: *American Journal of Hospital Pharmacy*, September, 1989.

Health Maintenance Organizations

A Health Maintenance Organization (HMO) both insures and dispenses health care. In 1970, a "think tank" named Interstudy coined the term "Health Maintenance Organization" to describe such an institution. Although seemingly recent organizations, HMOs have existed for a considerable time as prepaid health plans.

The cost-containment mechanisms within prepaid health plans have a direct impact on the marketing of pharmaceuticals to HMOs. HMOs dispense health care to a voluntarily enrolled population; they finance this health care by spreading the cost among all enrolled beneficiaries and providers on a prepaid basis. The prepaid aspect of financing health care refers to the practice whereby HMO members prepay their medical fees before their anticipated needs are met, and providers of this anticipated health care are paid in advance of dispensing their professional services.

Prepaid health plans, such as HMOs, collect money in advance of the demand for payment of provided health services. This money goes into a collective pot and is disbursed to physicians, nurses, hospitals, pharmacies, etc., under a well-controlled system that maintains these providers as salaried or as contractually capitated employees of the HMO. To give additional incentive to restrict provider-controlled demand for prepaid funds, these HMO-associated health professionals often receive some type of bonus for limiting the frequency and expense of their services. Concurrently, these providers generally receive no additional payment if their demand for service payment exceeds the prepaid funds available.

To market pharmaceuticals successfully to the HMO industry, suppliers must understand not only the cost-containment factors built into the HMO, but also the variety of arrangements that exist between the provider of health care and the insurer reimbursing the provider. Because the term "Health Maintenance Organization" stresses health maintenance, and because it has been shown that HMOs accrue the greatest portion of their documented savings by utilizing expensive hospital services approximately 30 percent less often than patients with fee for service insurance, drug utilization within the HMO accents symptomatic control of incurable

chronic illness and high use of drugs capable of curing acute distressing or infectious disease.

The actual pharmacy benefit of the HMO is provided by a system that attempts to control prescribing practices as well as dispensing costs. Both these factors are important considerations to the drug manufacturer and to the supplier interested in selling to the HMO market.

Surrogate Buyers

Third-party reimbursement can be provided either by government programs or by private insurance programs. Medicaid drug benefits cover both in-hospital and out of hospital drug use in nearly all states, although the extent of coverage varies dramatically. Medicare benefits now include outpatient drugs. Private insurance generally covers inpatient drugs through basic hospital insurance; outpatient drugs are written into the insurance as an extra.

The high percentage of patients covered for both inpatient and outpatient drugs has minimized the compromising of drug selection and purchasing. Due to competition among pharmaceutical companies in efforts to increase their share of this growing market, hospitals have been able to purchase quality products economically through the bid solicitation process and group purchasing. Therapeutic evaluation committees normally do not compromise necessary therapy for the sake of cost.

However, third-party payers continue to scrutinize patient drug charges, just as hospital administrators continue to look for ways to decrease pharmacy budget expenditures. In order to enjoy a considerable share of this large and growing market, the pharmaceutical marketer will need to be continually conscious of economic factors, remain alert to influences that change these factors, and adopt marketing strategies accordingly.

SUBSTITUTES

There are three kinds of substitution which may threaten the pharmaceutical marketer:

- Substitution of an original chemical entity with a generic version.
- Substitution of a product type or class with a chemically different, but pharmacologically similar product.
- Substitution of medication with a non-medication treatment or preventive measure.

We will examine each in turn.

*Substitution/Drug Product Selection**

A "drug" may be defined as a substance endowed with some action on living matter. This substance may have an established or nonproprietary or generic name, a chemical name, and one or more brand names. The American Medical Association (AMA) and the United States Pharmacopeia (USP) have established a combined nomenclature committee to meet with industry to provide a single and suitable established or nonproprietary or generic name for each drug in general use. The term "United States Adopted Name" or "USAN" is used to designate the established name. Although the finite definition of "generic" means a class of substances having the same biologic properties, "generic" has customarily been used as a synonym for established or nonproprietary names.

The practice of assigning brand names is not new, as evidenced by the first recorded brand name, Epsom Salts, for magnesium sulfate in 1698 in England. In the seventeenth and eighteenth centuries, brand-name medicines were generally called patent medicines, which were usually mixtures of several substances whose chemical composition was either unknown to the manufacturer or was a closely guarded secret.

The United States patent law was enacted in 1790 and has remained unchanged, even though efforts were made by Senator Kefauver to change the law in the early 1960s. The life of a patent is 17 years from the date of issue (with a few exceptions, see Chapter 2); trademarks, however, which are protected by the Lanham Trademark Act, are unlimited as to their life span.

The so-called miracle drugs, such as the sulfonamides, the penicillins, and chloramphenicol, were discovered and then sheltered under the protective roof of patents to provide profit potential. The first broad-spectrum antibiotic to be marketed was Aureomycin (American Cyanamid-Lederle Laboratories), launched in 1948 as a brand-name product. It had no chemical name because none was assigned, and it could only be prescribed by its brand name. Only the manufacturer to whom the discoverer assigned the patent could legally produce the drug in this country unless others were licensed by the manufacturer who owned the patent. Thus, brand names became useful as a marketing tool.

In the decade 1950 to 1960, the development and marketing of drugs by

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*Some of the material in this section was prepared by Dr. Max Ferm and Dr. Edward Stempel and appeared in the Third Edition of this book.

brand names reached unprecedented proportions. Some of these drugs were diuretics, hormones, antihypertensives, non-narcotic analgesics, antibiotics, and tranquilizers. Because the investment of millions of dollars in research for new and better drugs was a risky prospect, manufacturers charged high prices to recover their invested capital and to counteract the obsolescence of their existing products.

In December, 1959, Senator Kefauver's much publicized hearings on monopoly in the drug industry began. Subsequently, Senator Nelson's hearings suggested that generic drugs cost less than their brand-name counterparts. In 1966, the Task Force on Prescription Drugs recommended generic prescribing of drugs, and projected a wholesale cost savings of $41 million if 63 products were prescribed exclusively by generic names.

During the years of the Brand Era, physicians became accustomed to prescribing trademarked products by brand name because of the massive and successful promotional marketing programs of pharmaceutical manufacturers. Manufacturers became concerned that prescriptions for their trademarked products might be filled with a substitute product, which is now popularly termed as the generic equivalent. In the 1950s the drug industry enjoyed much prestige, and there were some attempts at counterfeiting products. Through the impetus of national organizations, notably the American Pharmaceutical Association (APhA), pharmaceutical manufacturers went on record as supporting the enactment of antisubstitution laws. By 1970 the APhA reversed its stand of favoring the repeal of antisubstitution laws because the justification for these laws was no longer valid, and pharmaceutical education was training pharmacists as the best health practitioners for selecting the brand of drug from among multisource products. Furthermore, the continued expiration of the many drug patents was coupled with the entry of large brand-name-oriented manufacturers into the "branded generics" line—nonproprietary or generic products manufactured and distributed by these large brand-name-oriented manufacturers. All these factors helped repeal antisubstitution laws and grant pharmacists responsibility for drug product selection. The early effects can be seen in the data in Table 3-13.

Since 1972 most states have repealed existing antisubstitution laws by providing drug product selection legislation. There are several factors operating to increase the share of the generic prescription drug market: (1) fewer new products; (2) expiration of patents; (3) generic prescribing; (4) maximum allowable cost (MAC) on government-paid prescriptions; and (5) drug-product selection. The terms of the U.S. 1988 Catastrophic Drug Bill make it clear that Federal encouragement of this trend will continue.

TABLE 3-13. Patent expiration, competition, and market position

Brand Name	Manufacturer	Year of Patent Expiration	Market Size* ($ millions) Drug Store	Hospital	Number of Competitors Brands	Generics	Loss of Market Share from Patent Expiration to 1979 (%) Drug Store	Hospital
Atarax	Roerig	1976	16.5	14.2	1	5	2.1	1.7
Compazine	SmithKline	1976	9.4	4.4	0	2	1.2	1.1
Darvon	Eli Lilly	1972	14.6	3.2	3	19	9.5	25.1
Diuril	Merck	1974	14.7	0.9	0	5	7.4	9.5
Doriden	CIBA, USV	1971	8.8	0.5	0	6	2.1	0
Gantanol	Roche	1976	5.1	0.5	0	2	0	0
Librium	Roche	1976	54.7	4.5	3	17	7.2	9.0
Placidyl	Abbott	1975	4.3	0.4	0	0	0	0
Pro-Banthine	Searle	1970	4.6	1.0	0	10	1.8	9.6
Robaxin	Robins	1973	4.5	1.2	2	20	4.7	22.9
Tandearil	Geigy	1973	6.5	0.3	0	0	0	0
Thorazine	SmithKline	1970	21.6	13.4	2	5	9.5	28.2

*Market size in the year before patent expiration.

Source: Market size data are from *U.S. Pharmaceutical Market, Drug Stores and Hospitals*, Ambler, PA: IMS America (various years). Number of competitors' data are from U.S. Department of Health and Human Services. Approved Prescription Drug Products, Washington, D.C., 1980.

Generic companies may be categorized as manufacturers, distributors, or manufacturers/distributors. A typical manufacturer of generic drugs produces between 20 and 40 different products, principally for generic distributors (although some are much larger). The company will have a limited marketing organization directed toward the sale of its products to large purchasers such as distributors, the federal government, chain drug stores, and hospitals. Some also engage in selling to foreign government markets, particularly in less developed countries in which a generic industry has yet to develop. Because of limited physical capability, a highly competitive market, and broad product lines these manufacturers cannot afford to maintain large inventories. They must therefore be capable of switching their physical resources quickly to meet market demands. Generally, products are produced with the manufacturer's label, but it is not uncommon to find the distributor's label affixed for those who are capable of buying in larger quantities. In essence, they are private-labeling to a segment of their market, and it is not unusual to find a product manufactured by one company bearing a number of different labels. These are easy for the pharmacist to detect as a result of state laws requiring the manufacturer's name on the label. Prior to the institution of such laws, it could only be determined that the distributor was not the manufacturer by noting on the label the words "distributed by" or "manufactured for."

Distributors range in size from comparatively small operations, producing $200,000 to $1 million gross volume and serving a city or county, to companies with sales in excess of $60 million serving the country from one large regional center or from several distribution warehouses strategically located in various parts of the country. The larger companies can also be distinguished by the package, which usually includes the label of the distributor.

It is difficult if not impossible to count the number of generic distributors because many are small and unidentifiable. Moreover, the mortality rate of small- to medium-sized companies is high, a point worthy of further discussion.

Because price is the dominant factor for generic companies, the gross margins are small. A typical distributor margin may range from 20 to 30 percent (brands may range from 60 to 90 percent). All operating expenses must be deducted from this, including overhead, selling, distribution and, perhaps most important, inventory. Generic distributors are, in effect, specialty wholesalers who are expected to offer a full range of products in all dosage strengths and economical package sizes. As such they probably handle an inventory of 1000 or more different packages. The cost of main-

taining a large inventory is extremely high in relation to the gross profit, and often requires supplemental financing.

Companies do survive and, in some cases, thrive. The answer appears to be a combination of rapid growth, adequate capitalization, tight control of expenses, and a degree of business, particularly financial, sophistication not commonly found in a "me-too" industry comprised of small companies.

The advantage of controlling manufacturing while engaging in broad market distribution appears obvious. Thus this combination offers the greatest potential for market penetration and success. Interestingly, when manufacturers venture into broad retail distribution, they do so on a limited basis with modest or no gain. However, when distributors acquire manufacturing, the combination appears to meet with greater success. It can be hypothesized that marketing acumen is more important than technological capability, and that a large customer base is more easily maximized by a dependable source of products than is a source of products attempting to find new outlets. On this basis, it makes sense that major brand-name manufacturers who enter the generic marketplace rely upon their own distribution resource and buy most of their generics from manufacturers rather than utilizing their own manufacturing facility.

Therapeutic Substitution

During the past few years, a large portion of the drug substitution controversy has shifted from the generic substitution issue to the newer and perhaps even more controversial topic of therapeutic substitution. Therapeutic substitution, in contrast to generic substitution, involves the act of dispensing a different therapeutic alternate of the drug prescribed, that is, a different therapeutic moiety with similar pharmacological or therapeutic classification and anticipated similar results. Pharmaceutical industry proponents fear that therapeutic substitution will retard incentives for research and development. Manufacturers note that existing patent laws provide an economic incentive for the search and development of innovative drug products. However, they fear therapeutic substitution will circumvent patent exclusivity incentives by allowing product substitution.

Decisions in drug treatment therapies have traditionally been based upon the product's safety and effectiveness in accordance to patient specific health requirements. However, considerations now tend to include the economic aspects of treatment choices. Therapeutic substitution practices have evolved, along with drug formularies and generic product selection processes, as effective methods for controlling costs in a variety of health care settings, most particularly hospitals and other organized environments.

Therapeutic substitution has been practiced in hospitals, with the active support and participation of physicians for several years. Operating within the auspices of the hospital, pharmacists have entered into the debate which has thus far focused on the therapeutic, economic, legal, and professional implications upon which the issue turns.

It should be obvious to the marketer that widespread acceptance of the practice as described would diminish the value of patent protection and likewise serve to force a transfer of promotional effects to some ultimate decision maker . . . if that decision maker can be identified.

Non-Drug Substitutes

There have long been efforts to find substitute therapies for medications. While it is unlikely that drug treatment will disappear, some categories of therapy may be vulnerable to non-drug substitution. Among potential substitutes which should be a part of the environmental scan described in the previous chapter are:

- Therapeutic foods and diet therapy
- Monoclonal antibodies
- Biofeedback
- Psychotherapeutic breakthroughs
- New ways of stimulating the immune system
- Electrical stimulation
- Acupuncture
- Surgery
- Liquor
- Hypnosis

SUPPLIERS

While it is certainly true that the chemical and other raw materials used in the manufacture of pharmaceuticals are essential to that manufacturer, they are seldom a factor in the overall structure of the industry. (Although the petrochemical concerns during the Carter Administration were very real.)

There are suppliers to the industry whose services and products can be an important asset when available and impediment when they cannot be obtained. They fall into the categories of pharmaceutical technology and information. Each can be critically important to the success of marketing strategy. The pharmaceutical information suppliers are generally included in the area of market and marketing research and will be considered in a

later chapter. Suppliers of pharmaceutical technology will be examined briefly here.

At the outskirts of the pharmaceutical industry, or at least invisible to the public and to many professionals, are a number of firms who have developed pharmaceutical techniques which, when combined with the breakthrough molecular developed by other (usually larger) companies can result in a product with a substantial competitive edge. Sometimes such a combination means an advantage in entering a market. At other times it may provide protection from generic competition. Some of the more obvious and frequent applications of this principle have come in the area of prolonged release, but there are others.

Alza is a company that for many months lived on the stock market without a product. Investors bet on the development of drug delivery technology that could be supplied (sold) to other companies for application to old or new medicines.

Product Resources International developed a "whip" for delivery of the antacid, Maalox, and then searched for other drugs to incorporate into this vehicle.

The risk of total, or even partial reliance on suppliers of this kind is, of course, that they will some day become one's competitors. On the other hand, few companies have the resources and the talent to be *totally* self-reliant in research and development of finished drug products. There are other important suppliers of resources to the pharmaceutical industry. An example is the financial community. Pharmaceuticals require substantial amounts of capital and investments by stockholders. Who are they? Snider, in a message in *Pharmaceutical Executive* (July, 1987) raised the suggestion that the *true* owners of many pharmaceutical corporations are the institutional investors—banks, mutual funds, insurance companies—who owned 60 percent of all drug stocks outstanding.

Also, it should be noted that the industry is dependent for its future on the creative minds of its physical and biological scientists and its business executives. In a very real way, then, colleges, universities, and graduate schools are all vital suppliers. The pharmaceutical industry has a critical need for such manpower and self-interest should dictate active support of the programs.

CASE IN POINT

Elan Pharmaceutical

In 1988, Elan Pharmaceutical climbed above 10 to close the year with a net gain of 2-1/8. The primary catalyst for its movement all year was

speculation on FDA approval of a sustained release formulation of Marion's Cardizem calcium channel blocker using an Elan formulation.

Approval was initially anticipated at the beginning of 1988 and Elan's stock climbed accordingly to above 12 at the end of February. As delays continued on the approval, the stock sagged back down until FDA disclosed that the application was close to approval at the beginning of November at what time FDA officially listed the product as "approvable." Elan stock behaved as if the major hurdle had been cleared. Elan's next major development project is a nicotine patch with Warner-Lambert.

Elan is undertaking an effort to expand outside the area of formulation development into the area of low-tech delivery. In 1988, it purchased a major stake in O'Brien Pharmaceuticals, an enteral nutritional marketer and then followed that up with an agreement to purchase another enteral distributor, Knight Medical, for $23 million, including incentive payments of up to $15 million. On January 13, Elan reported that it will finance part of the Knight purchase with a private placement of convertible subordinated notes.

Source: *FDC Reports*, January 16, 1989.

POTENTIAL ENTRANTS

Competitive analysis requires that assessment of potential entrants be done at two levels: the potential to enter the pharmaceutical industry by companies without pharmaceutical experience and the potential of a pharmaceutical company to enter a market (e.g., ophthalmics) in which it has not operated previously.

One of the most persuasive examples of the difficulties associated with entering the prescription drug industry is the number of unsuccessful attempts by major chemical manufacturers to do so.

- DuPont, even after the purchase of Endo, has not become a factor in the industry.
- Mallinckrodt tried and failed.
- Monsanto ultimately purchased Searle.
- ICI similarly found Stuart a necessity for industry entry.

Clearly, chemical technology is not a sufficient qualification for drug industry success. Neither is it necessarily a barrier (consider Hoechst, Merck, Bayer and others).

The pharmaceutical industry is one of high risk, great capital requirements, and a long period to payoff, at least for new drug developments. In

addition to the financial barriers there are major regulatory hurdles, both within countries and between countries, that must be surmounted.

One study of new drug development in the U.S. in the period 1963 to 1984 showed that although there has been a recent increase in the number of new chemical entities being tested by U.S. firms, an increasing proportion are acquired from outside the firm. Moreover, a growing number of acquired new chemical entities are coming from sources outside the United States, particularly Japan. These and other trends suggest an overall decline in research activity in the United States. At the same time, foreign firms are becoming more active, foretelling greater competition in the United States for both market share and research resources. The analyses also show a continued increase in synthesis-to-approval time, surpassing 13 years in the early 1980s, and rising success rates, reaching about 12 percent by the late 1970s (Clinical Pharmacology and Therapeutics. *43*(3): 290-301, March, 1988.)

The cost of new drug development is large and increasing and constitutes a potential barrier to market entry. A study published in 1987 by the Pharmaceutical Manufacturers Association underscores this (*The Cost of Developing A New Drug*, by Steven N. Wiggins.)

The approach in this study uses data on the approvals of new chemical entities (NCEs), the level of research spending for human use pharmaceuticals worldwide, and the stringency of U.S. government regulation in various therapeutic classes. The author estimates the economic relationship between vast values of research spending and regulation, and NCE approval rates in a given year for the period from 1970 through 1985.

Based on NCEs approved between 1970 and 1985, the estimate of the out-of-pocket cost for an approved NCE is $65 million in 1986 dollars. Using an 8 percent interest rate to account for the opportunity costs of research funds invested, the total cost for an approved NCE is approximately $125 million.

Cost increases can be traced to several major changes in pharmaceutical research. Perhaps the most important trend underlying cost increases is the increasing research focus on chronic and degenerative diseases. Drugs designed for such diseases generally require more extensive development and testing, resulting in increased cost. In addition, research on complex drug delivery systems has resulted in sharp cost increases.

A related study (*Journal of Health Economics*, Vol. 5: 153-177, 1986) by Joglekar and Paterson explored the profitability of investing in research and developing these new chemical entities (NCEs). A 36-year investment horizon was projected, based on a survey of research and development costs and on extensive U.S. sales data. Analysis was after taxes. The

average NCE produced a real internal rate of return of 6.1 percent and a net present value of $76 million in 1976 dollars. Break even with an opportunity investment in corporate bonds occurs on average after 12 years of sales. Risk is apparent in that after 24 years of sales some two-thirds of NCEs return no more than the bonds do. The median NCE, not recovering average research and development costs, produces a negative return. Results were, however, highly sensitive to drug price increases and early replacements by generics.

The issue of generic replacement in the marketplace or, from a different perspective, barriers to the successful entry of a generic into the marketplace is very important. It is one that has stirred a lively economic debate, international in scope, which involves patent protection.

In the pharmaceutical industry, two separate forces influence the effective duration of patent protection. On the one hand, because of the lengthy regulatory approval procedures, many observers argue that the effective life of a pharmaceutical patent is reduced by 7 to 9 years. On the other hand, offsetting this shortened effective patent life is the possibility that patentholders may reap the benefits of their patent monopoly beyond the date of patent expiration due to brand loyalty made possible by trademark protection. Recent work suggests that the possibility of extended patent life is a natural advantage captured by first entrants due to the search costs inherent in gathering product information on newer brands. (This is a search cost which the U.S. F.D.A. claims to ameliorate by assuring bioequivalency.)

Using data from the government reimbursement segment of the Canadian pharmaceutical market, McRae and Tapon (*Journal of Health Economics*, 4:43-62, 1985) have provided empirical evidence on the strength of post-patent barriers to entry in the drug industry. This question is a topical one in the United States. A bill (Waxman-Hatch) extending the patent life of new drugs became law in 1984. This legislation compensates drug manufacturers for the time lost while awaiting F.D.A. approval of new drugs. Their paper shows that the degree of post-patent protection is strongly influenced by the various types of retail sales regulations.

In an editorial following the above study, Scherer (*Journal of Health Economics*, *4*:83-84, 1985) offered some observations suggesting future change.

> The extension of new drug patent protection periods coincide with administrative efforts to accelerate the FDA's new drug approval process and eliminate excessively costly test and documentation requirements. At the same time, advances in the theory of pharmaco-

logical action in humans are making it possible to hand-craft particular molecules to have a specific desired therapeutic effect. This signals a gradual move away from the "try every bottle on the shelf" approach that previously dominated the search for new drug entities. The consequence will probably be a reduction of preclinical (and pre-patent) research costs. These changes may portend a second golden age of pharmaceutical innovation (the first, triggered by the methodological advances associated with the discovery of streptomycin, having petered out in the late 1950s).

It is unlikely that the luster of this new era will be dimmed much by the easier entry of generic competitors to the dozens of important drugs whose patents have recently expired, or are about to expire. Two main considerations lead me to this conclusion.

Most importantly, the drugs that will experience new or invigorated generic competition have already been discovered and tested. Post-1984 discoveries will, under the present system, not encounter such competition until the 21st century dawns.

The only plausible negative link between more competition on old drugs and R&D on new drugs could occur if R&D must be self-financed out of the profits from past successes. It has been shown that the theoretical conditions under which diminished capacity for self-financing retards technical progress are fairly restrictive. Also, it seems clear from the large flow of new venture capital to infant biotechnology firms that internal financing is not essential for pharmaceutical innovators with promising know-how and/or patented concepts.

*Market Entry Through Business Combinations**

Growth can result from one of two forms of expansions, internal and external expansion. External expansion is achieved by buying some or all of the assets of another firm. It is usually attained by the use of what is called the "business combination" and, in some cases, may be preceded by a joint venture or agreement. The assets obtained may range from some facility, personnel, or stock to the complete purchase of the firm, which may include subsidiaries. Table 3-14 shows some forms of business combinations.

*Most of the material in this section was written for the Third Edition by Robert J. DeSalvo.

TABLE 3-14. Forms of business combinations

Horizontal Combination	Vertical Combination		Conglomerate Combination	
A business combination between two companies selling identical, similar, substitutable goods and services at the same stages of production or distribution same types of customers.	A business combination that combines two or more companies' operations at different levels in the channel of distribution, from extraction or production of raw materials to the marketing of the final products. Within this form of combination, there are two subgroups.		A business combination in which there is no relationship between or the combining companies in regard to the stages of production or to the service furnished. Within this form there are two subgroups.	
	Forward Vertical Combination A business combination between two or more companies engaged in different stages of production and distribution of the final product. The combining company's stage of production is subsequent to that of the parent company.	Backward Vertical Combination A business combination between two or more companies engaged in different stages of production and distribution of the final product. The parent company's stage of production is subsequent to that of the combining company.	Circular Combination A business combination by which the joining companies' products or services are unrelated but may be distributed through the same outlets.	Mixed Combination A business combination that includes characteristics of at least two of the other forms of combinations, even though one form may be more dominant.

Source: Adapted from: Federal Trade Commission Report on the Merger Movement, 1978, p. 23.

The most frequently used method of external expansion is the acquisition. Over 95 percent of all business combinations in the drug industry utilize the acquisition type of business combination. This provides the most flexibility for achieving the mutual satisfaction of the firms involved, and in turn affects the tax considerations of the acquisition. The acquired may range from the entire firm, in which case it would appear to be similar to the merger, to the acquisition of certain assets. An example is the Dow Chemical Company's acquisition of the pharmaceutical business of Richardson-Merrell, Inc.

Although not a business combination in the true sense because there is no change of ownership, the joint venture has been utilized increasingly by many firms as a means of expansion. In some cases it serves as the precursor to an actual business combination. Usually the joint venture is an agreement between two or more firms to undertake some marketing function—for example, distribute products in a foreign country or work together to develop some type of new delivery system. A large number of joint ventures have been undertaken with foreign firms, illustrating the interest of the drug industry in expanding markets on an international scale.

The combinations that drug industry firms have been involved in are usually horizontal or conglomerate in form. Although both of these forms characterize the business combinations that are taking place, the number of conglomerates has been increasing at a faster rate. Business combinations between firms within the industry result in various degrees of product integration. The amount of integration depends upon the product similarity, identification of product with its manufacturer, size of the companies involved, outlets available, amount of distribution desired, and the parent company's extent of control. An example of integration in the drug industry is the Pfizer purchase of J. B. Roerig Company. Both firms manufacture prescription-legend and nonprescription-legend drugs. In both cases the same outlets are available, but the J. B. Roerig Company has been operated as a fully owned subsidiary maintaining its own sales force.

The most representative business combination of the vertical form was the Merck & Company merger of Sharp & Dohme. Merck was primarily engaged in developing, manufacturing, and distributing chemicals, while Sharp & Dohme was primarily a pharmaceutical and biological product manufacturer that processed chemicals into finished products and marketed them to members of the medical profession. Another example of vertical integration is that of drug wholesalers acquiring manufacturers of drugs as well as medical supplies and equipment.

CASE IN POINT

Choosing an OTC Partner

While the Upjohn Company and Marion Laboratories are clearly very much in the pharmaceutical industry, when each determined to enter the consumer markets in a major way with OTC products converted from the prescription marketplace, each elected to find a partner familiar with the very different world of consumer marketing. Upjohn chose Bristol-Myers to sell its Ibuprofen (which it had on license from Boots). Marion picked Schering to start early on sucralfate. In 1988, before but anticipating approval of an Rx-to-OTC shift, Schering detail staff were "rented" by Marion to assist in promotion of the product to physicians.

Source: *FDC Reports*, January 16, 1989.

CONCLUSION

Attempts to analyze or characterize the pharmaceutical industry are confounded by its complexity. Even focusing on the manufacturing component leaves one with a kaleidoscopic collection. In contrast with, for example, the automobile industry, the pharmaceutical industry consists of literally hundreds of companies producing thousands of products for markets with varying levels of power and overlaid with several types of regulation.

The potential entrant does so at his peril. Yet the glamor, the sometime profitability, and the virtual assurance of some kind of future market, guarantee that there will always be candidates for a place in the industry.

It is essential to remember, again, that the pharmaceutical industry is really several industries. There is a prescription drug industry, an OTC industry, a cardiovascular industry, a generic industry, a hospital industry . . . the list could go on. Industry analysis, then, using the Porter model or any other paradigm, should be approached from the perspective of its relevance to the analyst and his competition.

Chapter 4

The Customers

In the previous chapter considerable attention was given to the buyers in the Porter Model of Competition. Absent from the discussion was the most important buyer of all, the patient/consumer. The omission was, of course, intentional. The consumer requires special attention and, in fact, rarely buys directly from the manufacturer of either prescription or non-prescription drugs.

Also absent from Porter's model was the physician. In this case the omission results from the unusual circumstances in the pharmaceutical industry wherein for prescription drugs at least, the ultimate consumer is minimally involved (at present) in the drug selection process.

In this chapter we will focus on the patient/consumer and on the prescriber. In both cases we will provide a description of who they are and what is known about how and why they behave from the point of view of market analysis and the strategy formulation that results from that analysis.

MARKETS: DEFINITION AND STRATEGIES

Even the most colloquial use of the term marketing implies the existence, somewhere, of a market. But what constitutes a market? If this question were asked of 100 marketing executives in the pharmaceutical industry, almost certainly 100 different answers would be given. Even the American Marketing Association has, through the years, provided as many as four definitions for the term:

1. The aggregate of forces or conditions within which buyers and sellers make decisions that result in the transfer of goods and services.
2. The aggregate demand of the potential buyers of a commodity or service.
3. The place or area in which buyers and sellers function.

4. (As a verb) To perform business activities that direct the flow of goods and services from producer to consumer or user.

Probably the most useful of these definitions is the second, which emphasizes the importance of demand for the product. This in no way negates the correctness of the other definitions, which are proper in suitable context. The particular advantage of the second definition lies in its ability, upon clarification, to serve simultaneously as a definition and as an introduction to market segmentation.

Aggregate demand refers to the composite of the individual demands of all the potential buyers of a product. Each market is made up of a number of different market segments, each composed of a group of buyers or buying units (in the special case of the pharmaceutical industry, prescribers, or prescribing units), who share qualities that make that segment distinct and give it significance to marketing. Another way of stating this is that a market is not only an aggregate demand for a product but consists of the sum of the demands of different market segments.

Even a single characteristic common to a group of people is sufficient to classify this group as a market. For example, the use of cosmetics is great enough to group a population of women into the cosmetic market. Past use of cosmetics is not a sufficient qualification for marketing purposes. The marketer is also interested in those who may buy cosmetics in the future. For this portion of the market it would perhaps be better to use the term prospect, rather than market. Differentiation within the market, however, does not end here. Continuing with the cosmetic example we might speak of the luxury cosmetic market when referring to a specific segment of those who use (or may use) cosmetics. The door-to-door market is a further type of qualification that may be desirable, which may be broken down to the "Revlon" market, the "Maybelline" market, and others.

The importance of subclassifications within the market is easily exemplified within the ethical pharmaceutical industry. It seems safe to state that no one within the entire population is immune from being classified in some portion of the prescription drug market, particularly if we are to include prospects. Thus, if we are to speak only of the ethical drug market in its most general terms, we must include the entire population.

The pharmaceutical market is unique in the importance of the influence of a nonpurchaser on the purchasing habits of the ultimate consumer. Because of the veto power of physicians in regard to the acceptance of a prescription drug, it becomes necessary to classify physicians as thoroughly as the patients. A further peculiarity of the pharmaceutical market is the importance of the disease entity. With a few exceptions, such as the oral contraceptives, incidence of disease is an important classificatory de-

vice for identifying and quantifying a market for a prescription drug product.

The crux of any strategy formulation effort is market definition. The problem of identifying competitive product/market boundaries pervades all levels of marketing decisions. Such strategic issues as the basic definition of a business, the assessment of opportunities presented by gaps in the market, the reaction to threats posed by competitive actions, and the decisions on major resource allocations are strongly influenced by the breadth or narrowness of the definition of competitive boundaries. The importance of share of market for evaluating performance and for guiding territorial advertising, sales force, and other budget allocations and the growing number of antitrust prosecutions also call for defensible definitions of product/market boundaries.

Defining the market is a difficult task, however, since as already noted, market can be defined in many ways.

Traditionally, market boundaries have been defined in terms of product/market space. For example, consider the following definitions: A market is sometimes defined as a group of firms producing identical or closely related products. . . . A preferable approach is to define the markets in terms of products. . . . [What is meant by] a close relationship among products? Goods and services may be closely related in the sense that they are regarded as substitutes by consumers, or they may be close in that the factors of production used in each are similar (Asch, *Economic Theory and the Antitrust Dilemma*, Wiley, 1970).

A market usually is identified with a generic class of products. One hears of the beer market, the cake-mix market, or the cigarette market. These are product markets, referring to individuals who in the past have purchased a given class of products (Sissors, *Journal of Marketing*, July, 1978).

These two definitions view the market as either who the buyers are or what the products are. In the first definition, the buyers are implicitly assumed to be homogeneous in their behavior. The second definition propounds that the products and brands within the category are easily identified and interchangeable, and that the problem is to search for market segments.

CONSUMERS

Who They Are

The market segment just mentioned refers to some homogeneous set of customers with (presumably) similar needs and characteristics. The large

market has a variety of submarkets or segments which vary substantially. One of the crucial elements of marketing strategy is to choose the segment or segments that are to be served. This, however, is not always easy. There can be different methods for dissecting the market. Deciding which method to use may pose a problem. Segmentation is aimed at increasing the scope of business by closely aligning a product or brand with an identifiable customer group.

Segmentation criteria will vary depending on the nature of the market. In marketing, one may use simple demographic and socioeconomic variables, personality and lifestyle variables, or situation-specific events (such as use intensity, brand loyalty, attitudes, etc.) as the bases of segmentation. For prescription drugs such factors as nature of the illness and types of third-party payment become important (see Table 4-1).

The key is to choose a variable or variables which so divide the market that customers in a segment have similar responsiveness to some aspect of the marketer's strategy. The variable should be measurable, i.e., it should represent an objective value such as income, rate of consumption, frequency of buying, etc., not simply a qualitative viewpoint such as the degree of customer happiness. Also, the variable should create segments which may be accessible through promotion or product development.

Once segments have been formed, the next strategic issue is deciding which segment should be selected. The selected segment should comply with the following conditions.

1. It should be one in which the maximum differential in competitive strategy can be developed.
2. It must be capable of being isolated so that the competitive advantage can be preserved.
3. It must be valid, even though imitated.

TABLE 4-1. Bases for pharmaceutical customer segmentation

Consumer Markets	
1.	Demographic Factors (age, income, sex, etc.)
2.	Socioeconomic Factors (social class, stage in the family life cycle)
3.	Geographic Factors
4.	Psychological Factors (lifestyle, personality traits)
5.	Consumption Patterns (heavy, moderate, and light users)
6.	Perceptual Factors (benefit segmentation, perceptual mapping)
7.	Brand-Loyalty Patterns
8.	Medical Condition

The choice of strategically critical segments is not a straightforward task. It requires a careful evaluation of business strengths as compared with the competition. It also requires analytical marketing research to uncover market segments in which these competitive strengths can be significant.

In a population that is changing and growing as rapidly as ours, the use of statistics in a text such as this seems almost pointless, because data become immediately obsolete. Statistics can be used as examples, however, to point out relationships, even though the numbers themselves may be outdated.

Study of the size and character of the market obviously involves more than mere nose counting (although this may be of paramount importance to the antihistamine manufacturer). The demographic data that may be necessary for any evaluation of the consumer market for prescription drugs must include, among other factors, the sex, age, and income of the population. For other types of products a great many other considerations, such as occupation, religion, educational status, and mobility must also be considered. An example of market variability is provided by the data in Table 4-2, which deal with physician visits, a precursor to most prescriptions.

From the manufacturer's viewpoint, sex is an important demographic characteristic. It has been shown that women comprise somewhat more than their expected half of the population, and this trend is expected to continue. Perhaps even more important, as far as the manufacturer is concerned, is the finding that women account for significantly more than their share of the health care market, prescription drugs included. The obvious special interest in the sexual makeup of the population by the manufacturers of such drug products as estrogens, vaginal creams, and oral contraceptives would seem to require little elaboration.

Data on age are of interest in a general way to all of industry. The relative proportion of the population in each age category is important not only for purposes of forecasting demand for an individual class of prescription products (e.g., antispasmodic for infant colic), but also to help direct research efforts. Particularly important trends for the pharmaceutical industry are found in the 0- to 19-year and 65+ age categories. Not only do these groups offer specialized product development opportunities, but they are the two categories most frequently considered in the development of government health care programs. Both of these considerations must enter into the long-range planning of pharmaceutical manufacturers. A further consideration is the fact that these two segments of the popula-

tion demand proportionately more health care than do other segments of the population.

Because level of income determines the total available monies for expenditure on drug products, this statistic becomes extremely important. A further consideration is the importance of income levels in determining the type and level of health-care purchases. For example, the greater the affluence of a given family unit, the more likely for its members to seek medical attention (with the potential of resultant prescriptions) for increasingly minor ailments. Those in the lower income brackets lean more heavily toward self-medication for such things as colds and aches and pains. (It should be noted that programs such as Medicaid may confound intuition in this regard and market research is essential.)

CASE IN POINT

Segmenting Elderly Markets

Even within segments based on a single characteristic there are often subsegments. In a study conducted at Georgia State it was concluded that people age along biophysical and psychosocial lines in different ways. Four categories were identified to illustrate this phenomenon:

- *Health hermits, who made up 38% of the survey respondents, are in good health but have little interest in staying active or making social contacts. They are an especially good market for tax and legal advice, home entertainment, do-it-yourself products and domestic services. They can be reached most effectively through direct mail and print media.*
- *Ailing outgoers, about 34% of the respondents, are in poor health but are still socially active and health-conscious because of an unwillingness to accept "old-age" status. This category would be the target of planned communities, medical and health services, and leisure marketers. The best ways to reach them are through cross-selling (pitching related products at the same time), sales promotions and special services.*
- *Frail recluses, about 15%, are also in poor health but are socially and psychologically withdrawn. They make good targets for home health-care marketers, medical services and home entertainment concerns, and are best reached through mass media and cross-selling.*
- *Health indulgers, the remaining 13%, are outgoing and in good*

TABLE 4-2. Physician contacts, according to place of contact and selected patient characteristics: United States, 1987

Characteristic	Physician Contacts	Place of Contact: Doctor's Office	Place of Contact: Hospital Outpatient Department	Place of Contact: Telephone	Place of Contact: Home
	1987	1987	1987	1987	1987
	Number per person	Percent Distribution			
Total	5.4	57.1	14.1	13.4	2.1
Age					
Under 15 years	4.5	57.9	12.8	17.1	*0.7
Under 5 years	6.7	57.6	13.0	18.3	*0.6
5-14 years	3.3	58.2	12.6	15.6	*0.8
15-44 years	4.6	56.4	14.5	12.3	0.7
45-64 years	6.4	56.9	15.3	12.2	3.6
65 Years and over	8.9	57.8	13.8	9.9	8.6
65-74 years	8.4	59.1	14.7	9.3	6.3
75 years and over	9.7	55.9	12.7	10.7	11.9
Sex					
Male	4.6	57.0	15.7	11.4	1.8
Female	6.0	56.9	13.1	14.8	2.3
Race					
White	5.5	58.6	12.8	14.1	2.0
Black	5.1	47.2	23.5	7.8	3.1

Characteristic	Physician Contacts	Place of Contact: Doctor's Office	Place of Contact: Hospital Outpatient Department	Place of Contact: Telephone	Place of Contact: Home
	1987	1987	1987	1987	1987
	Number per person	Percent Distribution			
Family Income					
Less than $10,000....	6.8	43.8	19.2	12.8	3.9
$10,000-$14,999.....	5.6	51.1	17.8	13.4	1.7
$15,000-$19,999.....	5.2	54.7	16.8	12.6	1.8
$20,000-$34,999.....	5.2	59.6	12.6	14.9	1.3
$35,000 or more.....	5.4	62.3	11.2	13.8	1.7
Geographic Region					
Northeast.....	5.2	56.5	15.8	12.5	3.5
Midwest.....	5.6	53.2	14.5	15.6	1.7
South.....	5.1	61.1	12.6	12.3	2.2
West.....	5.5	56.4	14.4	13.4	0.7
Location of Residence					
Urban.....	5.5	55.7	14.6	13.8	2.1
Non-Urban.....	4.8	62.1	12.0	12.1	1.7

health; they still want to live well, see new places and do new things. Consumers in this category are ripe for financial services, travel and entertainment, clothing and high-tech products. The best ways to reach them: in-store special promotions, specialized print media and direct mail.

Source: *Wall Street Journal*, October 31, 1988.

How the Consumers Behave

Over four decades ago, psychologist Abraham Maslow noted that people typically try to fulfill some kinds of needs only after other, more primary needs have been satisfied. He identified five different need categories that can be arranged into a vertical hierarchy, with the most primary at the bottom step and those of the highest order at the top. According to this psychologist, an individual normally tries to satisfy the most basic needs first and, satisfying these, he is then free to devote his attention to the next on the list.

The Need for Self-Actualization. This is the desire to achieve to the maximum of one's capabilities and, although it may be present in everyone, its fulfillment depends upon the prior fulfillment of the more basic needs.

The Esteem Needs. People need both self-esteem, a high evaluation of self, and the esteem of others in our society. Fulfillment of these needs provides a feeling of self-confidence and usefulness to the world; failure to fulfill these needs produces feelings of inferiority and helplessness.

The Belongingness and Love Needs. The need for affectionate relations with individuals and a place in society is so important that its lack is a common cause of maladjustment.

The Safety Needs. In modern society these needs are more often reflected in the needs for economic and social security rather than in needs for physical safety.

The Physiologic Needs. This group includes hunger, thirst, sleep, and so forth. These are the most basic needs, and until they are satisfied other needs are of no importance.

At first glance it would seem that pharmaceuticals solve only the physiologic needs. New developments in prescription drugs, however, give promise of meeting more and more of these needs. Certainly many other products currently offered in pharmacies are designed to meet these specific needs. Interestingly, recent developments help us understand that pharmaceuticals, rather than exerting their power at the *bottom* of the list, may actually be most important at the *top*.

What is the ultimate motivation in life? Our minds are filled with Darwinian notions of survival, but survival needs are primary needs; they are basic needs, but they are not the ultimate needs in life. The ultimate need, the most far-reaching, comprehensive motive in life is self-fulfillment or self-actualization. But like most profound ideas, self-fulfillment is much easier to recognize when it is described than it is to define in precise terms.

Philosophers and theologians have argued about the meaning of life for centuries, and we surely do not want to join that argument. But there is still an important, unanswered question: What do people do when they have enough satisfaction for their physical, safety, belonging, and status needs? What do they pursue then? The answer is self-actualization, the complete fulfillment of all of their human capacities. This means enlarging and enhancing themselves. It means extending their personal identities, their individuality, their uniqueness.

It is easy to see that most of us are busy trying to fulfill more basic needs than self-fulfillment most of the time. We all spend most of our lives trying to stay alive and healthy, to be secure, to maintain our relationships with our family and friends, and to get some respect and recognition for who we are as people. Most consumers' minds are occupied with their efforts to stay well, get along with people, and look good while doing so. It takes a lot of time, experience, and maybe even some wisdom just to meet those basic needs. So most people do not really get to the point where they can pursue self-actualization until they have a few decades behind them. Pursuing this kind of need satisfaction is much more typical of the mature consumer than of younger people who are still striving for the more basic things in life.

A reference to elderly people usually conjures up images in people's minds of poverty and destitution, loneliness and ill health. In fact, nothing could be further from the truth. Only a very small fraction of elderly consumers in this society fit that stereotype. Yet most people think that way because elderly people in such unfortunate circumstances get most of the media attention. They certainly deserve our concern, but marketers should not generalize that image to the entire group.

We can point out one rather surprising statistic that may help dispel

some of the misconceptions about mature consumers: By the 1990's, about half of all the disposable personal income in this country will be in the hands of people over fifty years of age! These are precisely the people most likely to have reached a place in life where they can and do pursue fulfillment of their self-actualization needs.

It is also well to note that self-actualization can refer to getting the most out of the life one has, even if it is impaired. With that view the pharmaceutical industry in the latter part of the 1980's began earnest study of the role of their products in the "Quality of Life" of the chronically ill. Indeed, this attribute has become a part of both clinical trials and promotional themes.

While it is very useful, if not absolutely necessary, to examine the hierarchy of needs, we are not confined only to a vertical view. We can also look at consumer needs from a cross-sectional point of view as well. From this horizontal perspective, no single category of needs consistently takes precedence over the others. What is more, this approach permits us to identify more categories and specify them more precisely. These needs are not classified according to the sequence in which consumers approach them. Instead they are based on the kinds of concerns and activities that consumers associate with them. So these categories of needs are more often closely associated with particular types of consumer products, services, brands, and outlets.

In Table 4-3, 15 fairly distinct categories of consumer needs are listed on the left, followed by a brief description of each. Below each need category, several kinds of related pharmaceutical goods and services are identified.

The lists of goods and services certainly are not all-inclusive or exhaustive, but the products and services identified there are typical of goods that serve each kind of need. There is not a one-to-one association between different needs and various consumer goods. Obviously there is some overlapping. Yet this list of collateral needs is more fine-grained than only the five categories in the need hierarchy. So we can legitimately draw some generalizations about what goes with what—about the most common products and services associated with each type of need. It is easy to recognize the utility in doing so: By examining the different needs and the kinds of consumer goods most often used to meet them, one can identify the most appropriate needs for basing an appeal strategy for a particular product or service.

Needs lead to behavior and there are a number of models of consumer behavior available. We have chosen to use as a framework the model developed by Andrew Twaddle. It is simple but comprehensive, and is based on the concept that sickness is a decision-making career. Twaddle's

TABLE 4-3. Consumer needs and pharmaceutical markets

Achievement

The need to accomplish difficult feats; to perform arduous tasks; to exercise one's skills, abilities, or talents.

(Steroids, Ritalin, Vitamins, Appetite Suppressants, Tranquilizers.)

Independence

The need to be autonomous, to be free from the direction or influence of others; to have options and alternatives; to make one's own choices and decisions; to be different.

(Compliance Aids, Seizure Medicines, Patient Controlled Analgesic, Home Diagnostics, All-OTCs.)

Exhibition

The need to display one's self, to be visible to others; to reveal personal identity; to show off or win the attention and interest of others; to gain notice.

(Rogaine, OC's, Appetite Suppressants, Oral Contraceptives.)

Recognition

The need for positive notice by others; to show one's superiority or excellence; to be acclaimed or held up as exemplary; to receive social rewards or notoriety.

(Steroids.)

Dominance

The need to have power or to exert one's will on others; to hold a position of authority or influence; to direct or supervise the efforts of others; to show strength or prowess by winning over adversaries.

(P&T Committees, Physician Prescribing.)

Affiliation

The need for association with others; to belong or win acceptance; to enjoy satisfying and mutually helpful relationships.

(RPh./Professional Organizations, Senior Citizen's clubs.)

TABLE 4-3 (continued)

Nurturance

The need to give care, comfort, and support to others; to see living things grow and thrive; to help the progress and development of others; to protect one's charges from harm or injury.

(Mothers as advocates/surrogates for child, Geriatrics.)

Succorance

The need to receive help, support, comfort, encouragement, or reassurance, from others; to be the recipient of nurturant efforts.

(RPh counselor, MD satisfaction.)

Sexuality

The need to establish one's sexual identity and attractiveness; to enjoy sexual contact; to receive and to provide sexual satisfaction; to maintain sexual alternatives without exercising them; to avoid condemnation for sexual appetites.

(Sexual Dysfunction, Beta blockers, Oral Contraceptives.)

Stimulation

The need to experience events and activities that stimulate the senses of exercise perception; to move and act freely and vigorously; to engage in rapid or forceful activity; to saturate the palate with flavor; to engage the environment in new or unusual modes of interaction.

(Non-sedating Antihistamines, Caffeine, CNS Stimulants, Flavors - Cholybar, Ceclor.)

Diversion

The need to play; to have fun; to be entertained; to break from the routine; to relax and abandon one's cares; to be amused.

(Alcohol, Antidepressants, Minor Tranquilizers.)

Novelty

The need for change and diversity; to experience the unusual; to do new tasks or activities; to learn new skills; to

be in a new setting or environment; to find unique objects of interest; to be amazed or mystified.

(New dosage forms, self-monitoring, "Little, different, yellow, better.")

Understanding

The need to learn and comprehend; to recognize connections; to assign causality; to make ideas fit the circumstances; to teach, instruct, or impress others with one's expertise; to follow intellectual pursuits.

PDR's for Consumers, Counseling, PPI's/Antipsychotics, Ritalin.)

Consistency

The need for order, cleanliness, or logical connections; to control the environment; to avoid ambiguity and uncertainty; to predict accurately; to have things happen as one expects.

(Laxatives.)

Security

The need to be free from threat of harm; to be safe; to protect self, family, and property; to have a supply of what one needs; to save and acquire assets; to be invulnerable from attack; to avoid accidents or mishaps.

(Patient Medication Profiles.)

Source: Adapted from Settle and Alreck, *Why They Buy*, Wiley, 1986.

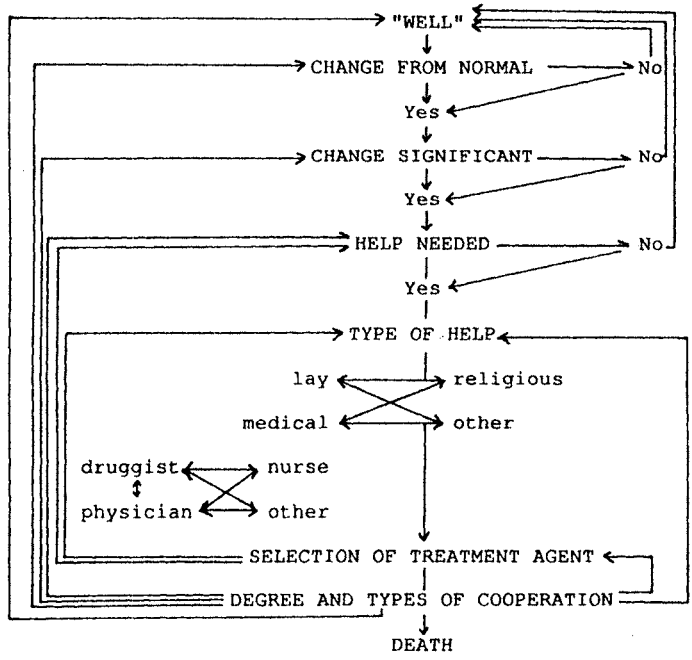
premise is that illness is an altered state of well-being about which an individual makes a series of decisions. These appear in Figure 4-1.

Has a Change from Normal Occurred?

Trying to define "normal" for society is difficult, but is not really necessary for the present discussion. Normal, for our purposes, and for those of the patient, is whatever the patient perceives it to be. For that reason, of course, the characteristics of normality vary from individual to individual.

In any case, changes from normal can take several forms. The most typical one is what we usually call symptoms. For most people pain is not

FIGURE 4-1. Decision steps in sickness career



Source: Twaddle, A. C., and Hessler, R. M.: *A Sociology of Health*, St. Louis: C. V. Mosby, 1977.

normal, nor is constipation. Thus, these symptoms represent a change from normality. Another kind of change is altered capacity—for instance, the inability to cut the grass without becoming winded. This kind of change may, of course, be attributed to something other than illness, such as aging. (Indeed some such changes should be so attributed, but stereotyping can result in misdiagnosis.)

It should be obvious that some people enter the health care system without experiencing any change from normality. Many hypertensive patients, for example, are diagnosed even though they are asymptomatic. Such patients begin their sickness careers as a result of routine checkups or screening programs.

Drug manufacturers and public health proponents also are concerned with helping people decide that a change has occurred. "Cancer's Seven Danger Signals" are described in terms of deviations from normality,

while some commercials for non-prescription drugs describe, or at least imply, physical changes that should (or should not) occur in a normal individual.

The role of tolerance threshold should be obvious. Some people stoically bear levels of pain that would send others immediately for help. Some variations are cultural—men are supposed to be macho—but ethnic variations in response to pain have also been demonstrated.

Symptoms are likely to be defined as serious in a direct relationship to their unfamiliarity to the patient or to the degree to which they seem threatening. Mechanic (*Medical Sociology*, The Free Press, 1968) has also found that symptoms that persist or recur tend to be viewed as serious.

Assumptions about cause include a component of ambiguity. The seriousness attached to back pain, for example, may differ depending on whether the patient believes it is due to muscle pain or to a kidney disorder. The same is true for assumptions about prognosis. Symptom seriousness appears to be related directly to the length of time it is expected to last, to the degree of incapacity expected to be associated with it, and to the degree to which death is thought to be a likely outcome.

Interpersonal influence often takes the form of what has been referred to as the "lay referral system"—that is, the network of friends and relatives who are consulted when a symptom is experienced. It should be apparent that the influence of these significant others is in turn a function of the degree to which they are influenced by their personal perceptions of the factors under discussion.

It is well known that many symptoms are experienced routinely by the population, yet many never do anything to relieve these symptoms. Some studies have shown that social stress from other life crises may be a trigger to action. A person who has lived with intermittent bouts of stomach pain may, stimulated by a divorce action, suddenly decide to seek medical care.

Treatability apparently affects perception of seriousness in that conditions perceived as untreatable are likely to take on the identity of handicaps rather than of sickness. Physical manifestations (such as visibility to the patient and to others) are likely to result in attaching greater seriousness to symptoms. The same is true for the way the patient handles his symptoms. Grimaces and groans by the patient, whether voluntary or involuntary, are likely to lead to a greater level of severity being attached to the condition by those around him.

It should be clear from the foregoing that health decisions are complex, subjective, often emotional, and subject to influence by others.

Significance of the Change

Among the factors that appear to enter into the patient's decisions concerning symptoms are the following:

1. Extent of interference with normal activities or characteristics.
2. The clarity of the symptoms.
3. The tolerance threshold of the symptomatic person.
4. The familiarity and seriousness of the symptoms.
5. Assumptions about cause.
6. Assumptions about prognosis.
7. Interpersonal influence.
8. Other life crises of the symptomatic person.
9. Assumptions about treatability.
10. Physical manifestations.
11. Impression management.

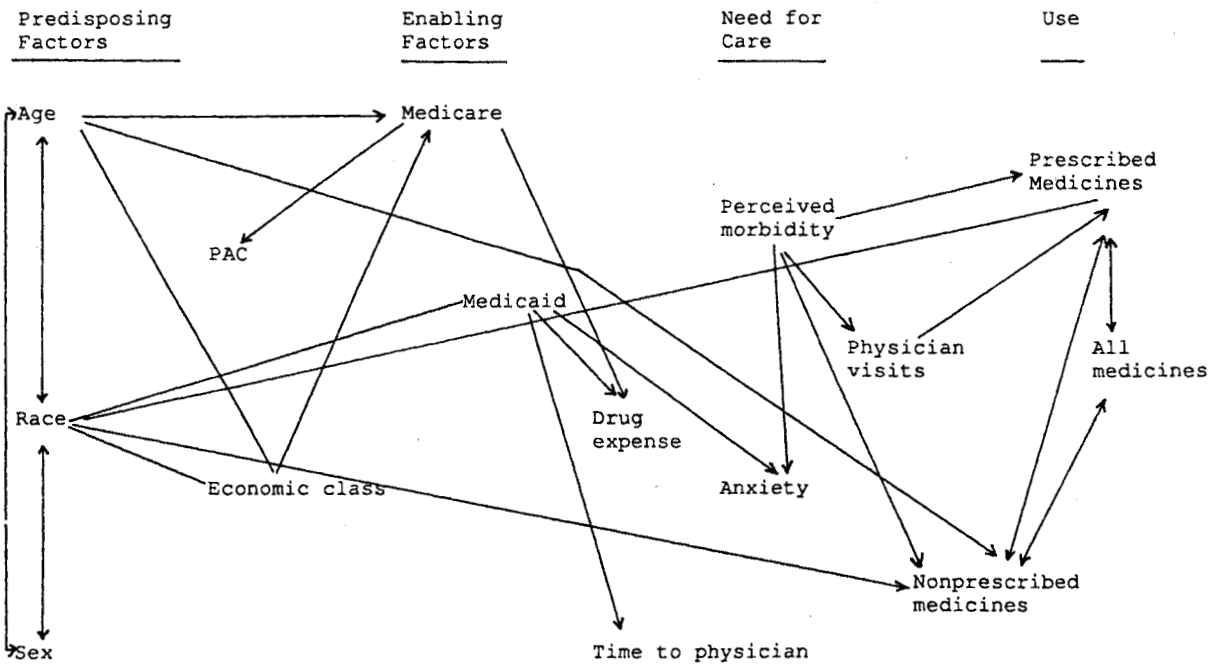
This list is not necessarily exhaustive, and the evidence supporting the impact of each factor is sometimes equivocal. Nevertheless, there is some evidence in each case that these factors play some (usually unquantified) role in the complex decision-making process of the patient as he pursues his sickness career.

It has also been found that the more a condition inconveniences an individual (or sometimes those with whom he relates), the more likely it is to be viewed as significant. The same is apparently true for symptom clarity—the more obvious the meaning of the symptom, to the patient or to those around him, the more significance will be attached to it.

Need for Help

We have shown that there are a number of often related factors involved in the decision that a symptom is significant. Even having made that decision, however, it is by no means universally true that the patient will decide to seek aid as opposed to self-treatment or even capitulation to the illness. Examples of the behavior variations involved have been shown in many studies. In one such study Bush and Osterweis (*Journal of Health and Social Behavior*, 1978) used a quantitative technique called Path Analysis to determine some of the factors involved in the use of prescribed and nonprescribed medicines. A simplified version of the "path diagram" that they produced is shown in Figure 4-2; the arrows in the diagram

FIGURE 4-2. Path diagram of factors related to medicine use



Source: Bush, P. J., and Osterweis, M.: Pathways to Medicine Use, *Journal of Health and Social Behavior*, 19: 179, 1978.

indicate the direction of influence. (The degree of influence has been omitted in the interest of simplicity.)

The main findings of this study of more than 2300 people in Baltimore were as follows:

- Perceived morbidity is the principal predictor of medicine use, especially prescribed medicine with physician intervention.
- Anxiety has an effect on the use of prescribed medicine.
- The more convenient and available medical care is perceived to be, the more likely persons are to use nonprescribed medicines.
- Age, sex, and race are factors in both types of medicine use, with males, nonwhites, and the young using fewer drugs.
- Neither Medicare, Medicaid, nor economic class had significant effects on drug use.

Type of Help Needed

Once the decision to seek help has been made the patient is still faced with a decision as to type. Although the physician is our society's model for primary care, he is by no means the only alternative. There are, for example, dentists, podiatrists, optometrists, chiropractors, clinical psychologists, and many other nonphysician health care providers. Choice of type will be a function of social, cultural, economic, educational, emotional, geographic, and legal factors.

Svarstad, in an unpublished paper, offered a process explanation of one such decision, the decision to self-medicate. From her review of the literature she suggested the following:

- As high as 20 percent of people use nonprescription drugs in response to an illness episode.
- Females make greater use of all types of drugs than do males.
- Little is known (or at least published) about the nature of individuals' decisions to use particular drug products or to follow a particular drug regimen.

Selection of Treatment Agents

For prescription drugs it is still accurate to state that most selection decisions are made by someone (usually the physician) other than the patient. That selection process will be reviewed later in this chapter. This is not to say that the patients have no interest in the process.

Stimson, in a British study (*Journal of the Royal College of General Practitioners*, 1979), found that patients were not as prescription-oriented when visiting the physician as many seem to believe. Rappoport, also in

England (*Journal of the Royal College of General Practitioners*, 1976), found that 56 percent of a sample of patients expected to receive a prescription. Perhaps more interesting was the finding that 24 percent intended to buy an over-the-counter (OTC) product from a pharmacy after leaving the physician's office. Perhaps most interesting, 50 percent of those who expected a prescription but did not obtain one intended to purchase a product for self-medication. To further confuse this issue, another study reported finding that patients who did not receive prescriptions reported more satisfaction with the communicative aspects of their visits to physicians than did patients who received prescriptions.

The consumer is, of course, intimately involved in the selection and purchase of non-prescription drugs. That process can also be a complex one. Figure 4-3 provides direction in understanding the process of self-medication on a qualitative level. The timing of the steps in this process and the quantification of the proportions of consumers who proceed through the various steps shown are a continuing challenge to OTC drug marketers.

CASE IN POINT

MD Recommendations for OTC's

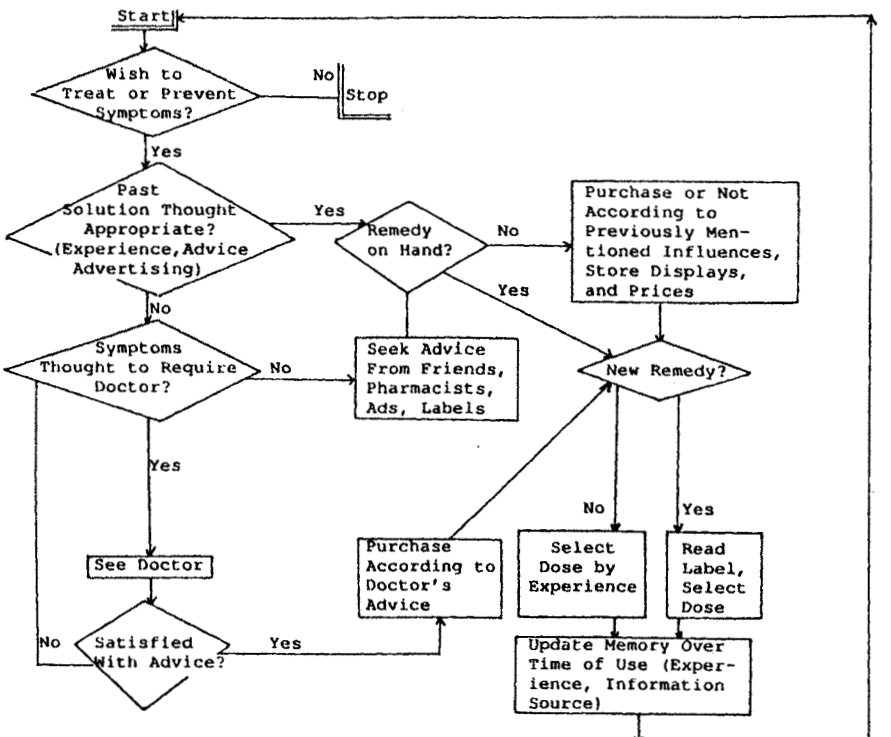
The January 27, 1989 issue of the Journal of the American Medical Association contained six advertisements for non-prescription drugs. Why? Surely the advertisers hope for and expect physician influence on consumer choice. Are these hopes and expectations realistic? Apparently yes.

More pediatricians recommend Tylenol than any other brand of over-the-counter pain reliever. Many other companies can share McNeil's satisfaction in knowing that their products, too, got the highest recommendations in their categories. Among them are household names such as Robins' Dimetapp and Robitussin for colds, Rorer's Maalox for upset stomachs, Parke-Davis' Benadryl for itching, Glenbrook's Phillips' Milk of Magnesia for constipation and Bayer (among aspirins) for pain, Lever's Dove soap, Richardson-Vicks' Chloraseptic for sore throat, and Whitehall's Advil (among ibuprofen) for pain.

What drove these brands to their lofty positions may be the one element they all share: even though they are consumer-driven products and any consumer can walk into a supermarket or a drugstore and just pick them off the shelf, they are all advertised to healthcare professionals.

Source: *Medical Advertising News*, March 1, 1988.

FIGURE 4-3. Self-medication model



From: Hustad, T. P., Courtney, A. E., and Heeler, R. M.: An Emerging Model for Purchase and Consumption of Non-prescription Drugs, *Journal of Consumer Affairs* 13(1): 81-85, 1979.

Patient Compliance

Patient compliance is crucial to successful therapy. It is also important to call attention to certain economic factors—notably, the various cost dimensions related to drugs—that may affect the compliance performance of the patient either positively or negatively. Aside from the medical implications, it should be clear that this is also ultimately a marketing issue at both the retail and manufacturers' levels.

The ninth edition of the *Schering Report* (1987) provided insights into the phenomenon of unfilled and improperly taken prescriptions. Each year, 100 million prescriptions go unfilled—resulting in a loss of $1.2 billion to the nation's pharmacies. Non-compliance is, of course, more than an economic problem for the pharmacist; it is a national health concern. An estimated 125,000 Americans die each year from failure to take their medicine as prescribed. There are also hundreds of thousands of unnecessary extra hospitalizations as well as a loss of 20 million workdays.

The scope of the problem is brought out by the following statistics:

- Seven percent of patients do not have their prescriptions filled.
- Fifteen percent of patients do not take their prescriptions for the full length of time.
- Thirty-two percent of patients do not have their prescriptions refilled, even though they need to do so.

Among patients who did not have their prescriptions filled after their visit to the doctor or who did not take the medication for the full length of time directed by the physician, there were some interesting observations based on demographics. The tendency for non-compliance seemed to be higher among:

- younger adults;
- better educated patients;
- those living in large urban markets; and
- those with a new medical problem.

Patients who were taking several medications each day provided an interesting scenario. As the number of medications taken each day rises, the rate of non-compliance, in terms of taking medicine for as long as directed, drops. For example:

- When no other medication is taken daily, 17 percent of patients stop taking the medicine prematurely.
- When one other medication is taken daily, 16 percent stop their new prescription prematurely.
- When two other medications are taken daily, 7 percent stop the new medicine prematurely.
- When three or more other medications are taken each day, only 4 percent stop taking the new medicine.

The majority of people (70 percent) who stopped taking their medication prematurely said they felt better and their health problem no longer bothered them. Other reasons were that they did not feel better after taking the medication, they had side effects, and the medication made them feel worse.

PRESCRIBERS

Gosselin has called prescription drugs "directed consumer goods." Another way of stating this is that prescription medication sales result from derived demand—that is, the sale of a prescription drug is not based on any choice of the consumer but rather on that of the physician. For this reason, the physician also constitutes a market for prescription drugs. Many of the same factors that affect consumer purchase patterns also affect the prescribing habits of the physician. Other recognized factors also influence the physician's decision to prescribe a given medication.

Perhaps no other group in the United States or the world has been so thoroughly classified, categorized, and identified as has the American physician. An example of just how thoroughly this has been done is shown in Table 4-4, in which physicians are classified by primary specialty and type of practice. Although there is no point in presenting them here, data are available that show all the figures presented in Table 4-4, and that provide a further breakdown by geographic area as well as prescribing patterns. More will be said of this in Chapter Five.

These data are obtained from such sources as the American Medical Association, and are constantly being updated. By using computers, changes resulting from deaths, relocations, and changes in practice can be noted and reflected in tabular form within days. Some ways in which these data are used will be presented here.

TABLE 4-4. Physicians, according to activity and place of medical education, 1970-1986.

Activity and place of medical education	1970	1986
	Number of Physicians	
Doctors of medicine	334,028	569,160
Professionally active	310,845	505,750
Place of medical education:		
U.S. medical graduates	256,427	393,314
Foreign medical graduates	54,418	107,436
Activity:		
Non-Federal	281,344	483,812
Patient care	255,027	436,877
Office-based practice	188,924	325,757
General and family practice	50,816	53,622
Internal medicine	22,950	52,287
Pediatrics	10,310	22,530
General surgery	18,068	23,542
Obstetrics and gynecology	13,847	23,580
Other specialty	72,933	150,196
Hospital-based practice	66,103	111,120
Residents and interns	45,840	77,618
Full-time hospital staff	20,263	33,502
Other professional activity	26,317	46,935
Federal	29,501	21,938
Patient care	23,508	16,985
Office-based practice	3,515	1,221
Hospital-based practice	19,993	15,764
Residents and interns	5,388	2,858
Full-time hospital staff	14,605	12,906
Other professional activity	5,993	4,953
Inactive	19,621	46,835

Physician Specialty

The number of physicians in a given specialty is important, if for no other reason than budgeting of advertising expenditures. It can be determined without too much difficulty who among the physician specialists are most likely to use a certain prescription drug in their practice. Identification of physicians by specialty can be helpful to advertisers in determining the size of the physician audience and in finding the relative use of a product by specialists as opposed to general practitioners.

Age

Pharmaceutical advertisers frequently omit physicians over 65 years of age from their direct mail advertising. This is based on the assumption that this group of physicians is less active in practice than their younger counterparts. Age, however, cannot always predict the activity or importance of the physician. Patients, particularly the elderly, tend to continue going to the older physician, with whom they have built up an accord over the years. Nevertheless, age is a factor in promotional decisions.

The Academic Market

The teacher is of interest to manufacturers who are attempting to have their products accepted as a standard item. Insofar as they influence the future prescribing habits of their students, the medical school instructor is important for marketing activity far beyond that justified by their sometimes limited practice.

In addition to demographic factors, methods have been devised for identifying other segments of the physician market. Fisher-Stevens has developed a profile of physicians based on their tendency to try new drugs. An example of such a profile is shown in Table 4-5.

Other profiles are available from this and other firms, so we have a high prescribers market. Another publication is sent to residents, interns, and decision makers in the hospital. The decision makers market includes chiefs of service, directors of intern and residency training, directors of medical education, professors in the university-affiliated teaching hospital, and medical consultants to the Armed Forces. Another source has identified such groups as "known steroid users," "known tetracycline users," etc. The possibilities for identifying and segmenting physicians in the United States seem to be endless. It seems certain that efforts to find new ways of identifying submarkets among physicians will continue.

Dentists

There are presently more than 140,000 practicing dentists in the United States, with nearly one third of them having staff affiliation in hospitals. In the limited sphere of their use of drugs, dentists can be an important source of prescriptions.

Dentists are estimated to account for nearly 50 million prescriptions annually. Among the types of medications administered, prescribed, and dispensed by dentists are narcotic analgesics, non-narcotic analgesics, antibiotics, nasal decongestants, sedatives, tranquilizers, maintenance vita-

TABLE 4-5. Fisher-Stevens Physicians' Practice Profile – Innovator/Traditionalist Counts

Specialty	Innovator	Early Adopter	Early Majority	Late Majority	Tradi-tionalist	Total
General Practice	323	2,879	3,135	5,593	1,737	13,667
General practice subspecialty*	163	584	616	1,077	468	2,908
Family Practice	182	1,772	2,280	3,062	638	7,934
Internal Medicine	404	2,276	2,512	4,365	1,187	10,744
Internal medicine subspecialty**	506	578	446	743	282	2,555
Osteopathy	274	1,651	1,878	2,477	804	7,084
Psychiatry***	408	1,087	1,214	2,086	1,101	5,896
Cardiology	316	541	447	690	251	2,245
General Surgery	239	1,482	1,610	2,761	1,179	7,271
Orthopedic Surgery	91	662	856	1,296	442	3,347
Pediatrics	230	1,244	1,348	3,250	1,561	7,633
Urology	103	532	417	606	174	1,832
Obstetrics/Gynecology****	480	2,063	2,197	3,462	1,376	9,578
All Other Spec.*****	47	85	93	153	76	454
Unspecified	68	395	358	574	311	1,706
Grand Total	1,834	17,831	19,407	32,195	11,587	84,854

*Emergency medicine, General preventive medicine, occupational medicine, public health, physical medicine, pulmonary diseases.
**Diabetes, endocrinology, gastroenterology, geriatrics, hematology, infectious diseases, neoplastic diseases, nutrition, rheumatology.
***Child neurology, child psychiatry, neurology, psychiatry.
****Gynecology, obstetrics and gynecology, obstetrics.
*****Other recognized AMA specialties that are not in one of the above groups or who are not a GP, FP, IM, DO, PD, CD, GS, ORS, U, US.

Source: Fisher-Stevens, Inc., 1981.

mins, fluoride tablets, fluoride gels, fluoride solutions, fluoride/vitamin combinations, and topical steroids.

Podiatrists

Podiatrists or chiropodists treat a variety of conditions, including ingrowing toenails, tumors, bone growths or deformities, abscess drainage, and cysts. The method of treatment by podiatrists sometimes includes drugs, although in some states their use of drugs and anesthetics is limited. Degrees awarded to this group include Doctor of Surgical Chiropody (DSC), Doctor of Podiatry (PodD or PD), and Doctor of Podiatric Medicine (DPM).

There are approximately 10,000 podiatrists in the United States, the majority in solo practice. They are concentrated in the Northeast and on the West Coast. Podiatrists are estimated to use as many as 15 drugs per day, with 3 or more of those uses being in the form of prescriptions. A study in one state showed that more than half of podiatric prescriptions were in the following therapeutic categories: oral antibiotics, topical antifungals, non-narcotic analgesics, topical antibiotics, and escharotics.

Veterinarians

Although the area of market opportunity in the field of veterinary medicine is considerably different from that for humans, many of the same drugs are employed, sometimes in the same packages and dosage forms. The field has grown rapidly in recent years, particularly in the small animal field as the nation's pet population has grown in numbers and received increasingly more medical attention.

There are more than 40,000 Doctors of Veterinary Medicine in the United States, and they are permitted to prescribe medications for animal use only.

Nurses

There are more than one million nurses in this country and, while it is difficult to quantify their influence on both prescription and nonprescription drug use, it is certainly substantial. There is a special class of nurse practitioners who have prescribing privileges in several states, and their practices are just beginning to be studied.

One study by the *American Journal of Nursing* indicated that nearly 90 percent of hospital nurses make suggestions about drugs ordered as they are required. In addition, nurses reported that they recommend initiating

therapy in such drug classes as psychotropics, analgesics, laxatives, and antiemetics.

Physician Assistants

Physician assistants (PAs) is another group of nonphysicians who influence drug use. They have the right to prescribe in the majority of states, usually with some form of physician supervision. In a study conducted by the journal, *Physician Assistant*, it was found that half of those responding issued 20 or more prescriptions per day. Among the most frequently prescribed drug categories were analgesics, antibiotics, antihistamines, antihypertensives, and cough and cold remedies.

Chiropractors

Although chiropractors do not represent a market force for prescription medications, members of this group do wield some influence among their patients. In many states they are limited to hand manipulation, and in a few states they are not granted licenses at all. In other states, however, they have branched into other methods of treatment, such as electrotherapy and diet.

Pharmacists

A handful of states in the U.S. have now enacted legislation permitting limited prescribing by pharmacists. In some cases this occurs under physician direction and using a predetermined protocol. In other cases, specifically Florida, pharmacists have been given authority to prescribe certain drugs independently. It is too early to determine the effects and the future of such programs.

*HOW THE PRESCRIBERS BEHAVE**

You have probably realized from discussions in the previous pages that the prescription drug market is unique because consumers have little input into the ethical drug selection process. Approximately 400,000 physicians in various specialties located throughout the United States decide which chemical entity should be taken for a diagnosed illness. This section focuses on the decision-making process that these physicians use when pre-

*Some of the material in this section was written by Jean Paul Gagnon for the Third Edition of this book.

scribing drugs. It presents a background on decision making and on models of physician prescribing behavior and surveys on factors affecting physician prescribing, and concludes with an explanation of observed behavior and suggestions for improvement.

Daniel Albert has suggested that:

> Decision theory is a group of related constructs that seek to describe or prescribe how individuals or groups of people choose a course of action when faced with several alternatives and a variable amount of knowledge about the determinance of the outcomes of those alternatives. (*Milbank Memorial Fund Quarterly*, 56:362, 1978)

Albert went on to state that decision theory is either descriptive (how people do behave) or prescriptive (how people should behave), and that decisions can be classified by the amount of knowledge possessed by the decision maker—for instance, decisions of certainty, in which each alternative course of action has a single well-specified outcome, uncertainty, in which each alternative course of action has a well-defined set of possible outcomes, each with a particular probability of occurrence, or ignorance, in which each action results in a range of possible outcomes but the probability of occurrence of each outcome is unknown. Using this classification of decision making, medical decisions, especially those concerning prescribing, are probably made under conditions of risk—uncertainty.

Others who have studied decision making have classified the behavior of decision makers into two types, rational and emotional. A rational buyer evaluates all alternatives completely, matches his needs with the respective abilities of the products available to fulfill these needs and, theoretically at least, makes his purchase with clear goals in mind. The emotional buyer, on the other hand, may be swayed by product attributes (or the advertising) having nothing to do with the actual need-satisfying properties of the product.

Some qualifications need to be made at this point. For one thing, there is the tendency to equate rational buying with intelligent buying. This assumes too great an ability on the part of the buyer to identify the important product qualities necessary for his complete satisfaction intelligently. In essence, then, the buyer may be rational but inept. It should also be pointed out that rational and emotional motives may occasionally be combined. A physician, for example, may use the most rational therapeutic approach when choosing the proper chemical entity for treating a given condition, and then may use completely emotional criteria for the choice of the brand of that drug to employ. The basic motivations behind a physician's choice of drug therapy must be considered to be rational. He would

be expected to select the product that would do the most good with the least possible side-effects, and perhaps the lowest cost. In most cases of drug selection, however, physicians try to make a rational decision under conditions of uncertainty.

Pharmaceutical marketers try to assist in this process. There are many interacting variables that influence a physician's ultimate selection of a drug. Thus, whether it takes place in the office of a general practitioner or that of a psychiatrist, it is never a simple operation involving only symptom and a treatment intended to eradicate the symptom. It always includes a multiplicity of components.

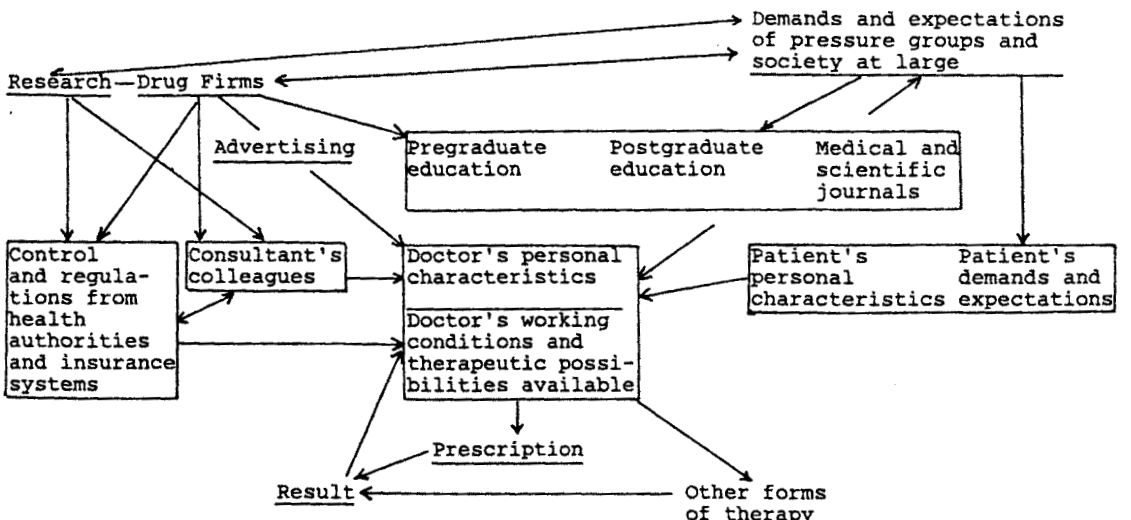
Included among the variables in the prescribing process are the clinical and behavioral characteristics of the patient, the patient's needs and expectations regarding treatment in the use of medication, the attitudes, expectations, and training of the treating physician, and the organizational and contextual constraints placed upon the doctor-patient relationship by features of the treatment and of the institution. Because physician prescribing is a system, it can be best understood by employing the methods of systems research.

Various researchers have examined the decision-making process behind physician prescribing and have proposed explanations for it. Knapp and Oeltjen (*American Journal of Public Health, 62,* October, 1972) in an experimental study of risk-benefit assessment by general practitioners and internists regarding drug selection, posited that the probability of a practitioner prescribing a drug for a particular case was a function of (1) physician expectancy that a beneficial effect on a patient's condition would occur if the drug were prescribed, (2) the amount of beneficial effect to be gained, (3) the expectancy of drug side-effects, and (4) the magnitude of these side-effects. Utilizing this analytic framework, the authors found "disease seriousness" and medical specialty to be highly related to perceived risks in the decision to medicate a patient in four hypothetical cases of hypothetical cases of hypertension.

Hemminki has reported that the major influences on prescribing are research and the pressures from drug firms, and proposed the simplified model in Figure 4-4 to describe the decision-making process for prescribing drugs. She observed that:

> Research and drug firms are closely dependent on each other, and may affect physicians through education, scientific journals, and advertising according to the doctor's personal characteristics, his work and his therapeutic opportunities and that patient demands and ex-

FIGURE 4-4. A simplified model of the factors that affect drug prescription. Note: Diagnosis considered constant



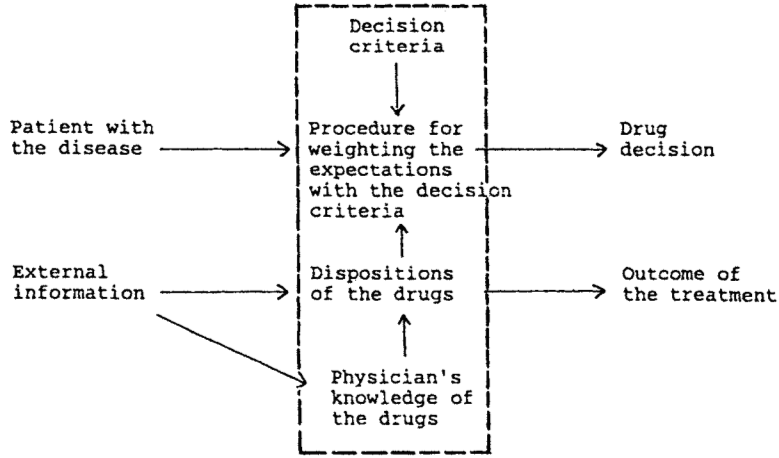
Source: Hemminki, C.: The Role of Prescriptions in Therapy, *Medical Care*, 13: 151, 1975.

pectations are controversial and might be largely created by doctors themselves.

Lilja, in a Swedish study, examined the product decision-making priorities of 118 general practitioners employed by the government. Using the method of regression analysis, he found that "high curing effect" was uniformly the most important consideration in the selection of a drug to treat hypothetical cases of adult diabetes and pneumonia. "Low side-effects" were found to be second in importance in selecting an antidiabetic medication, while "low cost" was found to be more important in selecting an antibiotic. Based on this study, Lilja proposed that physicians select drugs through a habitual or nonhabitual choice. Most of the drug choices a physician makes are habitual, and it was suggested that, in explaining how a physician may adopt a new drug, it is important to consider the habitual process outlined in Figure 4-5. The components within the dotted line in Figure 4-5 are in the physician's mind.

Benson, in his Ph.D. thesis (Sociology, University of North Carolina, 1980), has stated that there are two major defects in the models described above that limit their usefulness. First, most of them are based on studies that did not measure actual physician prescribing behavior but that used

FIGURE 4-5. The physician's nonhabitual choice process.



Source: Lilja, J.: How Physicians Choose Their Drugs, *Social Science and Medicine*, 10:363, 1976.

physician responses to simulate clinical situations. Inferring that such "proxy" behavior measures approximate actual clinical behaviors is highly problematic and thus limits study findings derived from the use of such a methodology. A second major problem with physician decision making, according to Benson, is that none of the studies attempted to examine simultaneously the influence of all interactive variables on the treatment decision-making process. Examining the influence of one or two variables separately severely restricts the interpretations that can be formulated.

It is obvious that a prescriber's drug selection decision process, like any consumer purchasing decision, involves the input of many variables. Unlike a consumer, however, the physician's decision to prescribe involves the input of unique parameters and carries with it a high degree of responsibility. Since the late 1940s there have been approximately 100 published studies that examined the influence of specific variables or groups of variables on physician prescribing behavior. In addition to these studies, there are certainly many hundreds of additional investigations that, for reasons of competition, remain in drug company files.

Other professionals, such as optometrists, physicians' assistants, dentists, podiatrists, veterinarians, and nurse practitioners, write prescriptions in all or many states. However, few studies or surveys have been performed to evaluate the sources of information used by these professionals for prescription drugs.

It is apparent from the results of studies on physician prescribing behavior that physicians use various drug information sources in the different stages of the drug selection decision-making process. What motivates a physician to decide on a particular drug? What is the decision-making scheme used by physicians?

First, a physician becomes aware of a particular drug through drug company advertisements or journal articles. Interest is piqued because of encounters with clinical situations that may warrant use of the drug or by an increased frequency of reports on the drug. At some point the physician decides to consider using the drug and begins an evaluation process. At this stage the physician looks for third-party endorsement of the drug and seeks information on the costs versus benefits associated with the drug's use. If all the information received is positive, the drug may be tried on a few patients. If the outcomes of these trials are acceptable, the physician may switch and may begin to prescribe the drug regularly. In essence, this is probably the scenario followed by most physicians.

Two stages of decision-making take place in drug adoption, deciding to

try a type of drug (primary) and then deciding on a specific drug product (selective).

The difference between primary and selective demand is particularly important to the marketing function. Primary demand is the demand for the type of product as distinguished from the demand for specific brands. In the drug field we might speak of the demand for antibiotics, for diuretics, or for oral contraceptives. We might differentiate various segments of this type of demand even more (e.g., the demand for sequential oral contraceptives, the demand for mercurial diuretics, the demand for broad-spectrum antibiotics). Yet each of these is a part of primary demand. As we shall see, every major new concept in product types and many major product type changes require the stimulation of primary demand. The change, innovation, or even the concept must first be validated within the mind of the decision maker before any effort is made to sell the benefits of one brand over another. It is clear that the first marketer of a new product line, if successful, must do much of the primary demand stimulation for competitors who will follow. Indeed, the number of such competitors may be a direct reflection of the innovator's success in primary demand stimulation.

We are all much more familiar with selective demand. Instead of promoting features and benefits of the product type or class, the manufacturer emphasizes the advantages of his own brands in comparison with competitors' brands. All primary demand stimulation, however, does not necessarily stop.

Not only do the messages differ but so does the nature of the promotional activities aimed, respectively, at primary and selective demand stimulation. The former tends toward a much higher informational content. In the pharmaceutical industry it is almost instructional in character. It is important, particularly when a product is new, to be certain that the physician is thoroughly versed in the proper dosage and administration. Potential trouble areas must be adequately explained to him. The physician who tries a new type of treatment for the first time and is disappointed in the results is not likely to try it again soon. The introduction of the oral contraceptives was certainly a good example of thorough explanations of the mechanism of action being given to both the physician and to the patient. Additional primary demand stimulation was required when the sequential versions were introduced.

Gosselin was the first to classify prescription drugs as "directed consumer goods." The description is particularly apt. Almost any product can be said to benefit from directed demand, at least insofar as it is possi-

ble to direct this demand through advertising. It is doubtful, however, whether or not any other good or service except for public utilities is less a matter of consumer choice than of prescription pharmaceuticals.

The principal director, of course, is the prescribing physician. In most cases this physician still finds it feasible to make a choice on his own. For a number of reasons the trend, if one exists, is for less discretion of choice by the physician. Drug committees, government agencies, and even individual pharmacies are helping in this "direction" demand.

Third-party programs, such as private health insurers, Medicaid programs, and health maintenance organizations, have a financial interest in the quality and cost of the drugs provided for their beneficiaries. They also have the size and the organizational ability to affect drug use significantly. As drug costs grow, so does the interest in establishing organizational controls over drug use. Examples of approaches being used include establishing formularies, setting drug cost limits, and developing auditing or drug utilization review procedures.

Formularies. A formulary is simply a list of drug products to be paid for by a program. If functioning properly, the choice of drugs included will be based first upon therapeutic considerations and second upon economic ones. The establishment of the content of the formulary should be firmly in the control of health professionals, including ample representation by pharmacists.

Cost Limitations. Programs such as the Maximum Allowable Cost (MAC) program of Medicaid have been established to limit drug product reimbursement to a predetermined level. As applied to multiple-source drugs, it encourages the dispensing of more economical products. Because MAC deals only with multiple-source drugs and not with drug selection otherwise, it has little influence on the appropriateness of prescribing.

Audit and Utilization Review Procedures. These procedures seek to develop profiles of prescribing for individual physicians in an attempt to detect patterns which are either outside normal ranges or of predetermined screening criteria for appropriate drug use. Because it is well established that much prescribing is now inappropriate, comparing individual prescribing patterns to average prescribing is not likely to be fruitful. On the other hand, use of predetermined screening criteria can be successful if the criteria are conscientiously constructed by well-qualified pharmacists and physicians. The process must include the necessary follow-through to correct problems detected from the review. Through the use of these and other approaches, third-party programs are in an excellent position to influence drug use.

CONCLUSION

Intuitively, identification of market segments among patients and their physicians should be simple. The patients would fit neatly into compartments designated by their medical condition and diagnosis. While there might be room for decision in the choice of a brand of analgesic, one should be able to assume that they would choose one of the brands and then use it.

In the physician market it should be even easier! Once the diagnosis was made, rational drug therapy should follow: "the right drug, for the right patient, at the right time, in the right amounts, and with due consideration of relative costs." After all, medicine, above all, is a rational profession.

In fact, of course, we are far from understanding the aberration in the marketplace of patient decisions and the decisions of their agents, usually physicians.

Patients sometimes do not have their prescriptions filled and often (even though they have paid good money for a doctor's advice) do not take the filled prescription as recommended . . . or at all. Physicians, in spite of the best efforts of a multibillion dollar drug industry and the most officious drug regulatory agency in the world, also sometimes prescribe drugs too much, too little, inappropriately, or for unapproved indications.

The pharmaceutical industry, while spending a great deal of money after the fact of drug prescribing and consumption for market research, has spent comparatively little on discovering the precursors to that behavior. Academics and government have done the majority of the research in these areas. Although the U.S. drug industry in recent years has discovered non-compliance and, in its own self-interest, tried to encourage change, research studies to explain the phenomena were until recently of little interest (as expressed by research support) to the companies with the most to lose.

Good marketing of good drug products will result in good therapy.

Chapter 5

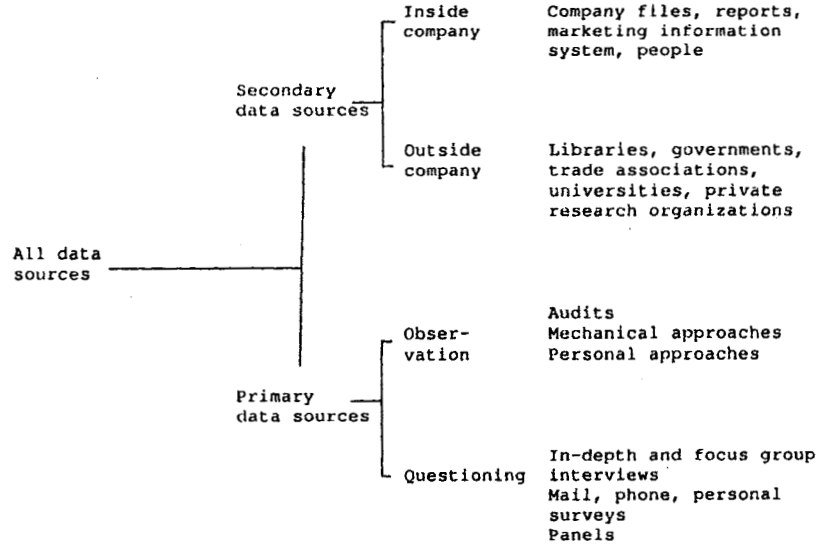
Market and Marketing Research

Market research and marketing research are terms used for a special, more focused kind of environmental scanning. (See Chapter 2.) Although the two terms are often used interchangeably, it is useful to distinguish *market* research—determination and assessment of the qualitative and quantitative dimensions of a market (however defined), from *marketing* research—analysis of the effects of the various marketing activities of a firm and its competitors.

Another useful distinction is that between primary and secondary research/data sources. That distinction is shown in Figure 5-1.

It has often been stated that, with regard to the marketplace in which it operates, the pharmaceutical industry is perhaps the most "data rich" of

FIGURE 5-1. Types of market data sources



all industries. As a result it is one of the most if not *the* most, sophisticated users of market and marketing research information. To a large degree, this wealth of data regarding the pharmaceutical marketplace is a function of the many inherently unique aspects of the pharmaceutical marketing process.*

In order to explain this statement, let us remember that pharmaceutical companies produce and market two types of products. One type is the prescription product that may be obtained by consumers only upon the presentation of authorization by a licensed prescriber. The other is the over-the-counter product that may be purchased without a prescription.

There has been an expansion of the over-the-counter pharmaceutical market in recent years, but the most fundamental business of pharmaceutical companies still remains the production and marketing of prescription pharmaceuticals. In the marketing segment of this activity, the industry is unique in that it does not usually market its products to the ultimate consumer, the patient, but instead to an intermediary, the physician (or other prescriber, such as a dentist). The primary target, then, of the marketing effort for these products is the has-been population of licensed prescribers in the country, rather than the consumers of the products. Another target of the marketing effort for prescription pharmaceuticals is the population of licensed pharmacists in the country, this group having assumed more importance recently because of their increased role as decision makers with regard to the specific brand of drug to be dispensed to the patient. Here too, however, the focus is on an intermediary rather than on the ultimate consumer.

The selling of prescription pharmaceuticals to the public also involves some atypical characteristics. Professional licensure is required for an establishment to stock and sell prescription products. Further, the seller (or dispenser) of these products must be licensed to do so. The selling of prescription pharmaceuticals to the public is thus restricted to the comparatively small numbers of pharmacists and pharmacies in the country rather than to the substantially larger number of retailers and retail outlets that would normally be the case for a consumer product.

Uniqueness also characterizes prescription products in the sense that, as mentioned previously, purchase of these products by consumers requires the presentation of authorization by a licensed prescriber in the form of a written prescription. A record of every transaction involving the sale or dispensing of a prescription drug to the consumer is therefore created and

*Most of the material in this chapter was written by Stephen Chappell for the Third Edition of this book.

maintained, with these records being specific to the patient, physician, pharmacy, and product.

In effect, product choice decisions and product movement in the multi-billion dollar prescription drug industry are accounted for or represented by what basically amounts to a relative handful of the population. The number of licensed prescribers of medication in the United States is probably about 500,000, and the number of registered pharmacists is roughly 150,000. There are approximately 55,000 retail pharmacies in the country and slightly more than 7,000 hospitals. Contrast these numbers, for example, with the potential hundred million decision makers who might be involved in a consumer product, and the many hundreds of thousands of outlets that might sell a consumer product with few, if any, records maintained regarding these decisions or sales.

These examples, along with other unique aspects of prescription product marketing, are of considerable importance in the gathering of data regarding the marketplace. In one sense, there is virtually no difficulty in finding physicians, pharmacists, pharmacies, or hospitals. Primarily because of professional licensure requirements, all are on continually maintained lists of one type or another. Additionally, the number of members in each of these groups is known to within a very small degree of error. The person who wants to know the number of physicians in the country does not have to initiate a study to find out this information. Consider this as compared to the problems that would be encountered by the researcher who wanted to know the number of coffee drinkers in the United States and wanted to conduct research among them—no list of coffee drinkers exists.

There is relatively little required of the researcher in the pharmaceutical marketplace in terms of characterizing potential research subjects. Information is available, for example, on the physician's type of practice, specialty, year graduated from medical school, medical school attended, and location of practice. Information is also available on retail pharmacies in terms of their type, size, and location. Hospitals are identified by type, bed size, affiliation with learning institutions, presence of a formulary, and whether or not certain types of equipment are available. This pre-characterizing of research subjects is generally not available to the researcher in the consumer marketplace.

Another element that facilitates the conduct of market research in the pharmaceutical marketplace is the fair amount of homogeneity that is found within and among the various groups of participants in the marketplace. Physicians and pharmacists, for example, have received the same basic education as other physicians or pharmacists. As with most pur-

chasers of consumer products, no wide variations from physician to physician are found in terms of socioeconomic considerations. Most participants in the health care area are professionals and tend to communicate on an inter- and intragroup basis better than the average consumer does with other consumers. Similarity in thinking and activity among the members of a particular group generally tends to facilitate researching of the group.

The conduct of market research in the prescription product area is also made somewhat easier than doing the same in the consumer sector because most of the decisions made by principals in the market are based on knowledge rather than on emotion.

Finally, in many segments of pharmaceutical market research, the researcher does not have to create or search extensively for records of fact regarding decision or activity. As pointed out earlier, for instance, records are required to exist for every transaction regarding the sale of a prescription product to a consumer.

In summary, many of the unique characteristics of prescription product marketing have the effect in one fashion or another of eliminating or minimizing many of the requirements and effort associated with market research in the general sense. This is certainly a major reason for the enormous amount of data available regarding the prescription product marketplace.

Of course one should not carry away the impression that market research in the pharmaceutical industry is an effortless undertaking. Although there are many areas of advantage relative to other industries, many of the peculiar aspects found in pharmaceutical marketing create complications with which the researcher has to deal. As one illustration, the construction of a sample of retail pharmacies has to take into consideration the fact that pharmacies vary a great deal in the composition of their sales volume. Some may fill only a few prescriptions yet have an extremely high volume of business overall. Others may do a negligible business in items other than prescriptions from several hundred physicians. The customary probability or random statistical sample of the drugstores in the country may not necessarily constitute a representative sample of the prescription market in the country.

The difficulties of market research have resulted in opportunities. Responding to these have been scores of companies who specialize in or devote at least a part of a longer business to pharmaceutical market and marketing research. In practice, much of the data gathering in the drug industry is done by such firms. The interpretation of these data, especially when coupled with internal company records, occupies much of the time and creativity of the market research personnel of pharmaceutical companies. This is not to say that they never design and execute their own data

collection projects, but rather that the integration of company records, available data services and custom designed studies is a challenge to the marketing strategist.

SECONDARY DATA FROM COMMERCIAL SUPPLIERS

A large number of market and marketing research services have been developed for the pharmaceutical industry by independent research companies, sometimes referred to as service agencies or suppliers. Many of these services have been in continuous operation since the 1950s; others were initiated over the years in response to changes in the marketplace and to concomitant changes in the information needs of the industry. A service offered to the pharmaceutical marketer that depicts the frequency and characteristics of substitution in retail pharmacies is important in today's market, but was obviously of no relevance prior to the repeal of antisubstitution legislation. Advances in technology have also been responsible for the development of new services by facilitating the collection and processing of information that was either not available previously or was too difficult to collect and process. As an illustration, the advent of pharmacy service systems has provided as a by-product millions of records of prescription dispensing information stored on computers, easily accessible for very detailed analyses.

The services provided by independent research companies are generally classified into two major categories—syndicated or custom. A syndicated service is defined here as one in which all subscribers receive identical information. These services are generally supported by a large number of subscribers. The custom service, on the other hand, is supported by only one client to whose specific needs the service or project is tailored. Only the contracting client receives the information in a custom project. Another categorization of these services is based on their periodicity or continuity. They may be periodic, continuing (and periodic), or ad hoc in nature.

Periodic and Continuing Audits and Surveys

There are seven general types of continuing audits or surveys of the pharmaceutical marketplace:

1. Retail pharmacy purchase audit.
2. Hospital purchase audit.
3. Warehouse withdrawal audit.
4. Retail pharmacy prescription audit.

5. Physician panels.
6. Promotional media audits.
7. Retail sales audit.

Broadly defined, these services are nationwide in scope, each covering one aspect of the pharmaceutical marketplace on a regular, periodic basis—monthly, quarterly, etc. With some exceptions, which will be noted, these audits present national (continental United States) estimates of activity—dollars, prescriptions, detail calls. These estimates represent projections of data collected from a sample constructed to be representative of the population, or universe—physician, hospitals, pharmacies—being studied. Again, in general, data are presented at the product level. Product level data are then summarized to therapeutic category or to manufacturer level, and these ultimately to a total marketplace figure. In addition to absolute volume estimates, market share and trend information are customarily provided.

Retail Pharmacy Purchase Audit

This is designed to provide a measurement of pharmaceutical product purchases by retail pharmacies. A purchase audit is, in effect, an "inflow" audit, measuring the flow of product (either directly from a manufacturer or from a wholesaler) into retail pharmacies. This is in contrast to an "outflow" audit such as the prescription audit, which monitors the flow of a product out of the pharmacy into the hands of the consumer. In theory, at any one point in time, the difference between an inflow audit and an outflow audit is represented by inventory on the shelf.

The methodology employed to collect purchase information focuses on two approaches: one for *indirect* (or through a drug wholesaler) purchases, the other for *direct* (from the manufacturer) purchases. For direct purchases, invoice auditing is employed. Individual pharmacies in the sample are audited monthly for all records of purchase. Indirect purchases are obtained from warehouse withdrawal data purchased from pharmaceutical wholesalers.

The scope of the retail pharmacy purchase audit is not limited to prescription, or legend, pharmaceuticals, but includes over-the-counter medications as well. The latter group is important; in 1988, O-T-C products accounted for slightly more than 20 percent of total drugstore purchase volume.

Hospital Purchase Audit

In general methodology, style, and form, this is a replica of the retail pharmacy purchase audit. The obvious difference is that this audit focuses on hospital purchases of pharmaceutical products. The hospital sector has increased substantially over the past decade as a market for pharmaceutical products. The growth in purchases of pharmaceuticals by hospitals has on a relative basis far exceeded that of the retail pharmacy segment. There are a number of reasons for this, but of probably prime importance to the pharmaceutical marketer is the fact that in many communities around the country the hospital has become more of a factor in routine patient care. The increase in the number of patient visits to hospital outpatient facilities has been remarkable in the past 10 years, as has been the growth in the filling of prescriptions by hospital pharmacies for these outpatients.

Given the focus of this text, descriptions of the above two audit types have been within the context of pharmaceutical products. Other related product areas are covered within the framework of retail pharmacy and hospital purchase auditing. From the former, purchase data are collected and compiled for toiletry and beauty aid products, and for veterinary pharmaceuticals. The latter yields data on purchases of hospital supplies (needles, sutures, drapes, x-ray film) and diagnostic reagents.

Warehouse Withdrawal Audit

This is a service that measures the withdrawal of pharmaceutical products from the pharmaceutical wholesaler and from major drug chain warehouses. Although this audit monitors withdrawal or outflow from warehouses, note that this is basically the same as measuring inflow to the pharmacy or hospital. Because it is, this service is actually similar to the purchase audits described above, and one may question the need for both types of services. Major differences, however, do exist. The purchase audits reflect all purchases by a pharmacy or hospital whether or not they were purchased directly from a manufacturer or from a wholesaler. Given the focus of the warehouse withdrawal audit on the warehouse segment only, purchases directly from the manufacturer are not represented in the auditing process.

On the other hand, although the purchase audits are based on samples of hospitals and pharmacies, the warehouse withdrawal study is, for all intents and purposes, a census of warehouse withdrawal activity for pharmaceutical products. The amount of data available from such a census is enormous as compared to that developed with the purchase audit. This mass of data provides the capability to isolate and analyze small segments

of the marketplace, such as zip code or specific sales territories. This capability is quite valuable in dealing with questions of individual territory potential and performance, needs for territorial realignment, or differential selling techniques.

Retail Pharmacy Prescription Audits

This is designed to measure the outflow of prescription drugs from the pharmacy into the hands of the consumer. In many ways, it may be logically argued that prescription audit data are the most sensitive indicators of prescription product performance in the marketplace. The prescription is not an expression of opinion, attitude, or speculation on the part of the prescriber but is a matter of record. As prescribers collectively change their minds about individual drugs or areas of therapy these changes are, in essence, automatically recorded in the prescription files of pharmacies. Prescriptions, further, are indicators of what is presently occurring in terms of demand. Purchase data, for example, may record a pharmacy's purchase of antibiotics in the month of August in anticipation of the antibiotic "season." That purchase record, however, does not signify current physician demand for antibiotics.

Prescription data are also viewed by most pharmaceutical marketers as the best indicators of the results of marketing or promotional efforts to create new business. If one looks at purchase data for an antihypertensive product it is impossible to sort out that portion of dollars representative of new business as opposed to that portion reflective of patients who are already using the product. New prescription volume for the same product, however, is a reasonably good indicator of the trend in generating new patient business for the product.

There are presently two primary methods of collecting data for continuing syndicated prescription audits. One method relies on a sample of retail pharmacies, with pharmacists in each of these pharmacies recording information regarding prescriptions filled by the pharmacy. The other method takes advantage of pharmacy service system-generated prescription records, and extracts required information from records stored on computers. Each method has inherent advantages and disadvantages. Pharmacy service system data is voluminous, and easily and quickly collected and processed. These data however, represent information only on what is dispensed by the pharmacy. The method that relies on pharmacist reporting of information produces a smaller volume of data and takes more time to collect and process, but yields information on what was prescribed by the physician as well as on what was dispensed by the pharmacist. Prescription data are available at national and sub-national levels, the latter

allowing prescription generation analysis at more discrete geographic levels.

In Tables 5-1 to 5-7, data are presented on the drug product, Cardizem. Examination of these data in their various audit contexts will surely demonstrate these strategic and competitive insights that can be gained from clever manipulation of the information supplied.

Physician Panels

These represent research services of a somewhat different type. One physician panel is a study of medical practice in the United States. Although most of the services discussed thus far are oriented toward the depiction of product movement in one way or another, this physician panel goes somewhat further in that it portrays usage of pharmaceutical products along a number of variables.

A sample of physicians is utilized. Each physician in the sample is asked to provide specific information regarding each patient seen during an assigned reporting period. Information requested includes diagnosis, patient characteristics, location of visit, drugs, if any, used to treat the condition, and action desired from these drugs. Beyond simple estimates of volume and trend of drug usage, data resulting from this study are used to determine such considerations as which conditions a drug is used for, by what specialty of physician, in what frequency, and for what patient type.

Another type of physician panel is designed to collect the daily new prescription output of individual physicians. Followed over time, data from this panel can demonstrate changes in prescribing habits by physician or groups of physicians based on specialty, age, location of practice, and prescribing volume. These data are often used to track new products, in which physicians are identified as to certain characteristics and monitored as to if and when they began to prescribe a new product, in what volume, for how long and how, if at all, previous prescribing patterns were altered.

Still other physician panels are maintained that are narrower in scope in terms of drug use or diagnosis areas, but that are more detailed in the information provided within these more limited parameters.

Promotional Media Audit

Three segments of promotional activity in the pharmaceutical marketplace are monitored by continuing audits—detailing, journal advertising, and direct mail advertising. Projections of detailing effort as perceived by

physicians in office-based practice, and the receipt of direct mail advertisements by this group of physicians, are made from information provided by samples of physicians who report on these respective promotional approaches. An audit that depicts the detailing of pharmacists is also available. The amount of dollars spent by pharmaceutical companies for the placement of advertising in professional journals is monitored for the industry, with the dollar estimate based on a census of all publications that carry ethical pharmaceutical product advertising.

Retail Sales Audit

This has historically been used primarily for nonprescription pharmaceuticals. One type of retail sales audit may be described as "opening inventory plus delivered purchases minus ending inventory." Mainly because of time and cost considerations, this type of audit is conducted for selected products of interest to the subscriber as opposed to the "all products, all categories" approach of most of the audit services already described.

These descriptions are of the general types of continuing audits and surveys offered to the pharmaceutical marketer. Although each has one major objective, you will readily understand that each of these provides data or information ancillary to the main objective but still of considerable use. Because the purchase audits, for example, collect unit and dollar information at the package size level, the opportunity exists for performing pricing analysis. The main use of prescription audits is to provide prescription counts by product, but information may also be collected on daily dosage, patient price, and number of units of drug prescribed. An analysis of dosage is, therefore, capable of being done.

It should also be pointed out that a great deal of work is done using segments of a particular study. Prescription data, for example, are studied to obtain both prescribing and dispensing information.

Finally, in recent years, much progress has been made in combining the information available in the individual audits into one general data base that offers the potential for an almost unlimited number of cross tabulations and interrelating exercises. (See the Case in Point following this chapter.)

Other Commercial Research Services

In 1988 both *Medical Marketing and Media* and the *Healthcare Business Directory* published descriptions of companies engaged in providing market and marketing research services to the pharmaceutical industry.

TABLE 5-1

NATIONAL PRESCRIPTION AUDIT — THERAPEUTIC CATEGORY REPORT
Add (000) to all figures
DECEMBER 1988 — 31700 CALCIUM BLOCKING — PAGE 410

PRODUCT MFR DOSE-FORM STRENGTH		CURRENT MONTHS						YEAR-TO-DATE				PHARMACY ACTIVITY				
		JUL	AUG	SEP	OCT	NOV	DEC	CURR YR	% CAT	PREV YR	% CHG	DISP AS WRIT	FILL BY OTH	SUB FOR BRD	FILL FOR GEN	UNSP PN
	PN	905	827	907	941	942	1030	11048		8971	23	92%	8%			
	DN	905	827	907	941	942	1030	11048		8971	23			3%	5%	
	DR	2159	2205	2142	2154	2161	2395	25151		20545	22					
	DT	3064	3132	3049	3095	3103	3425	36199		29516	23					
	DS	95151	97424	96003	96732	97204	106590	1110291		821012	35					
ADALAT MILES PHARM CAPS 10MG	PN	2	2	2	6	2	4	35	*	61	-43	35	1			
	DN	8	7	5	6	6	8	84	1	136	-38			43	6	0
	DR	12	19	17	16	16	16	216	1	301	-28					
	DT	24	28	22	22	22	24	300	1	437	-31					
	DU	2354	2554	2089	2141	2215	2365	29271	NA	42706	-31					
ADALAT MILES PHARM PRODUCT TOTAL	PN	2	2	2	6	2	4	36	*	63	-43	36	1			
	DN	7	7	6	7	7	7	90	1	142	-37			45	6	4
	DR	19	21	18	17	17	19	234	1	313	-25					
	DT	26	28	24	24	24	28	324	1	456	-29					
	DS	937	1000	840	841	873	930	11108	1	13001	-15					
CALAN SEARLE TABS 120MG	PN	6	6	5	6	6	7	74	1	109	-32	64	10			
	DN	5	5	6	5	5	6	71	1	107	-34			1	7	0
	DR	18	17	15	16	15	15	207	1	315	-34					
	DT	23	22	21	21	20	21	278	1	422	-34					
	DU	1812	1898	1778	1751	1680	1799	23448	NA	38561	-38					
TABS 40MG	PN	3	3	2	3	3	4	21	*	0	NC	21	0			
	DN	3	3	2	3	3	4	23	*	0	NC			0	0	2
	DR	2	2	3	4	4	4	22	*	0	NC					
	DT	5	5	5	7	7	8	45	*	0	NC					
	DU	386	424	419	509	545	658	3538	NA	0	NC					
TABS 80MG	PN	34	32	33	31	35	39	426	4	556	-23	300	126			
	DN	24	24	23	23	21	24	311	3	499	-38			1	9	0
	DR	69	68	63	63	60	64	888	3	1402	-38					
	DT	93	92	86	88	81	88	1179	3	1901	-38					
	DU	7815	7758	7317	7354	6947	7412	99485	NA	160801	-38					
CALAN SEARLE PRODUCT TOTAL	PN	43	40	40	41	44	49	523	5	665	-21	385	138			
	DN	32	31	31	31	29	33	405	4	807	-33			2	18	2
	DR	89	89	82	83	79	84	1098	4	1716	-36					
	DT	121	120	113	114	108	117	1503	4	2322	-35					
	DS	2987	2934	2777	2787	2643	2849	35665	3	54575	-33					

CALAN SR SEARLE																		
CAPLETS SR	240M	PN	191	199	202	208	216	240	2335	21	1218	92	2316	19				
		DN	194	203	202	212	220	241	2380	21	1239	80			6	37	0	
		DR	360	378	376	385	400	455	4069	16	1397	191						
		DT	554	581	578	587	620	696	6429	18	2838	144						
		DU	21514	22730	22587	23302	24337	27754	250485	NA	97164	158						
		DS	15061	16058	16150	16642	17403	19864	171747	15	56546	204						
CARDIZEM MARION																		
TABS	120MG	PN	4	4	4	4	4	5	45	*	12	275	45	0				
		DN	4	4	4	4	4	5	45	*	14	221			0	0	0	
		DR	9	10	10	10	10	12	101	*	18	461						
		DT	13	14	14	14	14	17	146	*	32	356						
		DU	1108	1211	1190	1221	1249	1458	12372	NA	2706	357						
TABS	30MG	PN	132	133	127	129	135	142	1587	14	1404	13	1587	0				
		DN	134	135	131	134	135	143	1612	15	1433	12			25	0	0	
		DR	334	334	326	320	324	355	3850	15	3483	10						
		DT	468	489	457	454	459	498	5462	15	4926	11						
		DU	44441	44416	43581	43294	43903	48136	518746	NA	471190	10						
TABS	60MG	PN	152	154	151	153	155	168	1821	16	1492	22	1821	0				
		DN	154	156	156	157	157	173	1865	17	1543	21			43	0	0	
		DR	424	431	417	416	416	462	4802	15	4183	17						
		DT	578	587	573	573	573	635	6767	19	5726	18						
		DU	54312	55482	54340	54245	54400	60684	640858	NA	545017	18						
TABS	90MG	PN	23	23	23	25	25	29	259	2	78	232	259	0				
		DN	23	23	23	25	25	29	261	2	78	235			2	0	0	
		DR	51	55	57	58	59	68	573	2	101	467						
		DT	74	78	80	83	84	97	834	2	178	366						
		DU	6722	7038	7262	7521	7632	8889	75662	NA	18412	361						
CARDIZEM MARION PRODUCT TOTAL		PN	311	314	305	311	320	343	3712	34	2986	24	3712	0				
		DN	315	318	315	321	321	350	3782	34	3068	23			70	0	0	
		DR	817	830	809	803	808	897	9428	37	7795	21						
		DT	1132	1148	1124	1124	1129	1247	13210	38	10863	22						
		DS	38868	39545	39218	39038	38270	43537	453142	41	338218	34						
DILTIAZEM MARION PRODUCT TOTAL		PN	4	4	9	9	2	8	70	1	81	-14	0	70				
		DN	0	0	0	0	0	0	0	*	0	NC			0	0	0	
		DR	0	0	0	0	0	0	0	*	0	NC						
		DT	0	0	0	0	0	0	0	*	0	NC						
		DS	0	0	0	0	0	0	0	*	0	NC						

'0' Less than 0.5% '+' More than +999% 'NA' Not available 'NC' Not computable

TABLE 5-2

	12 Mos.	Qtr.
Est. U. S. Appear. (000)	27002	6877
Sample Data		
Drug Appearances	4903	1286
Drug Uses	4995	1312

CALCIUM BLOCKERS

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Class 31700 Page 1001

Age	Total 12 Mos. No.	%	Male 12 Mos. No.	%	Female 12 Mos. No	%	Unspec. 12 Mos. No.
2 & Under	11	-	1	-	10	-	-
3-9	11	-	5	-	5	-	-
10-19	19	-	9	-	10	-	-
20-39	1046	4	547	5	414	3	84
40-59	6668	25	3547	30	2630	20	491
60-64	3051	12	1501	13	1326	10	224
65 +	15532	59	6085	52	8523	66	924
TOTAL	26337	100	11696	100	12918	100	1723
Unspec.	665		120		156		389

Form	12 Mos. No.	%	Qtr. %
Tb/Cp	25746	99	100
Liquid	-	-	-
Oph.	-	-	-
Otrc.	-	-	-
Nasal	-	-	-
Inj.	155	1	-
Top.	-	-	-
Supp.	-	-	-
A.O.	10	-	-
TOTAL	25911	100	100
Unspec.	91		

Concomitancy	12 Mos. No.	%
USED ALONE	7815	29
W/NITRITES/NITRATES	7428	28
W/BETA-BLOCKERS	3581	13
W/DIUR.OTHER NON-INJ	2403	9
W/DIGITALIS PREP	2323	9
W/ACE INHIBITOR	1907	7
W/ASPIRIN,APC,ETC.	1841	7
W/DIUR.K-SPARING	1612	6

Specialty	12 Mos. No.	%	Qtr. %	Drugs/ Phy. Yr.
GP-PT	1989	7	6	101
FP-PT	4094	15	15	131
Int.Med.	11436	42	40	243
Card.	6450	24	26	667
Gastro	188	1	1	42
Gen.Surg.	258	1	1	14
Orth.Surg.	37	-	-	3
A.O.Surg.	194	1	-	16
Ob/Gyn.	31	-	-	1
Ped.	9	-	-	-
ENT	7	-	-	1
Ophth.	18	-	-	1
Derm.	4	-	-	1
Allerg.	27	-	-	18
Urology	687	3	2	76
Psych.	48	-	-	3
Neur.	178	1	1	37
Osteo.	1351	5	5	91
TOTAL	27002	100	100	100

Diagnosis		12 Mos. No.	%	Qtr. %
07	DIS OF CIRCULATORY SYST	24729	90	91
4019	ESS HYPERTENSION UNSPEC	8031	29	29
4139	ANGINA PECTORIS NO HYP	4729	17	15
4149	CHR ISCHAEMIC DIS UNSP	1702	6	10
4029	HYPERT HRT DIS UNSPEC	1424	5	7
4130	ANGINA PECTORIS WITH HYP	1127	4	5
4140	CORONARY ATHERSCLERDSIS	1039	4	6
4119	OTH AC+SAC ISC HRT W/D H	922	3	-
4109	AC MYOCARD INF NO HYPER	916	3	3
4129	OLD MYOCARD INF NO HYPER	510	2	2
4280	CONGESTIVE HEART FAILURE	420	2	2
4145	CHR ISCHEMIC D UNS W/NTN	412	2	3
4273	ATRIAL FIBRILL+FLUTTER	366	1	2
4110	OTH AC+SAC ISC HRT W/NTN	313	1	-
4039	HYPERTENS RENAL DIS UNSP	303	1	1
4279	CARDIAC DYSRHYTHMIAS UNS	287	1	1
4270	PAROX SUPRAVENT TACHYCAR	205	1	1
4142	CORONARY ATHEROSCL W/NTN	204	1	1
4148	CHR ISCHAEMIC DISEAS OTH	152	1	-
4100	AC MYOCARD INF WITH HYPE	148	1	1

Desired Action	12 Mos. No.	%	Qtr. %
REL ANGINAL PAIN	6252	29	27
LOWER BLOOD PRES	3815	18	17
ANTIHYPERTENSIVE	3081	14	15
CALCIUM BLOCKER	1198	5	7
CURB CARD ARRYTH	1072	5	4
CORONARY VASODIL	1007	5	6
VASODILATOR	974	4	4
MAINTAIN BL PRES	509	2	2
CONTROL HEART RT	433	2	2
CARDIOTONIC	356	2	2
PROPHYLAXIS	339	2	3
PAIN RELIEF	247	1	1
SYMPTOMATIC	233	1	1
REL ANGINAL PAIN &			
LOWER BLOOD PRES	214	1	-
DIGITALIS EFFECT	194	1	1
REL ANGINAL PAIN &			
ANTIHYPERTENSIVE	152	1	1
RELIEVE HEADACHE	103	-	-
CURB CARD ARRYTH &			

Location	12 Mos. No.	%	Qtr. %
Office	17638	70	74
Home	218	1	1
Hosp.	6022	24	19
Teleph.	1173	5	4
Nurse Hm.	192	1	1
Other	126	-	-
TOTAL	25367	100	100
Unspec.	1835		

Region	12 Mos. No.	%	Qtr. %
East	6606	24	28
Midwest	8237	23	21
South	9348	35	35
West	4812	18	16
TOTAL	27002	100	100

Visit	12 Mos. No.	%	Qtr. %
First	2890	11	13
Subseq.	22702	89	87
TOTAL	25592	100	100
Unspec.	1410		

Issuance	12 Mos. No.	%	Qtr. %
Hosp.Ord.	5849	26	22
Admin.	5	-	-
Disp.	246	1	1
Rx	9357	42	42
Sample	716	3	4
Samp w Rx	411	2	-
Rec'm'nd	98	-	-
Sold	27	-	-
Not Iss.	5526	25	29
TOTAL	22234	100	100
Unspec.	4768		

Therapy	12 Mos. No.	%	Qtr. %
New	3770	15	13
Continued	21808	85	87
TOTAL	25577	100	100
Unspec.	1825		

4360	AC BUT ILL DE CEREB W/HT	130	-	1
4018	ESS HYPERTENS BEN COMPLC	111	-	-
4272	PAROX TACHYCARDIA UNSP	103	-	-
4254	PRIM CARDIOMYOPATHY OTH	90	-	1
4430	RAYNAUDS SYNDROME	89	-	-
4120	OLD MYOCARD INF WITH HYP	86	-	-
4292	CARDIOVASC DISEASE UNSP	70	-	-
4048	HYP HT+REN [illegible]S UNSPEC	70	-	-
4289	UNS ILL DEF+COMP HT SURG	62	-	-
4274	VENTR FIBRILL+FLUTTER	60	-	-
4350	TRANS CERE ISCHEM W HTN	55	-	-
4439	PERIPHERAL VASC DIS UNS	52	-	-
3949	DIS MITRAL VALVE OTHER	44	-	-
4251	HYPERTR AORTIC STENOSIS	40	-	-
4241	AORTIC VALVE DISORDERS	36	-	-
4319	INTRACER HEMORR NOS HYPR	35	-	-
4278	CARDIAC DYSRHYTHMIAS OTH	34	-	-
4389	AC BUT ILL DE CEREB NOM	28	-	-
4409	GEN + UNS ATHEROSCLEROSI	26	-	-
4240	MITRAL VALVE DISORDERS	23	-	-
4331	OCC+STEN PREC CAR ARTERY	21	-	-
18	SPEC COND N/O SICKNESS	1219	4	4
V70	POST OP SURGICAL EXAM	1002	4	3
V75	EXAM FOLLOW OTH TREATMEN	217	1	1
16	SYMPTOMS+ILL DEFINED CON	714	3	3
7865	CHEST PAIN	237	1	1
7999	UNK+UNSPEC CAUSE OTH	236	1	1
7840	HEADACHE	102	-	1
7851	PALPITATIONS	55	-	-
7804	DIZZINESS+GIDDINESS	36	-	-
06	DIS OF CNS SENSE ORGS	197	1	-
3489	MIGRAINE UNSPECIFIED	185	1	-
09	DIS OF DIGESTIVE SYSTEM	103	-	-
08	DIS OF RESPIRATORY SYST	98	-	-
4980	CHR-AIRWAYS OBSTRUCT NEC	51	-	-
4930	EXTRINSIC ASTHMA	23	-	-
03	ENDOC NUTR METAB IMMUN	87	-	-
2500	DIABETES MELL NO COMPLIC	27	-	-
2503	DIABETES WITH RENAL MANI	23	-	-
10	G U DISORDERS	71	-	-
5819	UNSPEC NEPHROTIC SYNDROM	23	-	-
13	MUSCULOSKEL+CONNECT TISS	52	-	-
05	MENTAL DISORDERS	46	-	-
17	INJURY AND POISONING	31	-	-
9800	OTH ACCIDENTS POISONINGS	23	-	-
14	CONGENITAL ANOMALIES	16	-	-
02	NEOPLASMS	15	-	-
01	INFECTIVE PARASITIC DIS	14	-	-
12	DIS SKIN SUBCUTAN TISSUE	10	-	-
11	COMPLIC PREG CHILDBIRTH	8	-	-
	TOTAL	27410	100	100

LOWER BLOOD PRES	102	-	-
MYOCARD STIMUL	82	-	-
CURB CARD ARRYTH &			
ANTIHYPERTENSIVE	81	-	-
CALCIUM BLOCKER &			
ANTIHYPERTENSIVE	78	-	-
REL ANGINAL PAIN &			
CALCIUM BLOCKER	66	-	-
CURB CARD ARRYTH &			
REL ANGINAL PAIN	55	-	-
LOWER BLOOD PRES &			
CORONARY VASODIL	50	-	-
REL ANGINAL PAIN &			
MAINTAIN BL PRES	49	-	-
PERIPH VASODILAT	48	-	-
INC CIRCULATION	48	-	-
CONTROL HEART RT &			
LOWER BLOOD PRES	48	-	-
ANTISPASMODIC	39	-	-
GI ANTISPASMODIC	37	-	-
CALCIUM BLOCKER &			
LOWER BLOOD PRES	33	-	-
CALCIUM BLOCKER &			
ANTISPASMODIC	33	-	-
REL ANGINAL PAIN &			
VASODILATOR	30	-	-
BETA BLOCKER	30	-	-
RELIEVE MIGRAINE	29	-	-
ANTIHYPERTENSIVE &			
VASODILATOR	25	-	-
ANTIHYPERTENSIVE &			
CORONARY VASODIL	25	-	-
CONTROL HEART RT &			
MAINTAIN BL PRES	24	-	-
CARDIOTONIC &			
CORONARY VASODIL	23	-	-
CALCIUM BLOCKER &			
VASODILATOR	23	-	-
CARDIOTONIC &			
LOWER BLOOD PRES	23	-	-
ANTISPASMODIC &			
VASODILATOR	20	-	-
CALCIUM BLOCKER &			
CORONARY VASODIL	19	-	-
CONTROL BEHAVIOR	19	-	-
REL ANGINAL PAIN &			
ANTIINFLAMMATORY	18	-	-
PROPHYLAXIS &			
CORONARY VASODIL	17	-	-
CARDIAC COMPEN	16	-	-
ANTIHYPERTENSIVE &			
DIGITALIS EFFECT	16	-	-
ALL OTHERS	388	2	2
TOTAL	21871	100	100
NO REASON GIVEN	5131		

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TABLE 5-3

	12 Mos.	Qtr.
Est. U. S. Appear. (000)	8861	2502
Sample Data		
Drug Appearances	1589	455
Drug Uses	1811	475

CARDIZEM

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Age	Total 12 Mos. No.	%	Male 12 Mos. No.	%	Female 12 Mos. No.	%	Unspec. 12 Mos. No.
2 & Under	9	-	-	-	9	-	-
3-9	5	-	5	-	-	-	-
10-19	4	-	4	-	-	-	-
20-39	188	2	108	3	52	1	9
40-59	2032	23	1180	28	728	18	124
60-64	1078	12	568	13	414	10	93
65 +	5387	62	2346	56	2785	70	276
TOTAL	8861	100	4211	100	3968	100	502
Unspec.	180		49		38		95

Form	12 Mos. No.	%	Qtr. %
Tb/Cp	8851	100	100
Liquid	-	-	-
Oph.	-	-	-
Otic.	-	-	-
Nasal	-	-	-
Inj.	-	-	-
Top.	-	-	-
Supp.	-	-	-
A.O.	-	-	-
TOTAL	8851	100	100
Unspec.	10		

Concomitancy	12 Mos. No.	%
USED ALONE	1940	22
W/NITRITES/NITRATES	4016	45
W/BETA-BLOCKERS	1229	14
W/ASPIRIN,APC,ETC.	824	9
W/DIUR.OTHER NON-INJ	734	8
W/DIGITALIS PREP	645	7
W/ACE INHIBITOR	542	6
W/DIUR.K-SPARING	372	4

Specialty	12 Mos. No.	%	Qtr. %	Drugs Phy. Yr.
GP-PT	559	6	6	28
FP-PT	1187	13	14	38
Int.Med.	3792	43	38	80
Card.	2844	30	35	273
Gastro	83	1	1	14
Gen.Surg.	51	1	-	3
Orth.Surg.	12	-	-	1
A.O.Surg.	50	1	-	4
Ob/Gyn.	-	-	-	-
Ped.	-	-	-	-
ENT	-	-	-	-
Ophth.	5	-	-	-
Derm.	-	-	-	-
Allerg.	1	-	-	1
Urology	136	2	1	15
Psych.	14	-	-	1
Neur.	19	-	-	4
Osteo.	328	4	4	22
TOTAL	8851	100	100	33

Diagnosis		12 Mos. No.	%	Qtr. %
07	DIS OF CIRCULATORY SYST	8033	90	89
4139	ANGINA PECTORIS NO HYP	2454	27	24
4148	CHR ISCHAEMIC DIS UNSP	919	10	17
4019	ESS HYPERTENSION UNSPEC	824	9	8
4109	AC MYOCARD INF NO HYPER	538	6	4
4140	CORONARY ATHERSCLEROSIS	497	6	8
4119	OTH AC+SAC ISC HRT W/O H	458	5	-
4130	ANGINA PECTORIS WITH HYP	454	5	6
4029	HYPERT HRT DIS UNSPEC	403	5	7
4129	OLD MYOCARD INF NO HYPER	278	3	2
4145	CHR ISCHEMIC D UNS W/HTN	197	2	4
4280	CONGESTIVE HEART FAILURE	182	2	1
4110	OTH AC+SAC ISC HRT W/HTN	126	1	-
4148	CHR ISCHAEMIC DISEAS OTH	88	1	1
4142	CORONARY ATHEROSCL W/HTN	85	1	1
4100	AC MYOCARD INF WITH HYPE	70	1	1
4038	HYPERTENS RENAL DIS UNSP	58	1	-
4279	CARDIAC DYSRHYTHMIAS UNS	50	1	-
4120	OLD MYOCARD INF WITH HYP	46	1	1
4292	CARDIOVASC DISEASE UNSP	41	-	-

Desired Action	12 Mos. No.	%	Qtr. %
REL ANGINAL PAIN	3303	47	46
CORONARY VASODIL	559	8	11
LOWER BLOOD PRES	482	7	4
CALCIUM BLOCKER	471	7	7
VASODILATOR	466	7	8
ANTIHYPERTENSIVE	278	4	4
DIGITALIS EFFECT	153	2	2
CARDIOTONIC	153	2	1
PAIN RELIEF	142	2	2
PROPHYLAXIS	138	2	4
CURB CARD ARRYTH	138	2	2
SYMPTOMATIC	78	1	1
MAINTAIN BL PRES	55	1	-
CONTROL HEART RT	48	1	1
REL ANGINAL PAIN & LOWER BLOOD PRES	45	1	-
REL ANGINAL PAIN & ANTIHYPERTENSIVE	35	1	-
REL ANGINAL PAIN & CALCIUM BLOCKER	33	-	-

Location	12 Mos. No.	%	Qtr. %
Office	5251	63	66
Home	82	1	2
Hosp.	2514	30	28
Teleph.	364	4	4
Nurse Hm.	85	1	1
Other	35	-	-
TOTAL	8320	100	100
Unspec.	541		

Region	12 Mos. No.	%	Qtr. %
East	1885	21	22
Midwest	2242	25	25
South	3202	36	37
West	1532	17	16
TOTAL	8861	100	100

Visit	12 Mos. No.	%	Qtr. %
First	991	12	12
Subseq.	7479	88	88
TOTAL	8470	100	100
Unspec.	391		

Issuance	12 Mos. No.	%	Qtr. %
Hosp.Ord.	2439	33	31
Admin.	-	-	-
Disp.	78	1	1
Rx	2706	36	36
Sample	125	2	2
Samp w Rx	92	1	-
Rec'm'nd	-	-	-
Sold	21	-	-
Not Iss.	2000	27	29
TOTAL	7462	100	100
Unspec.	1399		

Therapy	12 Mos. No.	%	Qtr. %
New	850	10	9
Continued	7562	90	91
TOTAL	8412	100	100
Unspec.	429		

4273	ATRIAL FIBRILL+FLUTTER	34	-	1
4272	PAROX TACHYCARDIA UNSP	32	-	-
4430	RAYNAUDS SYNDROME	27	-	-
4439	PERIPHERAL VASC DIS UNS	21	-	-
4369	AC BUT ILL DE CEREB MOH	20	-	-
4270	PAROX SUPRAVENT TACHYCAR	17	-	-
4254	PRIM CARDIOMYOPATHY OTH	.5	-	-
4274	VENTR FIBRILL+FLUTTER	15	-	-
4251	HYPERTR AORTIC STENOSIS	15	-	-
4380	AC BUT ILL DE CEREB W/HT	13	-	-
4241	AORTIC VALVE DISORDERS	11	-	-
4409	GEN + UNS ATHEROSCLEROSI	11	-	-
4018	ESS HYPERTENS BEN COMPLC	10	-	-
4048	HYP HT+REN DIS UNSPEC	8	-	-
3949	DIS MITRAL VALVE OTHER	7	-	-
4298	UNS ILL DEF+COMP HT SURG	7	-	-
3950	RHEUMATIC AORTIC STENOSI	5	-	-
18	SPEC COND W/O SICKNESS	502	6	6
870	POST OP SURGICAL EXAM	398	4	5
875	EXAM FOLLOW OTH TREATMEN	104	1	1
18	SYMPTOMS+ILL DEFINED CON	285	3	3
7865	CHEST PAIN	142	2	2
7989	UNK+UNSPEC CAUSE OTH	113	1	2
7802	SYNCOPE AND COLLAPSE	16	-	-
7851	PALPITATIONS	6	-	-
7840	HEADACHE	5	-	-
09	DIS OF DIGESTIVE SYSTEM	80	1	1
5301	ESOPHAGITIS	16	-	-
5751	OTHER CHOLECYSTITIS	12	-	-
5641	IRRITABLE COLON	11	-	-
5305	DYSKINESIA OF ESOPHAGUS	9	-	-
10	G U DISORDERS	20	-	-
6019	PROSTATE INFLAM DIS UNSP	15	-	-
06	DIS OF CNS SENSE ORGS	11	-	-
3488	MIGRAINE UNSPECIFIED	7	-	-
08	DIS OF RESPIRATORY SYST	10	-	-
4871	INFLUENZA+OTH RESP MANIF	8	-	-
02	NEOPLASMS	7	-	-
1829	MAL NEO BRONCH+LUNG UNSP	8	-	-
13	MUSCULOSKEL+CONNECT TISS	7	-	-
7221	DISP THOR+LUM DIS NO MYE	6	-	-
05	MENTAL DISORDERS	7	-	-
2953	SCHIZOPHR PARANOID TYPE	7	-	-
01	INFECTIVE PARASITIC DIS	8	-	-
0170	TB SKIN SUBCUT CEL TISSU	6	-	-
03	ENDOC NUTR METAB IMMUN	2	-	-
12	DIS SKIN SUBCUTAN TISSUE	1	-	-
	TOTAL	8950	100	100

MYOCARD STIMUL	29	-	1
GI ANTISPASMODIC	26	-	-
CALCIUM BLOCKER & ANTIHYPERTENSIVE	25	-	-
PERIPH VASODILAT	24	-	-
INC CIRCULATION	22	-	1
LOWER BLOOD PRES & CORONARY VASODIL	21	-	-
ANTISPASMODIC	20	-	-
CURB CARD ARRYTH & LOWER BLOOD PRES	19	-	1
REL ANGINAL PAIN & ANTIINFLAMMATORY	18	-	-
PROPHYLAXIS & CORONARY VASODIL	17	-	-
CARDIOTONIC & CORONARY VASODIL	17	-	1
CONTROL HEART RT & MAINTAIN BL PRES	15	-	1
CURB CARD ARRYTH & ANTIHYPERTENSIVE	15	-	-
ANTISPASMODIC & VASODILATOR	15	-	-
CALCIUM BLOCKER & CORONARY VASODIL	15	-	-
CURB CARD ARRYTH & REL ANGINAL PAIN	14	-	-
ANTIHYPERTENSIVE & DIGITALIS EFFECT	13	-	1
REL ANGINAL PAIN & MAINTAIN BL PRES	12	-	-
CARDIOTONIC & VASODILATOR	11	-	-
CONTROL HEART RT & LOWER BLOOD PRES	10	-	-
REL ANGINAL PAIN & VASODILATOR	9	-	-
CURB CARD ARRYTH & PAIN RELIEF	7	-	-
ANTIHYPERTENSIVE & VASODILATOR	6	-	-
INC MYOCARD CONT & VASODILATOR	6	-	-
CORONARY VASODIL & VASODILATOR	5	-	-
REDUCE ANXIETY	5	-	-
RELIEVE HEADACHE	5	-	-
CONTROL HEART RT & REL ANGINAL PAIN	5	-	-
CONTROL HEART RT & CALCIUM BLOCKER	5	-	-
ALL OTHERS	43	1	-
TOTAL	7030	100	100
NO REASON GIVEN	1831		

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TABLE 5-4

	12 Mos.	Qtr.
Est. U. S. Visits. (000)	8462	1906
Patient Visits w/drugs	7983	1827
Patient Visits w/o drugs	479	79
Sample Data:-Total Visits	1511	372

ANGINA PECTORIS NO HYP
(ISCA413.9)

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Age	Total 12 Mos. No.	%	Male 12 Mos. No.	%	Female 12 Mos. No.	%	Unspec. 12 Mos. No.
2 & Under	7	-	-	-	7	-	-
3-9	10	-	10	-	-	-	-
10-19	-	-	-	-	-	-	-
20-39	126	2	74	2	48	1	4
40-59	1651	20	888	24	620	15	143
60-64	962	12	481	13	418	10	63
65 +	5501	67	2221	60	2958	73	322
TOTAL	8256	100	3674	100	4050	100	532
Unspec.	205		1		47		157

Specialty	12 Mos. No.	%	Qtr. %	Visits/ Phy./Yr.
GP-PT	577	7	6	29
FP-PT	1366	16	13	44
Int.Med.	3519	42	37	75
Card.	2361	28	38	244
Gastro	71	1	1	16
Gen.Surg.	80	1	1	4
Orth.Surg.	7	-	-	1
A.O.Surg.	31	-	-	2
Ob/Gyn.	-	-	-	-
Ped.	-	-	-	-
ENT	1	-	-	-
Ophth.	-	-	-	-
Derm.	1	-	-	-
Allerg.	5	-	-	3
Urology	115	1	-	13
Psych.	3	-	-	-
Neur.	6	-	-	1
Osteo.	317	4	3	21
TOTAL	8462	100	100	31

Desired Action	12 Mos. No.	%	Qtr. %
REL ANGINAL PAIN	8463	64	59
VASODILATOR	500	4	3
CORONARY VASODIL	455	3	4
CURB CARD ARRYTH	446	3	4
PAIN RELIEF	434	3	3
ANTIPLATELET	352	3	5
DIURETIC	307	2	2
PROPHYLAXIS	225	2	3
CALCIUM BLOCKER	216	2	3
CONTROL HEART RT	200	2	1
ANTICOAGULANT	180	1	1
CARDIOTONIC	168	1	1
BETA BLOCKER	97	1	1
CORRECT K IMBAL	93	1	1
DIGITALIS EFFECT	80	1	1
INC MYOCARD CONT	68	1	-
REDUCE ANXIETY	61	-	-
CARDIOTONIC &			
REL ANGINAL PAIN	54	-	1
MYOCARD STIMUL	54	-	-

Drugs		12 Mos. No.	%	Qtr. %
31211	NITRITES/NITRATES	6243	64*	66*
72014	NITROGLYCERIN	1941	23	22
72068	ISORDIL	1334	16	18
72332	TRANSDERM-NITRO	630	7	5
72118	NITROBID	521	6	7
72356	NITRO-DUR	376	4	4
72252	NITROSTAT	339	4	5
72183	ISOSORBIDE DINITRATE	196	2	3
72139	SORBITRATE	167	2	2
72335	NITRO-DUR**	137	2	-
72333	NITRO DISC	122	1	2
72026	NITROL OINTMENT	88	1	-
72358	NITROLINGUAL SPRAY	73	1	1
72323	DILATRATE-SR	66	1	1
72371	DEPONIT	53	1	1
72368	NITROGARD	46	1	1
72331	TRIDIL	46	1	1
72001	CARDILATE	33	-	1
72293	SORBITRATE SA	24	-	-
72021	PERITRATE	24	-	-
31700	CALCIUM BLOCKERS	4729	55*	56*
72341	CARDIZEM	2454	29	32
72336	PROCARDIA	1162	14	14
72343	DILTIAZEM	247	3	4
72375	CALAN SR	213	3	2
72349	VERAPAMIL	159	2	2
72345	CALAN	145	2	2
72360	NIFEDIPINE	137	2	-
72342	DILTIAZEM	114	1	-
72347	ISOPTIN	41	-	-
72374	ISOPTIN SR	33	-	-
31410	BETA-BLOCKERS	1492	18*	21*
76107	TENORMIN	441	5	8
76055	INDERAL	374	4	3
76082	LOPRESSOR	251	3	5

Location	12 Mos. No.	12 Mos. %	Qtr. %
Office	5167	65	71
Home	88	1	2
Hosp.	2053	26	23
Teleph.	423	5	3
Nurse Hm.	117	1	1
Other	83	1	-
TOTAL	7931	100	100
Unspec.	530		

Region	12 Mos. No	12 Mos. %	Qtr. %
East	2051	24	28
Midwest	1842	22	16
South	2950	35	31
West	1619	19	25
TOTAL	8462	100	100

Visit	12 Mos. No.	12 Mos. %	Qtr. %
First	1275	16	15
Refer	441	35 **	
Subseq	6728	84	85
TOTAL	8004	100	100
Unspec	458		

** % of First Visits

Surgery	12 Mos. No	12 Mos. %	Qtr. %
Yes	20	-	-
No	8442	100	100
TOTAL	8462	100	100
Unspec			

INC CIRCULATION	50	-	-
LOWER BLOOD PRES	47	-	-
PROMOTE SLEEP	44	-	-
REL ANGINAL PAIN & VASODILATOR	38	-	-
CURB CARD ARRYTH & REL ANGINAL PAIN	37	-	1
REDUCE SWELLING	33	-	-
REDU FLUID RETEN	32	-	-
ANALGESIC	30	-	-
CARDIOTONIC & CORONARY VASODIL	29	-	-
ANTIINFLAMMATORY	28	-	-
REL ANGINAL PAIN & CORONARY VASODIL	26	-	-
SYMPTOMATIC	26	-	-
ANTI ULCER	25	-	1
REDU CHOLESTEROL	18	-	-
REL ANGINAL PAIN & PAIN RELIEF	18	-	-
ANTIDEPRESSANT	18	-	-
REL ANGINAL PAIN & CALCIUM BLOCKER	17	-	-
ANTACID	16	-	-
CONTROL HEART RT & CURB CARD ARRYTH	16	-	1
NON SPECIFIC	15	-	-
PAIN RELIEF & VASODILATOR	15	-	-
REDUCE TENSION & REDUCE ANXIETY	13	-	-
REL ANGINAL PAIN & ANTISPASMODIC	12	-	-
ANTIHYPERTENSIVE	11	-	-
DISSOLVE CLOT	11	-	-
STREN HEART BEAT	11	-	-
REDUCE TENSION	11	-	-
MAINTAIN BL PRES	10	-	-
REDU GASTRIC SEC	9	-	-
RED LIPID LEVEL	8	-	-
CONTROL EDEMA	8	-	-
PERIPH VASODILAT	8	-	-
REL LEG CRAMPS	7	-	-
ANTITUSSIVE	7	-	-
REDUCE ANXIETY & SEDATIVE UNSPEC	6	-	-
CONTROL VERTIGO	5	-	-
ALL OTHERS	112	1	1
TOTAL	12287	100	100
NO REASON GIVEN	2118		

76097	CORGARD	101	1	1
76128	INDERAL LA	90	1	1
76108	ATENOLOL	88	1	1
76071	PROPRANOLOL	85	1	1
76126	VISKEN	33	-	1
02140	ASPIRIN,APC,ETC.	644	8*	12*
41005	ASPIRIN	526	6	8
41012	ECOTRIN	91	1	3
41004	ASCRIPTIN	21	-	1
31500	DIGITALIS PREP	488	6*	6*
74014	LANOXIN	317	4	3
74040	DIGOXIN	158	2	3
41230	DIUR.OTHER NON-INJ	365	4*	4*
79097	LASIX	304	4	3
71847	LOZOL	25	-	-
31300	ANTI-ARRHYTHMIA	223	3*	2*
76039	QUINAGLUTE	57	1	-
76101	PROCAN SR	44	1	1
76166	ENKAID	27	-	1
76047	QUINIDEX EXTENTABS	17	-	-
31212	VASODL.COR.OTHERS	161	2*	3*
72080	PERSANTINE	146	2	2
41220	DIUR.K-SPARING	105	1*	2*
79095	DYAZIDE	53	1	1
79220	MAXZIDE	27	-	-
60110	POTAS.SUP.CHLORIDE	93	1*	1*
87217	SLOW-K	31	-	-
64121	MIN.TRNQ.BENZODIAZ	80	1*	1*
07156	ATIVAN	21	-	1
23400	ANTISPAS. OTHERS	70	1*	1*
04427	CARAFATE	31	-	-
04432	ZANTAC	20	-	1
04406	TAGAMET	19	-	1
31140	ACE INHIBITOR	70	1*	1*
71835	CAPOTEN	31	-	-
71864	VASOTEC	17	-	1
71863	CAPOZIDE	16	-	-
41210	DIUR THIAZ & REL	46	1*	-*
79027	HYDROCHLORDTHIAZIDE	37	-	-
11200	ANTICOAG..INJECT	42	-*	1*
77006	HEPARIN SOD	42	-	1
11100	ANTICOAG..ORAL	41	-*	-*
77000	COUMADIN	37	-	-
78800	MISC ETHICALS.OTHR	40	-*	1*
99999	MISC MISC	32	-	-
32110	CHOLEST.REDUCR RX	38	-*	1*
66070	MEVACOR	22	-	-
	ALL OTHERS	434	5*	5*
	TOTAL	15404	1.8	1.9

IMS 0703 11/82

* THERAPEUTIC CLASS PERCENTAGES ELIMINATE DOUBLE COUNTING I.E.,THE PATIENT RECEIVING MAALOX AND GELUSIL IS ONLY PERCENTAGED ONCE

TABLE 5-5

NDA SPECIALTY REPORT DECEMBER 1988

ADD (000) TO ALL FIGURES

USC/PRODUCT		ROLLING TWO MONTHS		
		DETAILS	MINUTES	DOLLARS
CARDIZEM	MARION	28	110	1,317
GP/FP/PT		11	38	508
IM		10	42	477
CD		3	14	158
GS		1	5	41
DO		2	7	87
ALL OTHERS		1	3	34
DILTIAZEM	MARION	1	3	30
IM		0	1	16
CD		0	1	6
DYNA CIRC	SANDOZ	0	0	6
ISOPTIN	KNOLL	3	8	138
GP/FP/PT		1	3	38
IM		1	3	54
CD		1	1	31
GS		0		2
DO		0	1	11
ALL OTHERS				
ISOPTIN SR	KNOLL	16	62	983
GP/FP/PT		7	26	412
IM		6	21	342
CD		1	4	75
GS		1	1	27
DO		2	6	106
ALL OTHERS		0	2	16
NIFEDIPINE	MILES PHAR			
NIFEDIPINE	PFIZER	0	2	19
CD		0	1	3

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YEAR-TO-DATE			CURRENT 12 MONTHS		
DETAILS	MINUTES	DOLLARS	DETAILS	MINUTES	DOLLARS
222	884	10,449	222	884	10,449
83	310	3,738	83	310	3,738
87	357	4,190	87	357	4,190
22	106	1,255	22	106	1,255
7	26	270	7	26	270
15	58	660	15	58	660
6	21	244	6	21	244
4	24	251	4	24	251
2	13	130	2	13	130
1	6	71	1	6	71
0	2	9	0	2	9
28	87	1,199	28	87	1,199
9	25	384	9	25	384
10	24	410	10	24	410
4	13	188	4	13	188
2	7	56	2	7	56
2	7	99	2	7	99
1	11	44	1	11	44
104	381	6,219	104	381	6,219
42	142	2,568	42	142	2,568
37	134	2,237	37	134	2,237
7	28	424	7	28	424
4	18	215	4	18	215
10	37	564	10	37	564
4	21	182	4	21	182
0	0	2	0	0	2
3	17	145	3	17	145
1	8	67	1	8	67

TABLE 5-6

NATIONAL JOURNAL AUDIT

DECEMBER, 1988 PAGES & COST (000)

PRODUCT		1987 DEC	1987 YR. TO DATE	JAN	FEB	MAR	APR	MAY
31610 HEMORHEOLOGICS								
TRENTAL	PAGES	65	714	60	65	77	56	76
HOEST-ROUS	COST	219	2504	220	254	287	210	254
CLASS TOTAL	PAGES	65	714	60	65	77	56	76
	COST	219	2504	220	254	287	210	254
31690 OTHER C V AGENTS								
DOBUTREX	PAGES	8	96	6	9	9	6	8
LILLY	COST	15	157	12	15	16	8	13
DOPAMINE	PAGES		3					
AMER REGNT	COST		8					
EPIPEN	PAGES		3					1
CENTER LAB	COST		9					3
EPIPEN JR	PAGES		3					1
CENTER LAB	COST		10					3
INOCOR	PAGES		304	41	44	43		
WINTRP PHM	COST		630	98	87	84		
CLASS TOTAL	PAGES	8	409	47	53	52	6	9
	COST	15	813	110	103	100	8	18
31700 CALCIUM BLOCKERS								
ADALAT	PAGES		2					
MILES PHAR	COST		2					
CALAN	PAGES		262	13	19	18	18	15
SEARLE	COST		1035	46	67	62	67	57
CALAN SR	PAGES		2850	86	238	242	242	284
SEARLE	COST		15487	552	1061	1120	1044	1268
CARDIZEM	PAGES	110	2433	145	86	104	89	137
MARION	COST	357	9458	502	304	423	335	398
DYNA CIRC	PAGES		1		4	3	2	17
SANDOZ	COST		4		9	10	6	54
ISOPTIN	PAGES		34	7	8	8	7	1
KNOLL	COST		105	26	31	29	20	5
ISOPTIN SR	PAGES	27	736	36	41	38	38	31
KNOLL	COST	123	2503	172	164	168	153	153
PROCARDIA	PAGES	105	1877	181	170	163	165	157
PFIZER	COST	370	6603	687	628	601	603	579

0 INDICATES LESS THAN 1 NC INDICATES NO CHANGE

EXPENDITURES BY CLASS

PAGE H 41

JUN	JUL	AUG	SEP	OCT	NOV	DEC	CURR 12 MOS	YR. TO DATE	YR. TO DATE % CHG 87/88
69	44	41	70	81	73	50	759	759	+6
258	159	148	253	292	282	177	2793	2793	+12
69	44	41	70	81	73	50	759	759	+6
258	159	148	253	292	282	177	2793	2793	+12
8	6	9	3	7		3	68	68	-29
12	13	9	8	11		4	121	121	-23
2	1	1					4	4	
5	5	2					15	15	+70
2	1	1					3	3	
5	2	2					13	13	+25
	15	19	20	20			202	202	-34
	36	38	38	37			418	418	-34
11	23	25	23	27		3	277	277	-32
23	56	51	46	48		4	566	566	-30
0		2			2		86	86	-67
3		3			5		308	308	-70
161	76	77	81	83	104	119	1793	1793	-37
677	245	309	327	328	427	465	7822	7822	-49
53	87	150	134	129	150	139	1403	1403	-42
183	310	560	510	454	560	493	5032	5032	-47
10	10	6	6	6	7	8	79	79	
32	27	19	21	20	22	28	246	246	
					3		34	34	-1
					15		127	127	+20
31			26	26	28		295	295	-60
141			137	140	166		1394	1394	-44
136	144	118	111	144	193	163	1842	1842	-2
506	528	443	411	524	723	605	6838	6838	+4

18% INDICATES OVER 999%

TABLE 5-7

NATIONAL MAIL AUDIT

DECEMBER 1988

DOLLARS (000), # ADS, CIRC (000)

PRODUCT		1987 DEC	1987 YR. TO DATE	JAN	FEB	MAR	APR	MAY
31690 OTHER C V AGENTS								
CLASS TOTAL 31690 OTHER C V AGENTS	$	2	5					
	# ADS	1	2					
	CIRC	5	9					
31700 CALCIUM BLOCKERS								
ADALAT	$		1	0			0	
MILES PHAR	# ADS		3	1			1	
	CIRC		19	5			5	
CALAN	$	3	85					
SEARLE	# ADS	1	6					
	CIRC	16	220					
CALAN SR	$	5	239	9	3			37
SEARLE	# ADS	1	12	1	1			1
	CIRC	16	455	17	7			34
CARDIZEM	$		909	83	59		70	192
MARION	# ADS		31	3	2		4	3
	CIRC		916	66	98		110	199
DYNA CIRC	$							
SANDOZ	# ADS							
	CIRC							
ISOPTIN	$		80					
KNOLL	# ADS		7					
	CIRC		355					
ISOPTIN SR	$	13	493	28	57	42	49	1
KNOLL	# ADS	2	37	2	4	1	3	1
	CIRC	42	1087	24	76	30	61	9
SAMPLE	$		28					
	# ADS		1					
	CIRC		19					
PROCARDIA	$	20	36					
PFIZER	# ADS	2	6					
	CIRC	35	83					

0 INDICATES LESS THAN 1

NC INDICATES NO CHANGE

EXPENDITURES BY CLASS

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JUN	JUL	AUG	SEP	OCT	NOV	DEC	CURR. 12 MOS	YR. TO DATE	YR. TO DATE % CHG 87/88
			3	4	4		11	11	+115
			1	1	1		3	3	+50
			6	10	10		26	26	+186
	1				1		3	3	
	1				1		4	4	+33
	14				8		30	30	+62
6							6	6	-93
1							1	1	-83
9							9	9	-96
81	87						217	217	-9
2	2						7	7	-42
114	61						232	232	-49
46	154	93			52	64	812	812	-11
1	5	2			1	1	22	22	-29
57	190	99			47	57	921	921	+1
2	3						4	4	
1	1						2	2	
8	9						16	16	
5	6		17	7	5	1	218	218	-56
1	2		1	2	2	1	20	20	-46
34	41		8	41	35	8	363	363	-67
				3	4		7	7	-80
				1	1		2	2	-67
				13	11		24	24	-72

HI% INDICATES OVER 999%

A total of 211 unduplicated listings were offered. (Interestingly, only 95 of these appeared in both publications.)

The variety of research services provided by these companies is extraordinary. Below is a partial list of words used by the companies themselves. It is obvious that the market research departments who require outside services have an extensive (perhaps bewildering) array from which to choose.

Ad Layout Testing
Ad Recall Studies
Attitude Measures
Audits
Brand Awareness
Brand Imagery
Concept Testing
Convention Surveys
Copy Testing
Corporate Image Studies
Distribution Analysis
Focus Panels/Groups
Mail Surveys
Mall Intercept
Market Share
Market Segmentation
Media Research
Medication Histories
Multivariate Statistics
Name Tests
Packaging Studies
Panel Studies
Penetration Studies
Personal Interviews
Prescription Audits
Product Positioning
Questionnaire Design
Readership Studies
Sales Force Effectiveness Studies
Sample Evaluations
Shelf Life Audits
Telephone Interviews
Tracking Studies

In addition to market research offerings, there are various other sources of information regarding pharmaceuticals, the pharmaceutical marketplace, and the population in general available to the pharmaceutical marketer or market researcher. These usually provide background information or intelligence, or are reference works. The *Pink Sheet* and *Scrip* are examples of publications that provide news or intelligence regarding the industry. Publications such as the *Merck Manual*, *Merck Index*, *AMA Drug Evaluations*, *Facts and Comparisons*, and *Remington's Practice of Pharmacy* are excellent for obtaining background information on diseases and drugs. The *Journal of the American Hospital Association* and its *Annual Guide* issue provide a wealth of demographic information on the hospital universe in the United States. Many government agencies publish a variety of reports and studies of potential interest, such as *United States Census Data*, the *Statistical Abstract of the United States* and, of more specific interest to the pharmaceutical market researcher, studies such as those of specific diseases and health care financing. Finally, *The Journal*

of Pharmaceutical Marketing and Management publishes original research.

COMPANY MARKET AND MARKETING RESEARCH ACTIVITIES

Because of the abundance of market and marketing research services offered to the pharmaceutical industry, one may be left with the impression that these offerings satisfy all the needs of companies, and that the function of the market research department within the company is simply to analyze the data provided in these services. This is not the case; many research studies are initiated, carried out, and analyzed by in-house personnel. Figure 5-2 provides an overview of this process. In some cases this is due to requirements of confidentiality. In others, company personnel may have more knowledge of a particular subject area. Third, there may be a need for correlation of the market research study with other areas of the company such as research and development of sales, and this is often more easily accomplished by in-house staff. Finally, a company may view the use of its own staff as being less costly than contracting out a project. Analyses of internal company data such as factory sales, promotional spending, and detailing call reports, also generally fall within the market research department's area of responsibility. A third major segment of activity is the analysis of data provided by independent research companies who work with these outside suppliers on particular projects.

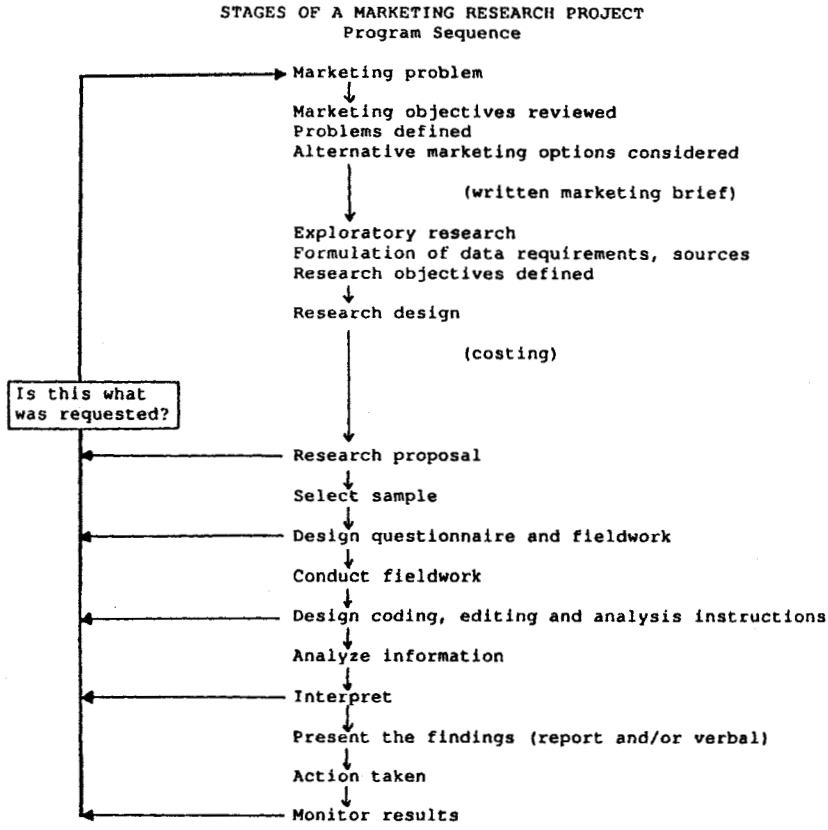
MARKETING DATA

Analysis and Interpretation

The successful analysis and interpretation of marketing data or, for that matter, any data, is contingent upon a number of factors. These factors are relevant whether the analyst is working with data reflecting a group of five physicians, or with data on the millions of transactions that are represented in the warehouse withdrawal audit.

Perhaps most of the significant factors in successful use of marketing data can be summarized by one word—understanding. The first element of understanding relates to understanding the question to be answered, or the problem to be solved. You might be surprised to learn how much effort is wasted in providing answers to the wrong question, or solutions to the wrong problem. Before beginning any research or analytic effort, the astute analyst hones in on the specific question to be answered. The

FIGURE 5-2. Stages of a primary marketing research project gathering primary data



Source: IMS America, System 300, Principles and Practice of Pharmaceutical Marketing Research, Descriptive Booklet.

analyst, for example, should not be satisfied with a request to "find out how physicians use product X." As a first step, what is meant by the term "use?" Does it mean used by diagnosis, by strength or dosage, for how long, singly or in combination with other products? The analyst should also determine whether the requestor means physicians in general or specialists, their use of the product overall or within a specific diagnosis, in the office or hospital, now or over a period of time. It is simply common

sense that the more detailed and specific the request, the more accurate will be the response to the request.

Understanding is also required of the information or data with which the analyst works. A primary requirement is a comprehension of the methodology employed to collect data or to compile information. If, for example, the data are collected from a sample of a population, the analyst must understand the makeup of that sample. What specific activities or characteristics of the population is the sample designed to reflect? How are potential participants in the sample selected? What is the response to the recruiting effort? Do the answers to the latter two questions suggest a bias in the results of the study? What device or method is used to collect the data? If a document, what pieces of information are requested on the document? What instructions are given to the participant for recording information?

Although these questions may appear to be more technical than practical, they are of utmost importance to the data analyst. An analyst familiar with the data collection methodology of a study, audit, or survey will better understand the objectives of the study, what questions it can answer and, equally important, what questions it cannot answer. The analyst responding to the request discussed above, as an example, will have to determine if data are available to answer the question and, if not, how to obtain the data.

As another element, if the data being analyzed are projected from a sample to represent a total population or activity, the user of these data should be familiar with the projection technique utilized, and the reliability of the resultant estimates. Meaningless data are frequently given the status of meaningful data by the analyst who is unaware of its limitations.

Furthermore, there should be a familiarity with the units of measurement or terminology used in an audit or study. Frequently, analysis of physician practice data involves the number of patients with a given disorder. The physician panel does not measure patients; it measures patient visits. The analyst who labels dollars found in the pharmacy purchase audit as manufacturer sales dollars for a product is incorrect. This audit measures purchases of a product by retail pharmacies. The difference might sound unimportant but, according to whether or not the product is purchased directly from a manufacturer or through a wholesaler, it could amount to 15 percent.

A complete understanding of each of the pieces of data used by the analyst is important not only within the context of successful use of an individual set of data, but also because of the differences that occur in conjunctive use of different sets of data. Often retail pharmacy prescrip-

tion data will indicate activities or trends dissimilar to those in the retail pharmacy purchase audits. If it is recalled that one of these audits measures outflow and the other measures inflow, many of these apparent differences can be easily understood and explained.

Beyond the necessity of understanding data, there is an equally important factor involved in working with data—the need to understand that all data are not to be taken at face value. The successful analyst is a questioning analyst. Although no one purposely causes errors to be made, errors do occur or, if not errors, then anomalies occur. The competent analyst does not accept these simply because they appear in black and white, but instead questions them and attempts to find out why they have occurred. In sum, defining and understanding the question or problem, understanding the data to be worked with, and possessing the ability to question are three major requirements for successful analysis and interpretation of marketing data.

There are other elements that contribute to proper as opposed to mediocre or complete as opposed to incomplete analytic efforts. Data should not be viewed in an isolated sense, but as part of different pieces or sources of data. The determination that new prescriptions for a product have increased is, by itself, an interesting point. Taking into account the fact that the number of new prescriptions have increased without any additional promotion of the product but with a doubling of promotion for a competitive product is even more interesting and of more importance.

The analyst will also try to explain as fully as possible the reasons for an occurrence. If sales of a product have risen 15 percent the analyst should try to determine if this is the result of real growth (growth in units) or simply the result of a price increase. If the growth is real, is it because there was seasonal stocking of the product or can it be determined that new prescriptions for the same time period showed the same kind of increase, indicating that physician demand was increasing? In general, the analyst understands the point that the answer to one question usually leads to other questions to be answered.

Applications and Uses

The services and data that have been discussed throughout this chapter have been labeled as market research, marketing research, or marketing services and data. Although these data are designed to measure or portray the marketplace in one way or another, and are perhaps of special importance to the marketer, their utility and application extend well beyond the sector of the marketing department. There are probably few areas in any

pharmaceutical company that do not, at one time or another, have use for these services and data.

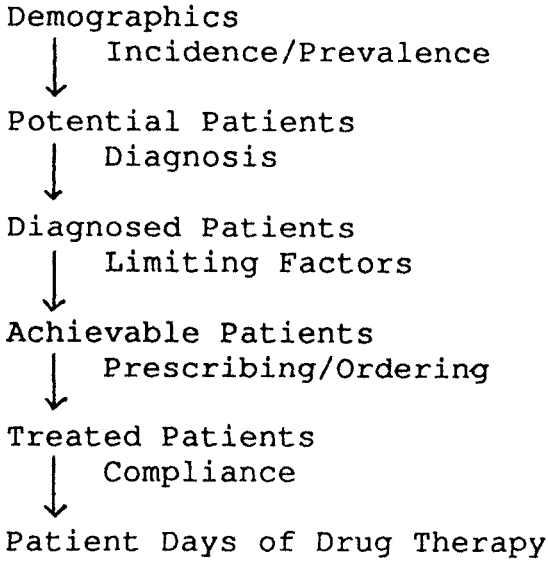
As an example, a major strategic question that companies have to deal with is research and development planning. What disease or product areas appear to warrant long-term research and development investment? Which seem to suggest the plausibility of short-term involvement? Marketing data can aid in this planning process in such areas as identifying market size and potential, whether or not there is available therapy, where therapy is available but not used, and what is to be the next logical step in therapy. Short-term focus is illustrated by analyzing the data to help identify areas that may be available for subdivision. The analgesic market, for example, is a broad one. Some companies have been successful in orienting their development efforts toward a segment of that market, such as migraine headache analgesia. Similarly, there has been success in the segmenting of the respiratory condition area by offering products specifically for sinusitis. Data analysis may help identify product sectors in which more convenient dosing of a drug would be beneficial to the patient and to marketing.

These data may be useful with regard to the serendipitous research and development discovery. Should the company that finds itself with a compound that appears effective in the treatment of a particular disorder pursue the study of the compound? Available data can help in this decision by delineating such parameters as the prevalence of this disorder, the potential market size, or drugs presently employed. It should be pointed out here that for neither directed nor serendipitous research results is market size or potential necessarily the key determinant in deciding whether to continue studying a product. Many companies have marketed drugs for treating minuscule patient populations.

It should also be noted that real market potential is affected by many variables. As Figure 5-3 shows the theoretical market potential may be considerably different from that which is ultimately realized.

There are other segments of the broadly defined development process that benefit from the use of marketing data. Diverse conditions such as osteoarthritis and hypertension are often found in the same patients. If an antiarthritic compound has a blood pressure-elevating property, this compound would not be used to treat arthritic patients who are also hypertensive. Data from physician panels on medical practice can quantify how frequently these conditions exist together, and thus suggest the minimization of usage potential that would be caused by this property of the compound. Questions on the need for specific dosage forms required for a

FIGURE 5-3. From theoretical to real market potential



Source: The MattsonJack Group. St. Louis, MO.

product may be answered by reviewing marketing data. Diagnosis data, for instance, would indicate that otitis media is mainly a disorder of pediatric patients. If an anti-infective with efficacy in otitis media cannot be formulated in liquid form, it would be used infrequently.

Data are useful in planning clinical trials. If a product demonstrates activity in more than one condition, data showing the relative importance of the various conditions might be used to determine for which condition clinical testing should be performed. Seasonality, regionality, and specialty data are also of interest in planning clinical trials. Companies may determine the combination of region, season, and specialty that are most likely to produce large numbers of patients with a specific condition.

Assuming that a product is to be marketed, or is on the market, the manufacturing area of a company needs direction in regard to how much of the product is required. Marketing data can be used to assist in these determinations. The need for samples, for instance, in terms of such factors as overall quantity or package size, is often decided by analysis of competitive sampling as shown by audits of promotional activity.

Corporate development departments rely on marketing data in many cases to analyze potential company or product acquisitions and licensing opportunities. Financial and legal personnel also have occasion to view market data as an aid in their activities.

The most frequent use of market data occurs, of course, in the marketing area of the company. One major use is for premarketing planning. Much of this use is involved with analysis of the market that the drug is to enter. A marketer needs to know various pieces of information to ensure successful marketing of a product. What physician specialties are important in a given therapy or diagnosis category? Is the hospital an important sector? What patient characteristics are apparent? What is the present state of the market in terms of competition? How do competitors promote their products? Are there presently unsatisfied portions of the market? Attitudinal research is generally carried out to determine how physicians perceive a proposed product or the advantages and disadvantages of currently available products. Advertising personnel study data to depict in print media a patient type that the physician finds relevant to the condition for which a drug is to be used.

Once a product is on the market, the main use of marketing data is to monitor the performance of a product across all the various aspects of the marketplace. Product sales, prescriptions, overall physician usage or by specialty or high prescribers, diagnosis, and location, for example, are all analyzed continuously to monitor progress of a product by itself as well as in relation to the market in which it competes. Invariably, this monitoring process reveals information that suggests the need for additional information or action, and the market or marketing research process takes another turn.

FUTURE CONSIDERATIONS

As Raymond Gosselin has so aptly stated, the task of market and marketing research is to keep those who need to be kept informed supplied with all the facts possible to amass. The extraordinarily dynamic nature of the pharmaceutical industry, coupled with the ever increasing ability to collect facts, suggest the need for an ability of the market research function to contribute even more significantly in the future. Although the pharmaceutical industry is, in fact, a "data-rich" industry, and much is presently known, much more needs to be known.

CASE IN POINT

Audit Data Applications in the Product Life Cycle

Do drug companies have more information than they can use competently? Perhaps, in some cases. In any case the integration of multiple data bases is crucial to allow strategic planning and rapid reaction to market conditions.

IMS America is probably the largest supplier of periodic audit and other types of market data for the pharmaceutical industry. As an aid to their clients IMS has prepared a Database Application Guide to suggest application of various data sources at different stages in a product life cycle. We recognize that a firm would certainly use other data sources, but the IMS application provides a useful study of how and when different kinds of data can be applied to marketing strategy.

This guide cannot take the place of an in-depth knowledge of the contents of the database, other data sources and a company's own business interests.

As a general model at all stages of product life cycle, the marketing process, in which market research plays an integral role, has a 5-part structure: (1) background and analysis in which the market situation is examined; (2) setting objectives based upon information received and goals chosen; (3) strategy development in which alternative ways to achieve the goal are identified; (4) strategy testing in which the alternatives are tested and one is selected for implementation; (5) monitoring the results of the implementation. Both secondary data, such as that provided by IMS America, and primary data, such as that gained from focus groups and surveys, are used in this process, each type lending particular insight to the questions that must be addressed.

Source: *IMS America*.

PRODUCT LIFE CYCLE

STAGE I: OPPORTUNITY ANALYSIS — **From 10 to 3 years pre-launch, the product has passed toxicological testing and is in Phase I human testing.**

Long before a new product is ready for market, company management needs some assurance that its market potential justifies further investment. The company does not yet know if it has a viable product. Market research must therefore provide insight on:

What is the Opportunity	**Data Resources** (See end of case for definitions of abbreviations)	
How is the market defined? -By diagnosis?	NDTI:	Diagnosis book - total visits, new starts, total patients.
Our drug is used to treat these diagnoses. What other drugs are used as well?	NDTI in IMSPACT ATX/MLK:	(for cardiovascular and musculoskeletal diagnoses only)
-By drug?	NDTI:	Drug book, NDTI in IMSPACT Leading diagnoses, concomitant products, desired actions
Our drug is like Product X. How is Product X being used?	ATX/MLK:	cardiovascular musculoskeletal drugs only
-By prescriptions and length of therapy?	NPA:	Therapeutic Category Report Basic Data - total patient days of therapy (non-hospital) IMSPACT - RXDAYS, THERDA
What are the major population/ disease trends in a diagnosis area?	NDTI:	demographic data - patient visits, patient visits, patient age, sex, race, etc.
	MLK:	(cardiovascular, musculoskeletal diagnoses only) trends

What is the Opportunity	**Data Resources**
How big is the market today? -By units?	USD, USH, FGCA, NPA, Regional Special Studies

-By dollars?	NDTI/USD diagnosis value (IMSPACT)
-By chemical weight?	USD, USH units in chemical weight in IMSPACT
How is it growing?	IMSPACT (used to trend USD, USH, NPA, NDTI): reprice, average, compound growth rate, trend, change in share, price index
Which doctors are in it?	NPA Specialty; NDTI Office/ Hospital Specialties receiving referrals
What is the Competition?	
Which are the competitive products?	NDTI Diagnosis, MLK
What are their key features and benefits?	
-By form, strength, dosage, package pricing	USD, USH, NPA, NDTI
How are they doing?	
-By form, strength, dosage, package, delivery system?	USD, USH, NPA, NDTI
Who are the companies involved?	USD, USH, NPA
What are their corporate commitments?	USD, USH, NPA, New Products in USD, NJA, NDA, NMA. Also: Company Annual Reports
What has been the cost of launching in this market to date?	NJA, NDA, NMA, Advertising to Sales, Promo Cost per Rx, USD, USH, NPA, NPD
What new products are in development?	New products in USD, IMS Pharmaceutical Marketletter Also: Industry Publications, Futures Group, FDC Pink Sheets, Scrip, Company internal reports on pharmaceutical research
Where is the new technology?	New Products in USD, Also: Industry Publications, Futures Group, FDC Pink Sheets, Scrip, Company internal reports on pharmaceutical research
STAGE II: STRATEGY DEVELOPMENT	**From 3 years to 6 months pre-launch, the product is in Phase III testing. The New Drug Application has been filed with the Federal Government, and the product is a reality.**

The year or two before a new product is expected to be launched is a crucial time period for Market Research. During this time, primary research plays an increasingly important role in defining product positioning. At this stage, IMS and other secondary data's key roles are in guiding primary research efforts by focusing the questions that need to be addressed, and in forecasting product potential based on historical analogies.

Positioning	**Data Resources**
Which are the competitive products for benchmarking?	NDTI, ATX/MLK
Which physicians use them? Age,	NPA Specialty, NDTI Doctor Region, City Size, Specialty; ATX/MLK MD List; NDTI in IMSPACT Per-MD Avg.
What promotional messages do physicians receive?	NJA and ad clips, NMA copies of mail pieces, NDA verbatims, NPD
How do physicians respond?	
-Do they use drugs as manufacturers intend?	NPA Basic Data (Rx size, Therapy Days), NDTI demographics, diagnosis, desired actions, MLK
-Where? Office? Hospital?	NDTI Location
-For what desired effects?	NDTI Desired Action
-With which patients?	NDTI Demographics
-Under what therapeutic conditions? (diagnoses)	NDTI Diagnosis, Blood Pressure
-In what therapeutic positions (first line?, add-on?, concomitant?)	NDTI Therapy, MLK

Positioning	**Data Resources**
-Where do new starts come from?	NDTI, MLK
What promotion has been effective and/or efficient?	
-Examine message effectiveness	NPD
-Examine media efficiency	NJA, NDA, NMA, compared with USD/USH or NPA
-Examine spending efficiency	NJA, NDA, NMA, compared with USD/USH or NPA
-Examine sampling efficiency	NDA, NMA
Forecasting	ATX/MLK, NPD and other audits as factored into forecasting models

The Research Process

Using the information gleaned from the above sources and expanded upon by primary research (focus groups, interviews, surveys, etc.), Market Research develops a perceptual map or other positioning model for the market, and forecasts product potential

from the assumptions drawn from the model.
After competitors are positioned, Product Management develops strategies for targeting the competitors through promotion, price, distribution, product mix, etc. Product Management works closely with Market Research to do this.

The process is redundant, with intense interplay between primary and secondary research. A model sequence might be:

1. Develop a background narrative of the market situation:
   -Set benchmarks
   -Follow competitive launch
   -Examine "noise level" in market
2. Review strategy and tactics of the competitors based upon:
   -Their key features and benefits
   -Market segment(s)
   -Promotional mix
   -Promotional message
3. Review objectives
4. Propose a strategy for your product:
   -Key features and benefits
   -Optimal market segment(s)
   -Optimal promotional mix
   -Optimal promotional message
   -Optimal strategy for entire product line
5. Test your strategy and revise as needed.

The IMS resources indicated can help in this process, but their chief contribution during this time is to focus the issues for primary research.

STAGE III:
LAUNCH PLANNING

Between 12 and 6 months pre-launch to launch.

During the hectic pre-launch period, the market researchers work closely with Product Management to provide insight on tactical issues. All efforts focus on how to bring the product to market with the greatest chance of success. Primary research is most important, however secondary research still provides key pieces of information.

Pricing Issues	**Data Resource**
What is the price of competitive products? -Per day? -Per course of therapy?	NPA Basic Data USD, USH (Historical Price)
Examine the value of our new product relative to the market.	NPA in IMSPACT: Pharmacy/Retail Pricing
Promotion Issues	
What are competitors' promotional expenditures in response to the coming launch?	NDA, NMA, NJA

-What is the mix of traditional media (journal, Mail, detailing)?	NDA, NMA, NJA
-What are their non-traditional media expenditures?	

Sales Issues

Which competitors have sales force strength?	PMRG data
How are they deployed?	NDA
-Where (geography, hospital/ non-hospital)	IMSPACT for data on sampling
-Which specialties?	Average number of sample packs, number of details with samples

Six months prior to launch, some issues need review. This is the final opportunity to fine-tune strategy for launch.

How should our salesforce be deployed?	
-Where?	DDD (Drug Distribution Data, a division of IMS) may be used to set up pre- and post-launch sales force deployment strategies, benchmarks, and goals.
-Which doctors will be targets?	Special studies may be designed for pre- and post-launch tracking, and for identifying early adopters.
Launch Objectives:	
-Market share?	USD/USH, NPA, etc.
-Target doctor penetration?	NDTI, ATX, NPA
-Diagnosis penetration?	NDTI, MLK
Sales projection for first year.	Forecasting model may include: NPD, NPA weekly, NPA, Quik-Script, ATX/MLK, USD/USH, DDD

STAGE IV: LAUNCH EVALUATION — **First three months after launch.**

In the critical early post-launch period, researchers closely track results. Sometimes prior to launch, the researcher will have already determined what measures are to be tracked, especially if special studies are required.

Physician Awareness and Adoption	**Data Resource**
How many doctors are aware of our product?	NPD
Is the message getting across as we intended?	NPD, NDA verbatims
How many physicians are trying our product?	Quik-Script, ATX/MLK

-Sticking with it?	Quik-Script, ATX/MLK
-Using it in place of what others?	Quik-Script, ATX/MLK

Sales Force Effectiveness

Did the sales force execute details as planned?	NDA verbatims
Have the details been effective?	ATX/MLK, LISTMATCH with MDLIST

Product Movement

How many new Rx's have been written? What size? Length of therapy?	Weekly NPA
How many refills? Size? Patient cost?	NPA Basic Data (monthly)
Market shares?	Bi-weekly NPA, USD/USH, ATX/MLK, Quik-Script

Competitors' Responses	**IMS Data Resources**
Price changes?	NPA Average Cost (Basic Data_ IMSPACT
Detailing changes?	NDA Verbatims - detailing mix
Promotional message changes?	NDA Verbatims - what was discussed NMA mail pieces

STAGE V: EXPANSION ANALYSIS	**Three months after launch until peak market penetration.**

After the product has been launched more or less successfully, researchers will be asked by Product Management to explore possible ways to extend the product's life cycle. New forms or package sizes may be added to the product line, approval for new indications may be sought, new promotional messages developed, or new specialties targeted.

Secondary Market Definition	**Data Resources**
Which therapeutic indications have potential?	NDTI signa and dosage
Which physicians (by specialty and other characteristics) to target for this therapy?	ATX/MLK

The Research Process

After considering such secondary data input, Market Researchers may return to internal resources and primary data to address how the product might be repositioned. For example: by a new patient profile? by stressing different features and benefits? with different packaging? After a secondary market is identified, the researcher performs an analysis of the opportunity it presents. This opportunity must be weighed against the cost of changes in marketing strategy.

How can we extend the line?	**Data Resources**
-Combinations?	NDTI concomitancy
-Formulations?	NPA Basic Data
-New dosage regimen?	
-Packages?	
-New delivery techniques?	

Both internal resources and primary data will again be involved in the analysis process.

Cost/Benefit Analysis	**Data Resources**
What is the potential of the secondary market?	
How is the secondary market defined?	NDTI, ATX/MLK, NPA
How big is it?	USD, USH, NPA
What are its trends?	IMSPACT

The Research Process

The strategic question which then faces Marketing Management, based upon the input from Market Research, is, "Should resources be allocated?".

STAGE VI:
RISK ANALYSIS

After peak market penetration when mature product's share begins to decline.

What is the competition?	**Data Resources**
Which are the competitive products?	
-By diagnosis, drug use?	NDTI
-By therapeutic category?	ATX/MLK
How are they doing?	USD, USH, NPA, Regional Special Studies, IMSPACT
Who are the companies	USD, USH, NJA, NMA, NDA, IMSPACT. Also: Company Annual Reports.

How can we protect our product?	
Who are the doctors who are loyal to our product?	ATX/MLK, NDTI, NPA Specialty

The Research Process

Once the doctors who are loyal to your product are identified, you can use primary research to explore why they prescribe it and how to keep their business.

When do we change the level of promotion?	
-What is the return on our promotional spending?	NJA, NDA, NMA, NPA, USD, USH, Special Studies
-Can we get a better return from reallocating promotional dollars to another product?	NJA, NDA, NMA, NPA, USD, USH, Special Studies

Description of Audits Referred to in This Case

U.S. Drug (USD) - A continuing monthly report on the volume, in dollars and in units, of ethical

pharmaceuticals, proprietary pharmaceuticals, and some diagnostic products purchased for resale by retail outlets (pharmacies, proprietary stores and discount houses) in the United States. This audit measures inflow of pharmaceuticals.

U.S. Hospital (USH) - A continuing monthly report on the purchase of ethical pharmceuticals, proprietary pharmaceuticals, and some diagnostic products, by hospitals in the United States. This audit also measures inflow of pharmaceuticals.

National Prescription Audit (NPA) - Measures the rate at which drugs move out of independent and chain retail pharmacies into the hands of consumers via formal prescriptions in the United States. As such, the NPA measures both what is prescribed by the physician and what is dispensed by the pharmacist. This audit measures inflow of pharmaceuticals.

National Disease Therapeutic Index (NDTI) - A continuing compilation of statistical and information about the patterns and treatment of diseases encountered in office based practice in the United States.

Audatrex (ATX) - Records and reports on the day to day uninfluenced prescribing activity of individual physician in office based practice. Provides insights into physician brand and company loyalty, brand switching, product displacement, therapeutic category prescribing profiles, and product acceptance forecasts.

Journal Audit (NJA) - Measures all pharmaceutical advertising expenditures for ethical, OTC, and proprietary manufacturers normally prescribed or recommended by physicians in a group of medical, dental, hospital and drug trade journals to include all significant advertising.

Mail Audit (NMA) - Measures ethical pharmaceutical advertising expenditures for all significant physician and pharmacy mailings by recognized pharmaceutical manufacturers for both prescription and non-prescription products.

Detailing Audits (NDA) - Estimates the personal selling activity directed to physicians in office-based practice by pharmaceutical representatives.

Medilink (MLK) - Based on Audatrex allows analysis of switching patterns and relationship between diagnosis and prescribing.

Drug Distribution Data (DDD) - Patterns of distribution of products through wholesalers and chain warehouses to ZIP codes or sales territories.

IMSPACT - Draws together seven major IMS data bases for a single, on-line database with some interactive capabilities online.

Chapter 6

Strategy Development in Pharmaceutical Marketing

An employment advertisement appearing in 1988 began: "Ten years from now Searle is going to rank among the top 10 pharmaceutical companies in the world." It was an excellent example of a clear, measurable corporate objective. Such objectives, their relationship to the corporate mission and goals, and the ways pharmaceutical companies determine their strategies are the subject of this chapter.

PLANNING AS A CONCEPT

"If you don't know where you're going, any road will take you there." Whoever coined the expression almost certainly did not have marketing in mind, but the advice is sound for pharmaceutical marketers. No one, except a joy rider, hops into a car and simply drives away. A destination is essential and, usually, some thought as to the quickest or most scenic or safest route. This simple example can be applied to any endeavor.

David Ewing in his *Practice of Planning* (Harper and Row, 1968) ascribes a variety of accomplishments to planning:

1. It leads to a better position or standing for the organization.
2. It helps the organization progress in the ways that its management considers most suitable.
3. It helps every manager think, decide, and act more effectively for progress in the desired direction.
4. It helps keep the organization flexible.
5. It stimulates a cooperative, integrated, enthusiastic approach to organizational problems.

6. It indicates to management how to evaluate and check up on progress toward the planned objectives.
7. It leads to socially and economically useful results.

Most firms plan. Most of the larger firms even have specifically identified units charged with the planning function. Some, it must be admitted, plan for the sake of planning. Catharsis, not creativity, may be the result. At its best and most successful, however, planning is a necessary prerequisite to the kind of growth suggested by the Searle advertisement.

Growth is a part of corporate life (see Table 6-1) but growth must be carefully planned: questions such as how much, when, in which areas, and where to grow, and who will be responsible for different tasks, must be answered. Unplanned growth will be haphazard and may fail to provide the desired levels of profit. Therefore, in order for a company to realize orderly growth, to maintain a high level of operating efficiency, and to achieve its goals fully, it must plan for the future in a systematic manner. Products, markets, facilities, personnel, and financial resources must be evaluated and selected wisely.

Today's business is more complex than ever. In addition to the keen competition that firms face from both domestic and overseas companies, a variety of other concerns such as environmental protection, employees' welfare, consumerism, and antitrust action impinge upon business moves. Thus, it is desirable for a firm to be cautious in undertaking risks. This again calls for a planned effort.

Many firms pursue growth internally through the research and development effort. This route to growth not only is time-consuming but also requires a heavy commitment of resources with a high degree of risk. In such a context, planning is needed to choose the right type of risks. When Merck, Sharp, and Dohme landed at the top of America's list of corporations in the late 1980's, the Merck Chairman left no doubt that this was accomplished by careful selection of research and development projects and a long-term commitment to their development.

Planning is also required in making a choice among the many equally attractive alternative investment opportunities a firm may have. No firm can afford to invest in each and every "good" opportunity. Thus, planning becomes essential in making the selection.

It is necessary for a company to be clear about the nature and scope of planning that it intends to adopt. A definition of planning should then be based on what planning is supposed to be in an organization. It is not necessary for every company to engage in comprehensive planning of the

TABLE 6-1. Reasons for growth

Customer Reasons

The product line or sizes too limited for customer convenience.
Related products needed to serve a specific market.
Purchasing economies: one source, one order, one bill.
Service economies: one receiving and processing, one source of a line of products.
Ability to give more and better services.
Production capacity not enough to fill needs of important customers who may themselves be growing.

Competitive Reasons

To maintain or better industry position, growth is necessary in any but a declining industry.
To counter or better chief competitors on new offerings.
To maintain or better position in specific product or market areas where competition is making strong moves.
To permit more competitive pricing ability by greater volume.
To possess greater survival strength in price wars, product competition and economic slumps by greater size.

Company Reasons

To fulfill the growth expectations of stockholders, directors, executives and employees.
To utilize available management, selling, distribution, research or production capacity.
To supplement existing products and services that are not growth markets or are on downgrade of the profit cycle.
To stabilize seasonal or cyclical fluctuations.
To add flexibility by broadening the market and product base of opportunities.
To attain greater borrowing and financial influence with size.
To be able to attract and pay for better management personnel.
To attain the stability of size and move to management-by -planning.

Wholesale, Retail Reasons

To add products, sizes, and ranges necessary to attract interest of better channel partners.
To make additions necessary to obtain needed attention and selling effort from existing channel partners.

same style. The basis of all planning should be to design courses of action to be pursued for achieving stated objectives in the future such that opportunities are marshalled and threats are guarded against. But the exact planning posture must be custom-made, based on the decision-making needs of the organization.

Forecasting considers future changes in areas of importance to a company and tries to assess the impact of these changes on company operations. Planning takes over from there to set objectives and goals and develop strategy.

No business, however small or poorly managed, can do without planning. There is little doubt about the importance of planning, but to be useful, planning should be done properly. Planning just for the sake of it can be injurious; half-hearted planning can cause more problems than it solves. In practice, however, many business executives simply pay lip service to planning, partly because they find it difficult to incorporate planning into their decision process and partly because they are uncertain how to adopt it.

Successful planning is hierarchical, beginning with the company mission and progressing through goals, and objectives to the strategies and tactics necessary to achieve them.

CASES IN POINT

Rorer Plans for Growth

For years, Rorer Group Inc. was regarded as a dull laggard of the drug industry. It had a tiny research budget and a weak prescription-drug line. Even its leading over-the-counter brand, Maalox antacid, was losing market share. To industry observers, management seemed to lack a strong sense of direction. In 1986, things began to change. Rorer surprised competitors by acquiring four pharmaceutical businesses from Revlon Group Inc., and doubled its size in the process. Rorer was revving up for a bid to become one of the top 15 drug companies, and take some risks to that end.

The company overhaul included abandoning all but the five most promising lines of drug-product research, and prowling for yet another major acquisition. In addition, a rejuvenated Maalox brand would share the spotlight with other ambitious plans. The company previously didn't place much emphasis on the development of prescription drugs and relied heavily on its workhorse, Maalox.

It was decided that research and marketing efforts will be limited to a select group of products in five areas: cardiology, gastroenterology, hy-

persensitivity, bone metabolism and hematology. The idea: to concentrate on products that can be developed quickly and that offer opportunities for sizable market-share growth.

The strategy is risky. By singling out a few areas of concentration, Rorer is putting itself under enormous pressure to be the first out of the gate with new products in those areas. Furthermore, the larger pharmaceutical concerns have far more research dollars to spend. The company C.E.O. recognized the risk, but insisted heavily in the research effort. In 1986 research expenditures were increased threefold to $70 million.

At the same time, he scrapped several Rorer and Revlon cardiovascular, antidepressant and gastrointestinal compounds that either were yielding unimpressive results in the research labs or that appeared to be "too little and too late" to have market impact.

Source: *Wall Street Journal*, April 13, 1987.

When Plans Crash

At the same time of their occurrence, some of these problems appear as calamities or catastrophes. Illustrations of the types of problems to which we refer are shown below. These problems may be difficult to predict but a prudent management anticipates that some or all of these problems will arise in its company during a five-year period.

1. Production Problems

Abbott's experience with intravenous solutions and Cutter's troubles with polio vaccines demonstrate production problems that may be difficult to predict and yet offer the potential for corporate disasters.

2. Product Problems

Product problems refer to those illustrated by Abbott's Cyclamate; Parke-Davis' Chloromycetin; Richardson-Merrell's Thalidomide; tetracycline producers' troubles with pediatric tooth staining.

3. Regulatory Problems

Few corporate planners acknowledged three to five years beforehand that amphetamine production quotas, combination drug restrictions, or Quaalude-type drug abuse problems were really going to hit their companies. In this category might be the unanticipated length of time in gaining FDA approval on a major new drug.

4. Forecasting Problems

The classical forecasting problem is remembered in the L-Dopa anti-Parkinson agent. Since forecasting is one of the essentials in a good five-year plan, overly optimistic forecasts can be disastrous.

5. Social Change Problems

Experience shows that major changes in social attitudes can have dramatic impact on business plans. Ross Laboratories and Mead Johnson certainly feel the decline of the baby population. Oral contraceptive producers faced an increase in the number of abortions and vasectomies that probably were not foreseen.

6. Price Problems

Roche Laboratories' problems with the British government (and others) on the price of Valium and Librium offer the prospect for such an extreme change in corporate profits that most planners would have been frightened to build such a possibility into a corporate plan.

7. Inflation Problems

When planners were dealing with steady inflation of 2 to 4 percent a year, errors were relatively easy to correct. Double digit inflation wipes out more planning assumptions and deflation is even more frightening to consider.

8. Business or Stock Problems

A miscellaneous category of problems covers such occurrences as the CIBA-Giegy merger; the Marion Laboratories-Alza courtship and resulting stock price drop on Marion.

Source: Thomas Sheahan in *Medical Marketing and Media*, November, 1974.

BUSINESS MISSION

Definition of business mission has an intimate, chicken-and-egg relationship to market boundary definition. On the one hand, business mission must be defined, at least in part, in terms of market scope. On the other hand, the market scope should emerge from the business mission. Mission is a broad term that refers to the total perspectives or purpose of a business. Traditionally, the mission of a business corporation was framed around its product line and expressed in mottoes such as: "Our business is textiles," "We manufacture cameras," and so on. The Mission Statement of Glaxo Laboratories (1987) is a good (and terse) example:

> We are in the business of providing pharmaceutical products of the highest quality that alleviate pain and suffering and enhance human health and longevity.
>
> To this end we commit all of our efforts to the discovery, development, production and marketing of medicines of the highest quality and efficacy.

The mission of a business is neither a statement of current business nor a random extension of current involvements. It signifies the scope and nature of business, not just as it is today, but as it could be in the future. The mission plays an important role in designating opportunities for diversification either through research and development or acquisitions. To be meaningful, the mission should be based on a comprehensive analysis of the business' technology and customer mission. Examples of companies with technology-based definitions are computer companies and aerospace companies. Customer mission refers to the fulfillment of a particular type of customer need, such as the need for basic nutrition, health care, or entertainment.

An adequate business definition requires proper consideration of the strategic 3 "C's": customer (e.g., buying behavior); competition (e.g., competitive definitions of the business); and company (e.g., cost behavior such as efficiencies via economies of scale, resources/skills such as financial strength, managerial talent, engineering/manufacturing capability, physical distribution system, etc., and differences in marketing, manufacturing, research and development requirements, and so on, resulting from marketing segmentation).

The mission deals with the questions: What type of business do we want to be in at some future time? What do we want to become? At any given point in time, most of the resources of a business are frozen or locked into their current uses, and the outputs in services and/or products are for the most part defined by current operations. Over an interval of a few years, however, environmental changes place demands on the business for new types of resources. Management has the option of choosing the environment in which the company will operate and acquiring commensurate new resources rather than replacing the old ones in kind. This explains the importance of defining the business' mission. The mission should be so defined that it has a bearing on the business' strengths and weaknesses. The Corporate Mission of Eli Lilly and Company, reprinted here, reflects some of these.

Corporate Mission: Eli Lilly and Company

> Eli Lilly and Company is a research-based corporation that develops, manufactures, and markets human medicines, medical instrument systems, diagnostic products, agricultural products, and cosmetics.
>
> To guide its affairs, the company follows certain fundamental principles. These principles, which we believe are in the best long-term interests of all shareholders, are the following:

The company is committed to the discovery and marketing of innovative products of the highest quality that offer benefits to customers in all of our markets.

The company is dedicated to the highest levels of ethics, integrity, and excellence in research, manufacturing, marketing, and all other phases of its operations.

The company recognizes a primary responsibility to its employees because of the key role employees play in the achievement of corporate goals. The company's objective is to attract and retain outstanding people at all levels and in all parts of the organization. It is committed to fair and equitable treatment of all employees and to policies and programs that offer the opportunity for employees to develop meaningful and rewarding careers.

The company feels an obligation to be a good corporate citizen wherever it operates.

MARKETING GOALS AND OBJECTIVES

Goals and objectives flow from and must be consistent with the company mission. There are differences of opinion about the definition of each. Goals are often described as long-term (5-15 years) accomplishments consistent with the mission. Objectives are often shorter term and should always be measurable. These terms are used interchangeably in practice, but within a company a commonly understood definition of both is essential.

Objectives form a specific expression of purpose, thus helping to remove any uncertainty about the company's policy or about the intended purpose of any effort. If properly designed, objectives permit measurement of progress. Without some form of progress measurement, it may not be possible to know whether adequate resources are being applied or whether these resources are being managed effectively. Finally, objectives facilitate the relationships between units, especially in a diversified corporation where the separate goals of different units may not be consistent with some higher corporate purpose.

Despite their overriding importance, defining objectives is far from easy. Defining goals as the future becomes the present is a long, time-consuming, and continuous process. In practice, many businesses are run either without any commonly accepted objectives and goals or with conflicting objectives and goals. In some cases, objectives may be understood

in different ways by different executives. At times, the objectives may be defined in such general terms that their significance for the job is not understood.

SETTING GOALS AND OBJECTIVES

The first step in the process of setting goals and objectives should probably be an inventory of objectives as they are currently understood. For example, senior executives may state what the current goals are and what type of company they want it to be in the future. Various executives will perceive current goals differently; of course they will have varying ambitions for the future. It will take several top-level meetings and a good deal of effort on the part of the CEO to settle on the final goals.

Each executive may be asked to make a presentation on the goals and objectives in the future. The executives should be asked to justify the significance of each goal in terms of measuring performance, satisfying environmental conditions, and achieving growth. Foreseeably, the executives will have different goals, or may express the same goals in terms that make them appear different, but there should emerge, on analysis, a desire for a common destiny. Sometimes inharmony of goals may be based on diverse perceptions of a business' resource potential and corporate strategy. Thus, before embarking on setting goals, it is helpful if information on the resource potential and corporate strategy is circulated among the executives.

Before finalizing the goal, it is necessary that the executive team show a consensus, i.e., each one of them should believe in the viability of the set goals and willingly agree to work toward their achievement. A way must be found to persuade a dissenting executive to cooperate. For example, if a very ambitious executive works with stability-oriented people, in the absence of an opportunity to be creative the executive may fail to perform adequately even on routine matters, thus becoming a liability to the organization.

Once broad goals have been worked out, they should be translated into specific objectives. This is an equally challenging task. Should the objectives be set so high that only an outstanding manager can achieve them, or should they be set so that they are attainable by the average manager? At what level does frustration inhibit a manager's best efforts? Does an attainable budget lead to complacency? A company might start with three levels of objectives: (1) easily attainable, (2) most desirable, and (3) optimistic. Thereafter, the company may choose a position somewhere between the most desirable and the optimistic objectives, depending on the

organization's resources and the value orientation of the management. In no case, however, should the performance fall below the easily attainable level, even if everything goes wrong.

The Concept of Strategic Planning

Strategy in a firm is concerned with the basic goals and objectives of the business, the product-market matches chosen on which to compete, the major patterns of resource allocations, and the major operating policies used to relate the firm to its environment.

Each functional area (e.g., marketing) makes its own unique contribution to strategy formulation at different levels. In a great many firms, the marketing function represents the greatest degree of contact with the external environment, the environment least controllable by the firm. In such firms, marketing plays a pivotal role in strategy development. (The Searle advertisement, quoted above, states: "Marketing is the force that drives our business.")

In its strategic role, marketing consists of establishing a match between the firm and its environment to seek solutions to problems of deciding how the chosen field(s) of endeavor may be successfully run in a competitive environment by pursuing product, price, promotion, and distribution perspectives to serve target markets. Marketing provides the core element for future relationships between the firm and its environment. It specifies inputs for defining objectives and helps in formulating plans to achieve them.

Strategy specifies the direction. Its intent is to influence the behavior of competitors and the evolution of the market to the advantage of the strategist. It seeks to change the competitive environment. Thus, a strategy statement includes a description of the new competitive equilibrium to be created, the cause-and-effect relationships that will bring it about, and the logic to support the course of action.

Planning articulates the means of implementing strategy. A strategic plan specifies the sequence and timing that will alter competitive relationships.

From Strategic Planning to Strategic Marketing

Marketing strategies should devise ways in which the corporation can differentiate itself effectively from its competitors, capitalizing on its distinctive strengths to deliver better value to its customers. A good marketing strategy should be characterized by: (a) a clear market definition; (b) a

good match between corporate strengths and the needs of the market; and (c) superior performance, relative to the competition, in the key success factors of the business.

Put together, the strategic 3 C's mentioned above form the marketing strategy triangle. All three are dynamic, living creatures with their own objectives to pursue. If customer needs do not match the needs of the corporation, the latter's long-term viability may be at stake. Positive matching of the needs and objectives of the two parties involved is required for a lasting good relationship. But such matching is relative, and if the competition is able to offer a better match, the corporation will be at a disadvantage over time. In other words, the matching of needs between the customer and the corporation must be not only positive, but better or stronger than that between the customer and the competitor.

When the corporation's approach to the customer is identical to that of the competition, the customer cannot differentiate between them and the result could be a price war, which may satisfy the customer's needs but not the corporation's. Marketing strategy must then be defined in terms of these three key constituents as an endeavor by a corporation to differentiate itself positively from its competitors, using its relative corporate strengths to better satisfy customer needs, in a given environmental setting.

Strategic marketing focuses on choosing the right products for the right growth markets at the right time. It may be argued that these decisions are no different from those emphasized in marketing management. However, the two disciplines approach these decisions from a different angle. For example, in marketing management, market segments are defined by grouping customers according to marketing-mix variables. In the strategic marketing approach, market segments are formed to identify the group(s) that would provide the company with a sustainable economic advantage over competition.

Today's business and marketing managers are faced with a continuous stream of decisions, each with its own degree of risk, uncertainty, and payoff. Broadly, these decisions may be categorized into two classes: *operating* and *strategic*. With reference to marketing, operating decisions are the domain of marketing management. Strategic decisions constitute the field of strategic marketing.

Operating decisions are those dealing with the current operations of the business. The typical objective of these decisions in a business firm is profit maximization. During times of business stagnation or recession, these efforts at increasing efficiency have typically encompassed a cost minimization perspective. Under these conditions managers are pressured

into shorter and shorter time horizons. All too frequently decisions are made regarding pricing, discounts, promotional expenditures, collection of marketing research information, inventory levels, delivery schedules, and a host of other areas with far too little regard for the long-term impact of the decision. As would be expected, the decision which may be optimal for one time period is not so in the long run.

The second category of decision making deals with the determination of strategy: the selection of the proper markets and the products that best suit the needs of those markets. While strategic decisions may represent a very small fraction of the multitude of management decisions, they are truly the most important as they provide the definition of the business and the general relationship between the firm and its environment. Despite their importance, the need to make strategic decisions is not always as apparent as is the need for successfully completing operating decision.

Strategic decisions are characterized by the following distinctions:

1. They are likely to effect a significant departure from the established product-market mix. (This might involve branching out technologically or innovating in other ways.)
2. They are likely to hold provisions for undertaking programs with an unusually high degree of risk relative to previous experience (e.g., using untried resources or entering uncertain markets and competitive situations where predictability of success is noticeably limited).
3. They are likely to include a wide range of available alternatives to cope with a major competitive problem, the scope of these alternatives providing for significant differences in both the results and resources required.
4. They are likely to involve important timing options, both for starting development work and for deciding when to make the actual market commitment.
5. They are likely to call for major changes in the competitive equilibrium, creating a new operating and customer acceptance pattern.
6. They are likely to resolve the choice of either leading or following certain market or competitive advances, based on a trade-off between the costs and risks of innovating and the timing vulnerability of letting others pioneer (in the expectation of catching up and moving ahead at a later date on the strength of a superior marketing force).

Table 6-2 offers some general examples of marketing strategy while Table 6-3 contains a list of selected tactics and strategies employed in the pharmaceutical industry. Dr. Max Ferm, pharmaceutical industry consul-

tant and strategist, has tested a variety of strategic considerations for pharmaceutical marketers (Table 6-4).

CASES IN POINT

KV Sets Objectives

KV Pharmaceutical was for years, by their own account, "engaged primarily in lower margin contract manufacturing." Their goal was to become "a worldwide leader in drug delivery research and commercialization." Toward that goal they established two group (Stage One and Stage Two) objectives. These were stated explicitly in the 1988 report to their stockholders.

TABLE 6-2. Major elements of marketing strategy and component activities

A. **Product Effort.** Includes product planning, product research and development, product testing, and the service accompanying the product.
Activities:
1. Market research relating to product planning, development, and product testing.
2. Technical research, development, and laboratory testing of new products and improvements of existing products.
3. Product research relating to the development of product styling and fashions.
4. Presale service such as product application engineering.
5. Postsale service such as product installation, maintenance, and guarantee service.

B. **Sales Effort.** Includes such areas as sales management, personal selling, advertising, promotional programs, and all other forms of marketing communications.
Activities:
1. Product branding and promotional packaging.
2. Printed media advertising in newspapers, magazines, and brochures.
3. Broadcast media advertising on radio and television.
4. Sales management and personal selling including all sales management activities (e.g., training supervision) and the sales efforts of company management personnel.
5. Special promotional activities such as promotional warranties, trade shows, dealer aids, and product displays.

TABLE 6-2 (continued)

C. **Distribution.** Includes the selection, coordination, and evaluation of channels, transportation, warehousing, and inventory control.
Activities:
1. Transportation.
2. Warehousing and inventory control.
3. Determination of the basic channels of distribution to be utilized.
4. Selection of individual establishments within the basic channels.
5. Manufacturer's efforts to develop and assist the channel of distribution.

D. **Pricing Effort.** Includes price determination, pricing policies, and specific pricing strategies over which some degree of control is exercised.
Activities:
1. Cost plus desired profit or standard cost pricing.
2. Pricing according to competitive levels, pricing at the prevailing competitive price.
3. Pricing at a certain percent above or below competitors' prices.
4. Pricing according to what the market will bear based on estimated value of the product to the consumer.
5. Pricing based on governmental rules and regulations.

Source: Clyde E. Harris, Jr., Richard R. Still, and Melvin R. Crask, "Stability or Change in Marketing Methods?" *Business Horizons*, October, 1978, p. 33. Copyright, 1978, by the Foundation for the School of Business at Indiana University. Reprinted by permission.

Stage One Objectives:

- *Develop diverse, distinct, commercially viable drug delivery technologies.*
- *Apply these new KV technologies to develop expanded markets for off-patent (and coming off-patent) drugs with annual sales of $50 to $400 million, and which would benefit from KV's innovations.*
- *Convince leading drug marketers throughout the world to utilize KV technologies to provide added utility to newly patented drugs as they progress from the laboratory to world markets.*
- *Conclude licensing agreements with pharmaceutical companies structured to generate royalties, manufacturing revenues and cash payments for development efforts.*
- *Select and develop specialty market niche products, and conclude agreements for marketing with 50/50 joint venture partners in the U.S. and other parts of the world.*

- *Develop a group of proprietary (not to be licensed) "Improved Drug Entities™" (patented or off-patented drugs that offer improved benefits and features through KV drug delivery technology) to be marketed or co-marketed exclusively by KV.*
- *Generate the capital necessary for the funding of development, clinical testing, regulatory approval and marketing of these proprietary new products.*
- *Make the necessary investments in facilities required for production of all new products inflowing from these programs.*

Stage Two Objectives:

- *Conclude additional joint venture and co-marketing arrangements to facilitate the quick launch of KV products into the marketplace.*
- *Conclude additional royalty producing licensing and manufacturing agreements to ensure a continuous stream of increasing earnings and new product introductions.*
- *Rigorously monitor, coordinate and expedite the development and approval of pipeline products for licensing, joint ventures, co-marketing and marketing.*
- *Expand Japanese Commercialization Opportunities.*
- *Expand commercialization in European and other international markets.*
- *Staff a marketing and field sales force of experienced, successful and talented personnel to spearhead KV's direct marketing initiative.*
- *Optimize existing technologies and develop new ones to provide for future needs of the medical profession and patients.*

Source: *K-V Annual Report*, 1988.

Glenbrook Changes Its Business Strategy

It was a tough eight years for Sterling Drug Inc. and its flagship brand, Bayer aspirin.

In 1975, Johnson & Johnson opened the advertising campaign that eventually converted millions of aspirin users to Tylenol. The campaign touted Tylenol's sole ingredient, acetaminophen, as the safe and gentle alternative to aspirin, which can upset the stomach.

But Sterling marketers repeatedly decided against introducing their top-selling overseas brand of acetaminophen to counter the Tylenol incursions. They struggled – unsuccessfully – to protect Bayer by bolstering aspirin's image.

TABLE 6-3. Marketing strategies and tactics

-Bundling of Products
-Bundling of Products and Services
-Bundling of Products and Services with Other Companies
-Capitated Arrangements
-Charge Backs
-Clinical Testing Arrangements
-Co-op Advertising
-Cost Benefit Studies
-Electronic Order Entry Systems
-Frequent Buyer Programs
-"Just-in-time" Inventories
-Off-balance Sheet Transactions
-Performance Contracts
-Price Bids
-Price Protection Contracts
-Partnership Arrangements
-Prime Vendor Arrangements
-Schools for Service Staff
-Tiered discounting Tied to Market-share Gains
-Strategic Alliances with Providers
-Strategic Alliances with Other Manufacturers and Suppliers

Source: Adapted from an article by Thomas W. Mader in *Pharmaceutical Executive*, August, 1989.

In 1983, the strategy shifted. "The Panadol Discovery," Sterling's U.S. introduction of the acetaminophen brand it has sold overseas for 25 years was part of an unusual $100 million campaign that sought to reverse years of overcautious marketing and outright misjudgment.

Tylenol had won back most of the 35% share it held in the analgesics

market before the October 1982 deaths of seven persons who took cyanide-laced capsules of the brand. But aggressive advertising by Anacin-3 and Datril, two once-dormant acetaminophen rivals, had opened up the market by telling consumers that all "aspirin-free" pain relievers are basically the same.

Now came Panadol, the first entirely new U.S. brand in years, yet one that can boast "world-proven" success (it is sold in 70 countries). The Panadol pitch aimed at the heart of the Tylenol market: women aged 18 to 40; frequent users who seek both strength and gentleness; doctors who recommend Tylenol; and Hispanics, a group that Tylenol was first to pursue.

More than 100,000 physicians—whose referrals helped build Tylenol

TABLE 6-4. Strategic considerations in marketing

```
The Product

  Single Source
     Therapeutic Advantage
     Third Party Formularies
     Cost/Benefit
     Dosage Form Development (oral, liquid, etc.)
     Qualities of Product (effect on other systems)
     Product Improvements (side effects, lower dose)
     Dose Range Development (low, high)
     Exclusivity Extensions (indication, clinicals, dose)
     Rx to OTC
     Packaging (unit dose, unit of issue, compliance)

  Multiple Source
     Defense (bid, deal)
     Offense (participate)

The Prescriber

  Single Source
     Demonstrable Effectiveness
     Competitive Advantages
     Clinical Support
     Ease of Use
     Clear Position

  Multiple Source
     Control (DAW)

Distribution Channels

  Direct to Retailer
  Indirect thru Wholesaler
  Warehousing Chains
  Closed HMO's
  Nursing Homes (consulting pharmacists)
  Mail Order (chronic)
  Hospitals
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TABLE 6-4 (continued)

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Pricing Policies

  Classes of Trade
  Single Class
  Frequency of Price Increase

Regulatory Considerations

  Medicare
  Medicaid
  NDA Revisions (tighten specs)
  Positive Formulary/Negative Formulary
  Establish Credibility at FDA
  Working Knowledge of All Divisions

Patient Considerations

  Involvement in Therapy (education)
  Self Evaluation
  Compliance Packaging
  Ease of Dosing
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Source: Dr. Max Ferm, Presentation at Japanese Pharmaceutical Executive Seminar, University of Mississippi, 1988.

into a $400-million-a-year brand – began receiving mailed Panadol samples, to send letters of endorsement – written and signed by computer – from the company's 12,000 U.S. employees to their family doctors.

Normally, sober medical journals now featured wry Panadol ads that picture Burger King and McDonald's, Coke and Pepsi, Avis and Hertz – and Panadol and Tylenol. The trade ad concludes: "A little healthy competition is good for everybody. Introducing Panadol, from the makers of Bayer aspirin."

The Panadol pitch may have been several years late, but as a result it could avoid some mistakes. Ads didn't mention Tylenol or the buzz-phrase "aspirin-free," because consumer surveys show that simply stating that it "won't upset the stomach" is enough. Nor did Panadol ads aim at the broad aspirin market, because "the switch to acetaminophen has already been made."

But more importantly, the Panadol introduction stood as the centerpiece of an unusual $100 million marketing overhaul for Glenbrook Laboratories, a cautious company hindered by its deliberative approach in the past. As Tylenol climbed to a dominant place in the market, Glenbrook marketers repeatedly stumbled. They failed at selling the acetaminophen brand, Bayer Non-aspirin, in 1976 because of the aspirin-associated Bayer name. They decided against marketing an "extra-strength" Bayer version despite growing consumer demand for more-potent products (500

mg per tablet instead of 325 mg). And until just recently, they lacked a "new" claim to spruce up the aging Bayer image—(the granddaddy of pain relievers, Bayer first hit the market in 1918).

The campaign involved 4 new brands and 13 new packages. Where would they fit? The company recognized that it faced skepticism from wholesalers and large retailers. It fought that skepticism with a filmed message from the CEO of Glenbrook (division of Sterling). In the film the CEO holds a giant-sized check for $100,000,000 (the promotional budget) and promises to change Glenbrook from "just an aspirin company" to "a total analgesics company."

Source: *Wall Street Journal*, April 29, 1983.

Marketing strategy may be defined in terms of the three key constituents—customer, competition, company—as an endeavor by a company to differentiate itself positively from its competitors, using its relative strengths better to satisfy customer needs, in a given environmental setting. The first strategic "C," the customer, was discussed in the preceding chapter. The company and the competitors are the subjects of the chapter which follows.

CASE IN POINT

How Fisons Managed Its Turnaround

The Early Years

The real beginning of the present Fisons group of companies can be said to lie in the amalgamation in 1929 of two agricultural fertilizer companies to form Fison Packard and Prentice. Up to the 1930s, growth had been by market penetration through horizontal integration in the fertilizer business.

The company expanded in the 1930s. The most important strategic acquisition was that of the Anglo-Continental Guano Works Ltd, in 1935, which effectively doubled the size of the company. Anglo-Continental was itself a large amalgamation of mainly fertilizer manufacturers and related companies. However, it also contained the Loughborough-based Genatosan company, a manufacturer of pharmaceuticals and fine chemicals, which constituted the entry of Fisons into the pharmaceuticals business.

The next key acquisition occurred in 1947 when the fine chemicals manufacturer, Wiffen and Son, of Fulham, became part of the group, joining the chemicals and biologicals division headed by Genatosan. This acquisition was important because Wiffen included the Loughborough Glass

Company, which would subsequently develop into the Scientific Equipment Division.

In the mid-1950s, the acquisition of Pest Control Limited moved Fisons into the agrochemicals business. The synergy with its current operations was such that the customers would be broadly the same as those for its fertilizers, with a common distribution channel, and there was a need to manage the concomitant R&D, in which Fisons would claim some expertise.

Through its acquisitions, Fisons had acquired, by the mid-1960s, a mixed bag of interests outside its mainstream activities in fertilizers, fine chemicals (and pharmaceuticals) and agrochemicals. The one factor linking these other activities was that they could all claim to be science based.

Towards the end of the 1960s, Fisons seemed to realize two things: first, that it was spreading its activities too thinly, and second, that it must lessen its dependence on fertilizers. Thus, in the latter years of the 1960s, Fisons entered a period of consolidation, divesting itself of many of its fringe businesses. Contrary to public announcements, Fisons still continued to invest heavily in the fertilizer business, although its dependence on these was lessened because of its large investments in pharmaceuticals.

The 1970s

In 1970, consequent on its new corporate policy, the company was organized, first, into three, and then, roughly a year later, into four operating divisions. These were Fertilizers, Agrochemicals, Pharmaceuticals and Scientific Equipment. In 1977, the horticultural activities of the Fertilizer Division were separated to form the Horticultural Division.

Around the middle of the decade, attempts were made to form a Merchanting arm, but this did not prove a successful split of activities, and was soon discontinued. Also, towards the end of the decade, Fisons invested a small amount in fish farming: this was not a success and was always very much a sideline.

As the company approached the 1980s, it is convenient to discuss it in terms of its divisions. (Editor's note – emphasis will be on the pharmaceutical division.)

The Pharmaceutical Division – The pharmaceutical industry can crudely be divided into ethical and over-the-counter (OTC) drugs; the former can only be obtained through a doctor's prescription, whilst OTC drugs are commercially available.

Until the late 1960s, Fisons' only major interest in ethical drugs was in the iron dextran line of blood volume expanders. Other pharmaceutical

interests were in OTC products, such as Bengers Food. The position changed radically with the discovery of the anti-allergy compound, disodium cromoglycate (DSCG), in 1968, and its subsequent exploitation, most notably as Intal. The impact of Intal on the division can be seen in the profit growth from £1.14 million in 1968 to £2.43 million in 1970 and to £5.6 million in 1973.

Summary

The 1970s saw Fisons developing all its mainstream businesses through acquisition, and, organically, by product and market developments. The acquisitions were particularly focused on continental Europe, Australia and the U.S. The agrochemical business developed several new herbicides and insecticides, while the Pharmaceutical Division was engaged in developing various formulations of DSCG. However, it is now realized that, in the 1970s, Fisons failed to exploit its very special position with DSCG, preferring to seek another wonder drug. Both its pharmaceutical and agrochemical activities in the U.S. were severely hampered by the choice of the company used to sell Fisons' products.

Throughout the period to 1980, two features stand out. First, Fisons seemed emotionally wedded to its fertilizer activities, not surprisingly perhaps since fertilizers contributed around 50 per cent of the company's turnover, and the chairman had grown up with this business. Second, Fisons did seem from a fairly early stage to see its strength lying in science-based products, and had invested heavily in R&D to stay in the forefront of research.

Analysis of Fisons' Businesses at 1980

The 1970s had not proved to be a successful decade for Fisons. In the severe economic climate of the late 1970s and 1980, with high inflation and high interest costs, Fisons' circumstances became even more straightened. A contributory factor to this gloom was the decision, taken in 1980, not to market the new drug Proxicromil, because it was found to cause cancer in animals. Proxicromil was seen at the time as the successor to Intal.

The strengths and weaknesses of Fisons' strategic business units within each of the five divisions as of 1980 will now be examined. Linneman's definition [1] of an SBU will be used, i.e., "a unit comprising product that may use the same production facilities and marketing channels and are affected by similar economic and competitive forces."

For "volume" businesses (see Hedley [2]), such as fertilizers and

agrochemicals, it is sufficient to analyze Fisons' position simply by considering the basis of competition within the industry. For the other Fisons' businesses, the wider-ranging methodology of Porter [3, 4] is appropriate.

The Pharmaceutical Division

The division was not competing in all sectors of the pharmaceutical industry. It let the giants like Glaxo concentrate on the high-volume markets, such as antibiotics and tranquilizers, and concentrated its main activities into the discovery, development, manufacture and marketing of anti-allergy pharmaceuticals. These drugs were based on disodium cromoglycate (DSCG), with the major product being Intal. Something like 60-70 percent of divisional sales were of these products.

The three other business areas involved the iron dextran range of products, the Sanatogen and vitamin health products and generic drugs. None of these areas had anything approaching the strategic significance to Fisons that the anti-allergy activity had had, and thus will not be discussed further.

Rivalry amongst competitors – *The pharmaceutical industry and the anti-allergic portions of it are well consolidated, concentrated and operate worldwide. The competitive position is shown by the data given below. Fisons would claim to have a competitive edge that it is about to exploit more fully, since its major product, Intal, is unique, in that it is a prophylactic, whereas all the anti-allergins are taken after allergic symptoms have developed.*

World Market Share by Product for Anti-Asthmatics

Product	*%*	*$ mill*
Ventolin (Glaxo)	*13.7*	*190*
Theo-Dur (Key and SP)	*9.0*	*125*
Zaditen (Sandoz)	*7.1*	*98*
Intal (Fisons)	*6.1*	*84*
Becotide (Glaxo)	*4.6*	*64*
Alupent (B-1)	*4.4*	*61*
Proventil (SP)	*3.8*	*53*
Rizaben (Kissei)	*2.9*	*40*
Bricanyl (Astra)	*2.7*	*37*
Berotec (B-1)	*2.3*	*32*
Others	*43.4*	*601*
TOTAL	*100.0*	*1,385*

Perhaps realizing the weaknesses of its size, Fisons engaged in several joint ventures with companies in the U.S. and Europe. Only in one case (Coopers Laboratories), however, did the company link with another to offset the costs of its large R&D activities; almost all of the acquisitions and joint ventures were to obtain production facilities or a sales force.

As the pharmaceutical industry is an innovative one, existing products, particularly ethical ones, are always under some threat from new products that can confer advantages of increased efficacy, better patient compliance, lower cost or greater cost-effectiveness.

Most pharmaceutical companies employ the defensive tactic of investigating closely related groups of compounds for each area of interest and patenting all products that they synthesize, even where most of the compounds involved are unlikely to be successful. If any of the compounds studied prove to be successful, this is the most effective tactic against competitors bringing out a chemically closely related product, and offers a measure of protection until the expiry of patents. Fisons relied heavily on this type of defense with its DSCG products.

The power of suppliers and buyers—*The suppliers to the pharmaceutical industry are weak, but potentially the buyers are very strong. Any pharmaceutical company trading in the UK ethical drug market faces a monopoly buyer in the form of the National Health Service. Not only does it regulate the distribution channels, i.e., pharmacies, but it also employs the majority of doctors empowered to prescribe the drugs. Furthermore, it is government that by negotiation, or, in rare cases, unilateral action, determines the price of ethical pharmaceuticals. A similar buyer pattern applies in many other countries.*

However, in some countries, including the UK, the power of the government is heavily constrained by the role of the doctor on the buyer side. The doctor jealously guards his/her right to prescribe the drug he/she deems best for a patient, yet there are few constraints in the costs so incurred; the doctor him/herself does not incur any financial penalty from prescribing a high-cost drug where a lower-cost and equally efficacious drug exists. Thus, in practice, the position of the pharmaceutical industry vis-à-vis its customer (who does not pay the bill) is not governed by the price of its products.

This aspect of the prescriber/payer relationship does not fit easily into the Porter methodology.

The threat of new entrants—*Well-established pharmaceutical companies have developed considerable economies of scale in all branches of their activities, especially in R&D. Some of the most successful pharmaceutical companies are also part of giant chemical groups, e.g., Hoechst,*

Bayer and ICI; this further endows an economy of scale to these companies' pharmaceutical activities.

In the anti-allergic field, Fisons were spending around £8 million in 1979 on R&D and were probably the world's biggest spenders in this specialized therapeutic area.

Even in the (small) field of anti-allergics, scale economies are substantial and any newcomer would have to match the level of R&D spending, together with assembling the production and a worldwide marketing capability. The large pharmaceutical companies not already in the anti-allergic field would find entry easier than complete outsiders, since there would be some measure of synergy between their current portfolio of products and any new anti-allergy ones.

Drug discovery and development is a long-term activity. Even for the largest pharmaceutical companies, the rate of discovery of a truly novel compound is of the order of one every 10-15 years, and it takes around ten years to progress from an initial discovery to the marketing of a successful product. There needs to be a considerable sum tied up in R&D, the return on which takes a long time to come through.

Substitutes—*Fisons is in the anti-allergy business, with products developed through a high-technology route. The expertise of a company in this business lies not only in its R&D expertise, but also in its knowledge of, and ability to implement, the procedures needed to get a drug accepted for human use. This expertise would be of little value if a "natural" product were developed, which could be sold "over the counter." The threat of substitutes to the business seem small.*

General factors—*National governments are responsible for the regulations covering the testing of drugs and their manufacture.*

The situation in the UK applies also to most developed countries and a UK company like Fisons often finds a "knock-on" effect in its export markets, especially if there has been any price restraint in the home market; foreign governments are unlikely to allow a higher locally equivalent price.

Competitive rivalry—*All of these SBUs were operating in businesses that were fragmented, with no obvious market leaders, except in small, specialized segments.*

Power of suppliers and buyers—*The power of suppliers was low, but this was not the case with buyers. All of the SBUs were heavily involved with governmental or quasi-governmental organizations—with hospitals, civil service research establishments, schools and higher educational establishments. As can be imagined, the power of such concentrated groups of buyers was high, and thus it was not easy for the industry to make*

money. Governments were doubly powerful, since their purchases not only secured keen prices, but also determined to a large extent the size of the market. The UK Government's activities in 1979 and 1980 had a large effect on depressing the total UK market.

Threat of entry – *Certainly, compared with pharmaceuticals, all of the SBUs that Fisons were operating in were easy entry areas. This was particularly true of educational and laboratory supplies. There were no great set-up costs and few significant ways of differentiating the products or services offered. There was more scope for doing this in scientific equipment, with the more technically complex equipment being developed.*

Substitutes – *There are not likely to be any substitutes in the laboratory and educational supplies fields. However, there were distinct trends away from "wet chemistry" analytical processes to instrumentation. This represented a shift towards electronics and computer skills, and away from the traditional areas of expertise.*

Summary

A good summary of Fisons' position in 1980 is that given by Newman [5]. He writes after Fisons' loss of the drug Proxicromil:

> *. . . Fisons was suddenly left with an awful-looking portfolio: a loss-making division that had little prospect of returning to profitability (fertilizers); an under-funded research-based business that could not hope to compete with the R&D investment of the chemical majors (agrochemicals); a division which was reeling under government cutbacks (scientific equipment); a small, under-developed business (horticulture); and a chief profit-maker (pharmaceuticals) which had suddenly lost its long-term growth product.*

It was this prospect that lead to the appointment of a new chief executive.

The period from 1980 to 1983 has thus seen consolidation in some areas and a major restructuring of the Fisons Group through the disposal of its agrochemical and fertilizer interests. However, it had also seen some growth. The pharmaceutical interests had been expanded with the acquisition in 1980 of Charnwood Pharmaceuticals in the UK, of Orbit Chemical Pty Ltd of Australia in 1982, and 1983, and absorbed into Charnwood Pharmaceuticals. Charnwood was destined to market Fisons' generic products.

Sound financial position would allow Kerridge, in his first annual statement as Chairman in 1984, clearly and publicly to enunciate a corporate strategy. This was the first time that a strategy had been so clearly stated;

previously, the direction had been much more low key if stated at all (e.g., "The Fisons Group is a researched-based organization relying on research and development for the steady production of new products and processes . . . " [6]

Kerridge wrote:

> *Our aim as a company is to achieve sustained growth, both in volume and in the quality of earnings. This is being achieved by the successful implementation of our declared strategy. This strategy is based on two precepts. Firstly, we wish to operate in industries of inherent attractiveness, which have potential for growth and a record of profitability for successful participants. Secondly, but of equal importance, we wish to be in clearly defined business segments where Fisons can reasonably aspire to being an effective competitor by virtue of its size and its financial and managerial resources. Our chosen areas of activity—Pharmaceuticals, Scientific Equipment and Horticulture—match these criteria both in terms of industry characteristics and of Fisons' ability to be a strong competitor. Our future policy will be to pursue further this strategy, firstly by achieving sustained organic growth, and secondly by supplementing this with appropriate acquisitions. Our performance in 1984 is clear evidence of the implementation of this strategy.*

This strategy had indeed been pursued in all of Fisons' major business areas over the previous few years. The Pharmaceutical Division continued with its heavy R&D expenditure, and was rewarded in 1984 with the launch of the DSCG-based Opticrom, and, in 1986, with the introduction of Tilade, a distinct new compound for the improved treatment of asthma and other reversible obstructive air-passages diseases. The division continued to be active with acquisitions, buying Laboratorieos Caesen in Spain in 1984, subsequently building a purpose-built factory there, and acquiring the Mexican pharmaceutical company, Bracco de México, in 1986.

Pharmaceuticals is a concentrated and well-consolidated industry. As has already been explained, this makes entry into it rather difficult. The difficulty also exists, albeit to a lesser extent, if Fisons wished to move into an area in which it is not already engaged. Thus it does not seem likely that Fisons will diversify widely within pharmaceuticals, but rather concentrate on product and market developments, particularly of anti-allergies, but also of its iron dextran and cardiovascular products.

Strategic Methodologies Used

From his study of the techniques and concepts used by UK strategic planners, Houlden [7] has produced a ranked list of the 21 found most useful. The most-used concept was that of purpose/mission/direction. Up to the crisis years, Fisons seemed to have the mission of being at the forefront of science-based research. This changed under Kerridge's leadership, with no clearly enunciated mission, but with the divisions called on to work to clearly defined objectives of profitability (defined as Return on Capital Employed) and growth. Significantly, perhaps, one of Kerridge's first moves as chief executive was to close down the major R&D activities of the Fertilizer Division and to put technical developments back with production and customer support, i.e., nearer to the customer. This move altered the balance from research to development, and fitted Kerridge's views that Fisons did not have a "science-based" mission decoupled from the marketplace; the fundamental posture was to be a marketing one.

Paradoxically, the failure of Proxicromil was a blessing in disguise to Fisons, since it forced the company to develop DSCG, rather than rely on the development of new drugs. This had the effect of again switching the emphasis within the company from a research-based to a marketing orientation.

During the 1970s, Fisons had been using Scenario planning and had used the results of both the PIMS programme and the Boston Consulting Group. Few formal techniques are used today. Since 1983, Fisons has three divisions operating in growth areas, and the emphasis has been to "stick to the knitting" [8]. Although this does not rule out the possibility of Fisons adding to its "three legs," this has meant that the emphasis is now on competitor analysis; again in keeping with Kerridge's view of Fisons being more "market driven."

Competitor analysis is not formally embedded in Fisons' corporate planning activities and highly organized, with the concept of SBUs used as a planning aid. The activities of all competitors is continually monitored, both financially and in terms of product and market developments. These actions and results are assessed formally at least annually and on an ad hoc basis if developments warrant a more specific enquiry, i.e., if Fisons is thinking about an acquisition.

Although industry analyses in terms of competitors are carried out, the wider aspects of the Porter methodology as such are not followed. Planning, and particularly acquisitions, are made in the light of the perceived balance of power in the industry.

It is interesting to see the change in role that seems to be taking place within successful corporate planning groups. From personal experience,

the role is now turning towards industrial and environmental monitoring. Within this, there is an emphasis on competitor monitoring, both to see what the competitors are doing and as an ongoing basis for acquisitions. These groups report directly to the Chief Executive and act as "staff officers," checking over proposals submitted to the board by the divisions. An important role that Kerridge has given to the central corporate planning unit is that of monitoring the consequences of the divisional proposals that have been accepted and implemented. Fisons now puts great emphasis on individual accountability.

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Source: Edited from Paul N. Finlay's paper in *European Journal of Marketing*, Vol. 22, No. 2, 1988.

Chapter 7

Corporate and Competitive Analysis

In their book, *Marketing Warfare*, Al Ries and Jack Trout (who made "positioning" a fifth "p" in the marketing mix) argue that the time of being customer-oriented is past, "to be successful today, a company must be competitor oriented." They say that "marketing is war where the enemy is the competition and the customer is ground to be won."

While we disagree with the first part of the Ries and Trout thesis the warfare analogy is a convenient one. We disagree because we believe that the customer will ultimately become one if a firm is more successfully customer-oriented than is that competitor. This is made possible, we will argue, by careful assessment of a company's own and its competitor's strengths and weakness and by using that assessment in the development of a strategic marketing mix.

CORPORATE ANALYSIS

Corporate Publics

The first consideration in the strategic process is to recognize the individuals and groups who have an interest in the fate of the corporation and the extent and nature of their expectations.

The following groups generally constitute the interest-holders in business organizations:

1. Owners
2. Employees
3. Customers
4. Suppliers
5. Banking community and other leaders
6. Government

7. Community in which the company does business
8. Society at large

For the healthy growth of the organization, all eight groups must be served adequately.

As the most progressive institution in the society, and especially as it operates in the field of health, the pharmaceutical corporation is expected to provide balanced prosperity in all fields. This new outlook extends the mission of the business beyond the primary obligation.

Corporate Resources

The resources of a firm are its distinctive capabilities and strengths. The resources are relative in nature and must always be measured with reference to competition. The resources can be categorized as financial strength, human resources, raw material reserve, engineering and production, overall management, and marketing strength. The marketing strategist needs to consider not only marketing resources, but also resources of the company across the board. For example, price setting is a part of marketing strategy, yet it must be considered in the context of the financial strength of the company if the firm is to grow as rapidly as it should. It is obvious that profit margins on sales, combined with dividend policy, determine the amount of funds a firm can generate internally. It is less well understood, but equally true, that if a firm uses more debt than its competitors or pays lower dividends, it can generate more funds for growth by decreasing profit margins. Thus, it is important in strategy development that all of the firm's resources are fully utilized in a truly integrated way. The firm that will not use its resources fully is a target for the firm that will—even if the latter has few resources. Full and skillful utilization of resources can give a distinct competitive edge to a firm.

Consider the following resources of a company:

1. Has ample cash on hand (financial strength).
2. Average age of key management personnel is 42 years (human resources).
3. Has superior raw material ingredients in reserve (raw material reserve).
4. Manufactures chemical intermediaries that go into the final product using the company's own facilities (plant and equipment).
5. The products of the company, if properly installed and serviced regularly, never stop while being used (technical competence).

6. Has a knowledge of, close relationship with, and expertise in doing business with the drug chains (marketing strength).

How do these resources affect marketing strategy? The cash-rich company, unlike the cash-tight company, will be in a position to provide liberal credit accommodation to customers.

A firm is a conglomerate of different entities, each having a number of variables that affect performance. How far should a strategist probe into these variables to designate the resources of the firm? Table 7-1 is a listing of possible strategic factors in different areas of a business. Not all of these factors will be important for every business; attention should be focused on those that could play a critical role in the success or failure of the particular firm. Therefore, the first step in designating resources might be to have executives in different areas of the business go through a listing like that shown in Table 7-1 and choose those variables which they deem strategic. Then each strategic factor may be evaluated either qualitatively or quantitatively to provide an overall picture of the strengths which a company may enjoy. Table 7-2 provides a partial listing. In pharmaceuticals, of course, products are critical. Weaknesses in marketing can do harm to a good product, but marketing strengths cannot long sustain a poor product.

Products: Portfolios and Life Cycles

A company analyzing its areas of strengths from a product perspective has several open approaches. Two, related, avenues to product strength assessment are portfolio analysis and life cycle analysis. Each has its critics and its weaknesses, but a discussion will permit an examination of some of the factors involved in self-assessment.

A good planning system must guide the development of strategic alternatives for each of the company's current businesses and new business possibilities. It must also provide for management's review of these strategic alternatives and for the corresponding resource allocation decisions. The result is a set of approved business plans which, taken as a whole, represent the direction of the firm. This process starts with, and its success is largely determined by, the creation of sound strategic alternatives.

The top management of a multibusiness firm cannot generate these strategic alternatives. They must rely on the managers of their business ventures and on their corporate development personnel. However, they can and should establish a conceptual framework within which these plan alternatives can be developed. One such framework is the portfolio matrix associated with the Boston Consulting Group (BCG). Briefly, the portfo-

TABLE 7-1. Some strategic factors in business

A. General Managerial
1. Ability to attract and maintain high-quality top management
2. Developing future managers for overseas operations
3. Developing future managers for domestic operations
4. Developing a better organizational structure
5. Developing a better long-range planning program
6. Achieving better overall control of company operations
7. Using more quantitative tools and techniques in decision making
8. Assuring better judgment, creativity and imagination in decision making
9. Ability to divest nonprofitable enterprises
10. Ability to perceive new needs and opportunities for products
11. Ability to motivate sufficient managerial drive for profits

B. Financial
1. Ability to raise long-term capital at low cost:
2. Ability to raise short-term capital
3. Ability to maximize value of stockholder investment
4. Ability to provide a competitive return to stockholders
5. Willingness to take risks with commensurate returns in what appear to be excellent new business opportunities in order to achieve growth objectives.
6. Ability to apply ROI criteria to R&D investments
7. Ability to finance diversification by means of acquisitions and in-house research and development.

C. Marketing
1. Ability to do better market research
2. Establishing a wide customer base
3. Establishing a selective consumer base
4. Establishing an efficient product distribution system
5. Ability to get good business contracts (government and others)
6. Assuring imaginative advertising and sales promotion campaigns
7. Using pricing more effectively (including discounts, credit, product service, guarantees, delivery, etc.)
8. Better relationships between marketing and new product research & development
9. Producing vigor in sales organization

D. Research and Development
1. Developing sufficient capacity for expansion
2. Developing better materials and inventory control
3. Improving product quality control
4. Improving in-house basic product research capabilities
5. Developing better ability to mass-produce at low per-unit cost
6. Relocating present production facilities
7. Better management of, and better results from, research and development expenditures
8. Establishing foreign production facilities
9. Developing more flexibility in using facilities for different products
10. Being in the forefront of technology and being extremely scientifically creative.

E. Products
1. Improving present products
2. Developing more efficient and effective product-line selection

3. Developing new products to replace old ones
4. Developing new products in new markets
5. Developing sales for present products in new markets
6. Diversifying products by acquisition

F. Personnel
1. Attracting scientists and highly technically qualified employees
2. Establishing better relationships with employees
3. Ability to get along with labor unions
4. Better utilizing the skills of employees

G. Materials
1. Assuring continuity of raw material supplies
2. Owning and controlling sources of raw materials
3. Bring "in-house" presently purchased materials and components
4. Reducing raw material costs

Source: Adapted from George Steiner, Strategic Factors in Business Success (New York: Financial Executives Research Foundation, 1969).

TABLE 7-2. Some areas of marketing strength

1. Excellence in product design and/or performance (engineering ingenuity)
2. Low-cost, high-efficiency operating skill in manufacturing and/or in distribution
3. Leadership in product innovation
4. Efficiency in customer service
5. Personal relationships with customers
6. Efficiency in transportation and logistics
7. Effectiveness in sales promotion
8. Merchandising efficiency--high turnover of inventories and/or of capital
9. Ability to influence legislation
10. Highly efficient, low-cost facilities
11. Ownership or control of low-cost or scarce raw materials
12. Control of intermediate distribution or processing units
13. Massive availability of capital
14. Widespread customer acceptance of company brand name (reputation)
15. Product availability, convenience
16. Customer loyalty
17. Dominant market share position
18. Effectiveness of advertising
19. Quality sales force

lio concept is used to establish the best mix of businesses in order to maximize the long-term earnings growth of the firm.

The portfolio approach has given top management the tools to evaluate each business in the context of both its environment and its unique contribution to the goals of the company as a whole and to weigh the entire array of business opportunities available to the company against the financial resources required to support them.

The portfolio concept addresses the issue of the potential value that a particular business has for the firm. This value has two variables: first, the potential for generating attractive earnings levels now; and second, the potential for growth, or in other words, for significantly increased earnings levels in the future. The portfolio concept holds that these two variables can be quantified. Current earnings potential is measured by comparing the market position of the business to that of its competitors. Empirical studies have shown that profitability is directly determined by relative market share. There are some types of businesses, however, in which the economies do not respond significantly to scale, and other factors are important determinants of return. In such cases the terminology for the earnings-potential yardstick may be changed from "market share" to "market leadership."

Growth potential is measured by the growth rate of the market segment in which the business competes. Clearly, if the segment is in the decline stage of its life cycle, the only way the business can increase its market share is by taking volume away from competitors. While this is sometimes possible and economically desirable, it is usually expensive, it can lead to destructive pricing and erosion of profitability for all competitors, and it ultimately results in a market which is ill served. On the other hand, if a market is in its rapid growth stage, the business can gain share by preempting the incremental growth in the market. So if these two dimensions of value are arrayed in matrix form, we have the basis for a business classification scheme. This is essentially what the Boston Consulting Group portfolio matrix is. Each of the four business categories tends to have specific characteristics associated with it. The two quadrants corresponding to high market leadership have current earnings potential, and the two corresponding to high market growth have growth potential.

The importance of growth variables for strategy development is based on two factors. First, growth is a major influence in reducing cost because it is easier to gain experience or build market share in a growth market than in a low-growth situation. Second, growth provides opportunity for investment. The relative market share affects the rate at which the business will generate cash. The stronger the relative-market-share position of a product, the higher the margins it will have, because of the experience effect.

Using these two dimensions one can classify businesses into four categories. Businesses in each category exhibit different financial characteristics and offer different strategic choices.

Stars. High-growth market leaders are called stars. They generate large amounts of cash, but the cash they generate from earnings and deprecia-

tion is more than offset by the cash that must be put back into these businesses in the form of capital expenditures and increased working capital. Such heavy reinvestment is necessary to fund the capacity increases and inventory and receivable investment that go along with market share gains. Thus, star products represent probably the best profit opportunity available to a company, and their competitive position must be maintained. If a star's share is allowed to slip because the star has been used to provide large amounts of cash in the short run or because of cutting back on investment and raising prices (creating an umbrella for competitors), the star will ultimately become a dog.

The ultimate value of any product or service is reflected in the stream of cash it generates net of its own reinvestment. For a star, this stream of cash is in the future, sometimes the distant future, and to obtain real value, the stream of cash must be discounted back to the present at a rate equal to the return on alternative opportunities. It is the future payoff of the star that counts, not the present reported profit.

Cash Cows. Cash cows are characterized by low growth and high market share. They are net providers of cash. Their high earnings coupled with their depreciation represent high cash inflows, while they need very little in the way of reinvestment. Thus, these products generate large cash surpluses which help to pay dividends and interest, provide debt capacity, supply funds for research and development, meet overheads, and also make cash available for investment in other products. Thus, cash cows are the foundation on which everything else depends. These products must be protected. Technically speaking, a cash cow has a return on assets which exceeds its growth rate. Only if that is true will the cash cow generate more cash than it uses.

Question Marks. Products which are in a growth market but have a low share are categorized as question marks. Because of growth, these products require more cash than they are able to generate on their own. If nothing is done to increase its market share, the question mark will simply absorb large amounts of cash in the short run and later, as the growth slows down, become a dog. Thus, unless something is done to change its perspective, a question mark remains a cash loser throughout its existence and ultimately becomes a "cash trap."

What can be done to make a question mark more viable? One alternative is to gain share increases for it. Since the business is growing, it can be funded to dominance so that it may become a star, and later a cash cow when growth slows down. This strategy is a costly one in the short run. An abundance of cash must be poured into the question mark in order for it to win a major share of the market, but in the long run this is the only

way of developing a sound business from the question mark stage. The other strategy is to divest the business. Outright sale is the most desirable alternative. But if this does not work out, a firm decision must be made not to invest further in the business, and the business must be allowed simply to generate whatever cash it can while none is reinvested.

Dogs. Products with low market share and positioned in a low-growth situation are called dogs. Their poor competitive position condemns them to poor profits. Because growth is low, there is little potential for gaining sufficient share to achieve a viable cost position. Usually they are net users of cash. Their earnings are low, and the reinvestment required just to keep the business together eats cash inflow. The business, therefore, becomes a "cash trap" which is likely to regularly absorb cash unless further investment in the business is rigorously avoided. An alternative is to convert dogs into cash if there is an opportunity to do so.

In a typical company there are products scattered in all four quadrants of the portfolio matrix. The appropriate strategy for products in each cell is given briefly in Table 7-3. The first goal of a company should be to secure a position with cash cows but to guard against the frequent temptation to reinvest in them excessively. The cash generated from cash cows should first be used to support those stars which are not self-sustaining. The surplus cash may be used to finance selected question marks to dominance. Any question mark which cannot be funded should be divested. A dog may be restored to a position of viability by shrewdly segmenting the market; i.e., rationalizing and specializing the business into a small niche which the product concerned may dominate. If this is not practical, a firm should manage the dog for cash; i.e., cut off all investment in the business and liquidate it when an opportunity develops.

There are two strategic questions that top management needs to answer: (1) How promising is the current set of businesses with respect to long-term return and growth? (2) Which business should be developed? maintained as is? liquidated? Following the portfolio approach discussed above, a company needs a cash-balanced portfolio of businesses, i.e., cash cows and dogs, to throw off sufficient cash to fund stars and question marks. There should be an ample supply of question marks to ensure long-term growth and businesses with return levels appropriate to their matrix position. In response to the second question, the capital budgeting theory requires the lining up of capital project proposals, assessment of incremental cash flows attributable to each project, computation of discounted rate of return of each, and approval of the project with the highest rate of return until available funds are exhausted. But the capital budgeting approach misses the strategic content; i.e., how to validate the assumptions

TABLE 7-3. Characteristics and strategy implications of products in the strategy quadrants

QUADRANT	INVESTMENT CHARACTERISTICS	EARNING CHARACTERISTICS	CASH-FLOW CHARACTERISTICS	STRATEGY IMPLICATION
Stars	-Continual expenditures for capacity expansion -Pipeline filling cash	Low to high	Negative cash flow (net cash user)	Continue to increase market share. If necessary, at the expense of short-term earnings.
Cash Cows	-Capacity maintenance expenditures	High	Positive cash flow (net cash contributor	Maintain share and cost leadership until further investment becomes marginal.
Question Marks	-Heavy initial capacity expenditures -High R&D costs	Negative to low	Negative cash flow (net cash user)	Assess chances of dominating segment. If good, go after share. If bad, redefine business or withdraw.
Dogs	-Gradually deplete capacity	High to low	Positive cash flow (net cash contributor)	Plan an orderly withdrawal so as to maximize cash flow.

of volume, price, cost, and investment and how to eliminate the natural biases. This problem is addressed by the portfolio approach.

Related to the status of a product in the company portfolio is that product's place in the "product life cycle."

Products tend to go through different stages, each stage being affected by different competitive conditions. These stages require different marketing strategies at different times if sales and profits are to be efficiently realized. The length of a product's life cycle is in no way a fixed period of time. It can last from weeks to years, depending on the type of product. Most discussions of this cycle divide it into four stages known as introduction, growth, maturity, and decline. There are many other opinions on stages of the product life cycle. Indeed, the very concept of a product life cycle has been the subject of some controversy. That is unfortunate, for it tends to diminish the value of a strategic analytical tool. Apart from the length of the life and stages of life of a product, *every* product has one. The ability to identify where a product is in a cycle and to predict or modify the length of that stage is a strategic marketing challenge. (See Table 7-4.)

Introduction is the period during which initial market acceptance may be in doubt; thus, it may be a period of slow growth. Profits are often nonexistent because of high marketing and other expenses. Marketing strategy during this stage is based on different combinations of product, price, promotion, and distribution variables. For example, price and promotion variables may be combined to generate the following strategy alternatives: (a) high price/high promotion; (b) high price/low promotion; (c) low price/heavy promotion; and (d) low price/low promotion.

In the introduction stage the new class of product is presented to the physician for the first time. Usually this will be a product that does something old in a new way (e.g., long-acting tablets), or does something that was not possible before (measles vaccine). Sales generally increase slowly in this stage. Physician habits must be broken, at least to the extent of trying the new product. Unless the medical profession has been awaiting this type of development for a long time (such as in the case of the oral contraceptives) this can be a slow process. The market for the product during this phase will be comprised of a small percentage of the medical population that is normally the first to try new drugs, and who are quite influential with their colleagues. If the product is as effective and safe as this core group wishes, word can be expected to filter down to the rest of the medical community.

The ease of introduction of a new product class can be expected to be

TABLE 7-4. Traditional product life cycle with strategies

CHARACTERISTICS				
Sales	Low Sales	Rapidly rising sales	Peak Sales	Declining sales
Competitors	Few	Growing Number	Stable number beginning to decline	Declining number
MARKETING OBJECTIVES				
	Create product awareness and trial	Maximize Market share	Maximize profit while defending market share	Reduce expenditure and milk the brand
STRATEGIES				
Product	Offer a basic product	Offer product extensions	Diversify forms	Phase Out weak items
Price	Use cost-plus	Price to penetrate market	Price to match or beat competitors	Cut Price
Promotion	Build product awareness among early adopters and dealers	Build awareness and interest in the mass market	Stress brand differences and benefits	Reduce to level needed to retain hardcore loyals

Source: Adapted from: Philip Kotler, *Marketing Management: Analysis, Planning and Control*, 5th Ed., 1984.

affected by the relative success of any previous efforts in this product class. The beta blockers serve as an example.

In the introductory stage direct competition may not be a problem although, if the product merely does a job in a new or better way, there may be difficulty in convincing the physician of the value of a change. Production cost, marketing costs, and prices are traditionally high during the introduction stage. Unless the product can be produced efficiently using existing equipment and in the face of unpredictable sales, the economics of mass production will be hard to realize. Marketing costs will reflect the special nature of promotion to stimulate primary demand. The promotional level usually maintained in later stages would probably not be suffi-

cient to introduce the new concept properly. If the new product represents a sufficiently radical departure from traditional therapy, it may conceivably be necessary to familiarize the general public, as well as the physician, with the new concept. The distribution portion of marketing costs will also be higher than normal, with the special problems of initial stocking of pharmacies and hospitals.

Survivors of the introduction stage enjoy a period of *growth*. During this period there is substantial profit improvement. Strategy in this stage takes the following shape: (a) product improvement—addition of new features and models; (b) development of new market segments; (c) selective demand stimulation; and (d) price adjustments.

During the growth stage there is widespread approval of the product concept. If the product successfully survives the introduction stage, which many do not, it can be expected that many more physicians will get on the bandwagon. During this stage the number of competitors will begin to increase. Either modifications of the original product or completely different products for the same purpose will appear. By this time production methods will have been established, with a frequent lowering of costs. Prices will tend to go down for two main reasons:

1. Increased sales will make some economies of scale possible.
2. The increase in the number of competing firms leads to both a theoretical and an actual tendency toward lower prices.

The growth stage sees promotional activities devoted to the stimulation primarily of selective demand. The advertiser no longer finds it expedient to promote the benefits and qualities of the product class, but rather to promote the advantages of his own brand in comparison with those of his competitors.

During the next stage, *maturity*, there is intense rivalry for a mature market. This leads to a proliferation of sizes, dose forms, and other product variants. Battling to retain the company's share, each marketer steps up promotion, and perhaps grants price concessions. Unless new competitors are obstructed by patents or other barriers, entry is easy. Thus, maturity is a period when sales growth slows and profits peak and then start to decline.

During the maturity stage competition reaches its peak. By this point all of the firms that have any hope of receiving a share of the market will be pursuing it. By virtue of the numbers involved some of these companies will be marginal from either a financial or technological standpoint. The total sales of the product class, which have been rising through the early stages, continue to increase, but at a decreasing rate. During this stage the struggle for sales to the large volume buyers (hospitals and government

agencies) becomes heated. The net effect is price competition for this business. As shall be seen in later chapters, promotion tends to change in emphasis, as does media, with less reliance on the detail man and more on journal advertising and direct mail.

Strategy in the maturity stage comprises the following steps: (a) search for new markets and new and varied uses for the product; (b) improvement of product quality through changes; and (c) new marketing-mix perspectives.

This stage marks the point at which the drug product has been tried and used for all remotely feasible indications (either with or without the blessing of the Food and Drug Administration or of the manufacturer), and has found its place in the therapeutic resources of the physician. New sales from this point on are strictly a function of population and incidence of disease. In addition, the past success of the product class may now be mitigated by products of a new type or changes in medical thinking. It is possible for the medical community to realize after a sufficient period of time that a product is simply not doing all of the things they thought it would.

During this phase all the product variations may be expected to appear. It is now seemingly desirable to have tablets, capsules, and liquid. A dermatologic form may be prepared, or a long-acting form, or a combination. The promotion may now attempt to add some vitality through efforts to segment the market by using special messages to separate physician specialties.

Finally, there is the *decline* period, which may be precipitous. Though sales and profits continue their downward trend, the declining product is not necessarily unprofitable. Some of the competition may have been removed by this stage.

There can be a number of reasons for the decline of a product class—most are related to the effectiveness of the product as compared to other means of therapy. If the decline is caused by a new product development, the decline may be rapid, with only those who are slow to change in any direction continuing to prescribe the product.

Promotion during this stage may again be aimed at stimulation of primary demand. The effort may be half-hearted, and may be aimed at only a core of physician-users. Some firms may now drop from the competition, leaving a potential marketing opportunity for those remaining. The profits may be slim, however, with many of the economies gone.

Of the four stages the maturity stage offers the greatest opportunity to shape the duration of the cycle. The choice of the right strategy here can be very beneficial, as a successfully revitalized product often offers a higher return on investment than does a new product.

Not all products follow a typical life cycle pattern, especially in a research-intensive industry. Further, a product may be participating in more than one cycle simultaneously . . . as a brand (Tagamet), as a product form (H_2 antagonist), and a product class (ulcer therapy).

Ansell (*Pharmaceutical Executive*, March, 1988) has argued, persuasively, that the traditional product life cycle market is not only inappropriate for prescription drugs, but also that its application may be dangerous . . . resulting in premature withdrawal of promotional support.

> There is an important difference between consumer goods and pharmaceuticals. The most powerful intellectual property available to a consumer company is branding, which can last forever. Hence, Coca Cola Corporation can phase in modifications and new lines when the time is ripe—perhaps to preempt a competitor initiative or when growth of an existing line is beginning to slow down.
>
> In pharmaceuticals, however, patent life is of supreme importance, not branding. Therefore, while a product remains on patent, a company should seek to exploit all significant opportunities as soon as they occur. Managers should not wait until the peak of the assumed product life cycle is approaching before pondering how to "extend" it. In pharmaceuticals, ideas taken up this late will materialize too slowly to come to the rescue.
>
> Where range extensions are "cosmetic" rather than direct revenue generators, their timing of introduction should depend on an appraisal of impending patent expiration, not on some hypothetical product life cycle. Company management should evaluate products whose patent life is already over on their intrinsic merits—not on the superficial shape of a life cycle curve.

Another life cycle critic, Merle Crawford (*Journal of Consumer Marketing*, *1*(3), 1984), has suggested that the issue is not whether life cycles exist (clearly they do), but rather what cyclical model is appropriate. He argues for a "product *evolutionary* cycle," based on a biological model. It is shown in Table 7-5. Crawford suggests that a given product may be *in* and influenced *by* the cycle stage of the class.

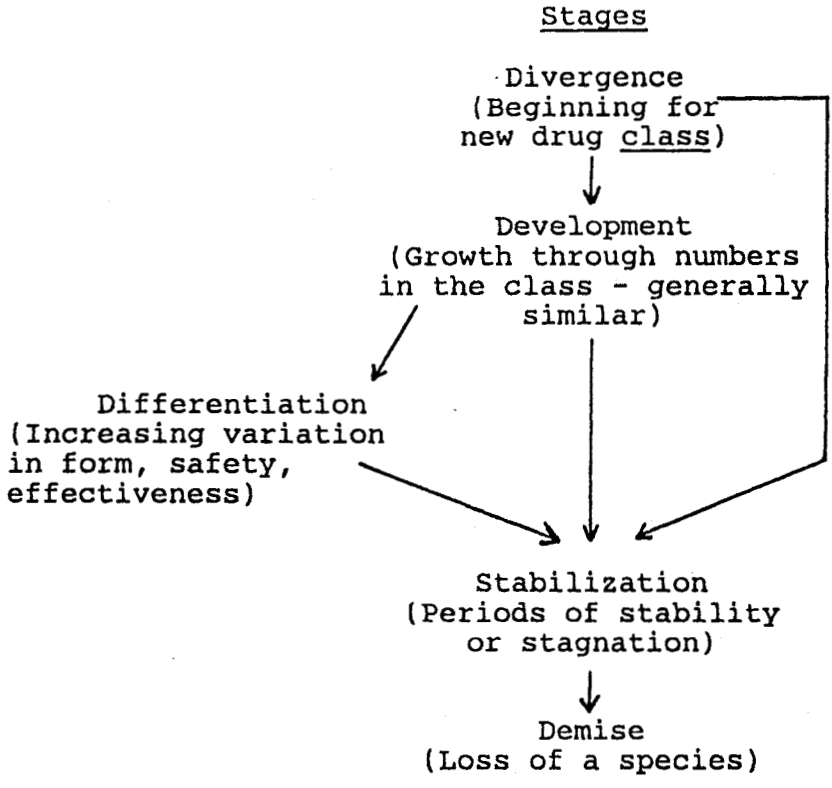
The biological analogy is particularly helpful in explaining the sources of change in evolution . . . what is causing it?

> In biology there are three sources. The first is internal to the specimens—gene sets. These gene sets encourage or print mutations and cross-breeding. They make copies and near copies. Second is the environment—where living conditions favor certain mutations or certain behavior changes. Increasingly cold winters, for example,

evolve elk with thicker hides and hair covering. Third, there is mediation, which is human beings. We have worked to eliminate undesirable species (the measles virus), to develop useful ones (hybrids of corn), and to control or maintain rare ones (zoo animals). Each biological evolution is motivated by a unique composite of these three forces.

Business, too, is affected by such sources of change. Business does have all three of the motivating forces. First, although there is no fixed, inherent "gene set" of change agents in any product, business has the equivalent of a gene set in management. Second, the very essence of marketing is helping the firm adjust profitably to the force of changing market conditions. Third, the equivalent of mediator or intervenor is gov-

TABLE 7-5. Stages in the biological evolutionary cycle



ernment; we have seen many product life cycles changed abruptly (for good or bad) by governmental rulings.

With this analogy in mind it should be easier to understand why individual products do not follow the traditional fixed-curve life cycle. (See Cases in Point.) Crawford suggests some strategic considerations in light of the evolutionary cycle concept.

1. Regarding sequences within a cycle:
   DON'T project a leveling just because growth is slowing.
2. Regarding product death:
   DON'T let a brand name die.
   DO have it evolve into new mutations which are growing in popularity.
3. Regarding market targets:
   DON'T stick with a market as it loses potential for you.
   DO seek out new users or new uses.
4. Regarding the nature of your product line:
   DON'T think of your next new product as a single entity.
   DO see it as the start of a sequence of products; seek evolutionary diversity to meet other needs and other opportunities.
5. Regarding those few cases where the fixed cycle seems to apply:
   DON'T give up without a fight.
   DO think of each item as one of a line of temporary products, and thus market the line, not the item.

CASES IN POINT

Portfolio Analysis of SmithKline Products

IMS America's National Disease and Therapeutic Index (NDTI) data were used to calculate percent market share and market growth for 18 SmithKline and 5 Beecham prescription drug products. Drugs used in the analysis were those appearing in the 1987 edition of the Physician's Desk Reference (PDR). The 1987 PDR was used to correspond with 1988 NDTI data, which are based on 1987 prescribing records. Generic labels (i.e., SmithKline's SK line) were excluded from the study due to the inability to distinguish generic products in IMS data. Prescription drugs not appearing in the 1987 PDR were not considered for this study. Nor were drugs not marketed in the U.S.

Each drug was first reviewed in NDTI "Drug" volumes to determine the condition for which it was most frequently prescribed. This was identified as the drug's primary diagnosis of use. Next, each drug was located

under its primary diagnosis in the NDTI "Diagnosis" volume. The drug class in which the specific drug appeared was recorded as well as the number of prescriptions written for the entire drug class, the number of prescriptions written for the specific drug and the total number of prescriptions written for all drugs listed under the primary diagnosis.

For example, Amoxil® was found in the IMS "Drug" volume to be most frequently prescribed for the diagnosis, unspecified otitis media. From the IMS "Diagnosis" volume it was determined that 34,042,000 prescriptions had been issued for otitis media. Of these 4,771,000 were for Amoxil. Finally, Amoxil was a part of the drug class, amoxicillins, for which a total of 12,525,000 prescriptions had been issued for otitis media.

If a drug was not listed by brand name under its primary diagnosis (i.e., it was listed only as "other products"), the second most common diagnosis was used for the calculation of market share and market growth. A drug which did not appear by brand name under either its primary or secondary diagnosis was omitted from the final portfolio analysis.

For purposes of this study, percent market share was defined by the formula

$$\text{percent market share} = \frac{A}{B} \times 100$$

where "A" is the number of prescriptions written for the drug under its primary diagnosis and "B" is the number of prescriptions written for the entire drug class in which the drug appeared under its primary diagnosis. For example, the percent market share of Amoxil® was calculated as

$$\frac{4,771,000}{12,525,000} \times 100 = 38.10\% \text{ of all brands}$$

of amoxicillin whose primary diagnosis was unspecified otitis media. Market growth, or the percent change in market, was defined by the formula

$$\text{market growth} = \frac{C\text{-}D}{C} \times 100$$

where "C" is the total number of prescriptions written for a drug's primary diagnosis in 1977 (1978 data was not available) and "D" is the total number of prescriptions written for a drug's primary diagnosis in 1988. Secondary diagnosis was used for calculations where primary diagnosis did not list a drug by brand name.

Some diagnosis categories had been modified by IMS during the 11

year comparison period. For example, while manic-depression appeared as a single classification in 1977, the 1988 data contained six subdivisions of manic-depression. Also, one drug, Stelazine®, was found to have been prescribed equally for paranoid schizophrenia, residual schizophrenia, unspecified manic-depression and unspecified schizophrenia. Separate calculations were made for each of these four diagnoses, however, only the diagnosis with the highest market share was used in the portfolio analysis. Each product for which market share and market growth could be determined were plotted on a Boston Consulting Group (BCG) Product Portfolio Matrix.

Figure 7-A contains the Product Portfolio Matrix for SmithKline. Most drugs (77.8%) fell into the "Question Marks" category. Two (11.1%) drugs fell into each of the "Stars" and "Dogs" categories. No products were determined to be "Cash Cows."

Figure 7-B contains a projected Product Portfolio Matrix for SmithKline-Beecham. Augmentin®'s strong presence in the "Star" quadrant slightly improved the merger portfolio over that for SK products alone. However, most products (78.3%) still fell into the "Question Marks" category and no "Cash Cows" were evident.

Regarding the SmithKline Beecham merger, Beecham has been described as "the driving force and the company in the strongest position to dictate terms." The current portfolio analysis appeared to support this statement. Still, the merger portfolio was not a substantial improvement over the SK profile. With no "Cash Cows," it appears that extensive product promotion will be required for SKB to push "Question Marks" and "Stars" into profitable products. Perhaps more promising is the SKB R&D portfolio which has been reported to contain 58 products (31-SK, 27-Beecham) in the clinical trial stage. At any rate, results of this study indicate that some of the financial benefits of the SmithKline-Beecham merger may not be apparent for several years to come.

Source: Special Report by Mary Monk.

Product Life Cycles in the Pharmaceutical Industry

Jernigan, in a 1989 master's thesis at the University of Mississippi plotted 15-year life cycle curves for new chemical entity prescription products introduced to the market in the years 1963-1972. Using an indexing procedure in which 100 is equivalent to the highest level of new prescription achieved in any of the 15 years post-launch. Figures 7-C to 7-G illustrate the diversity of his findings.

FIGURE 7-A. SmithKline product portfolio matrix, 1988

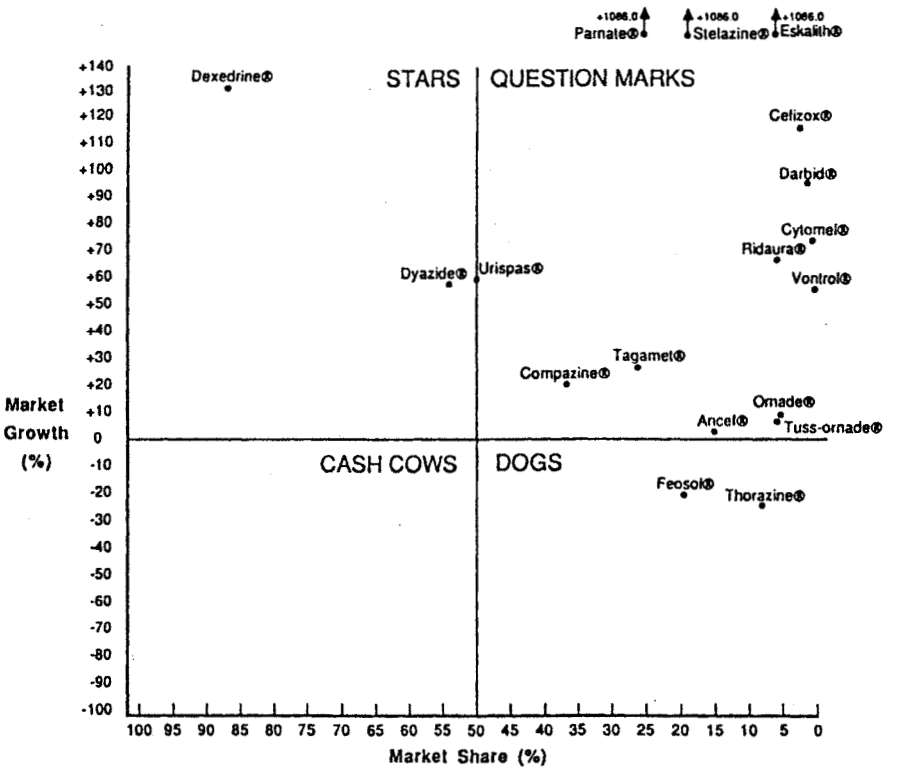


FIGURE 7-B. SmithKline Beecham product portfolio matrix 1988 (projected)

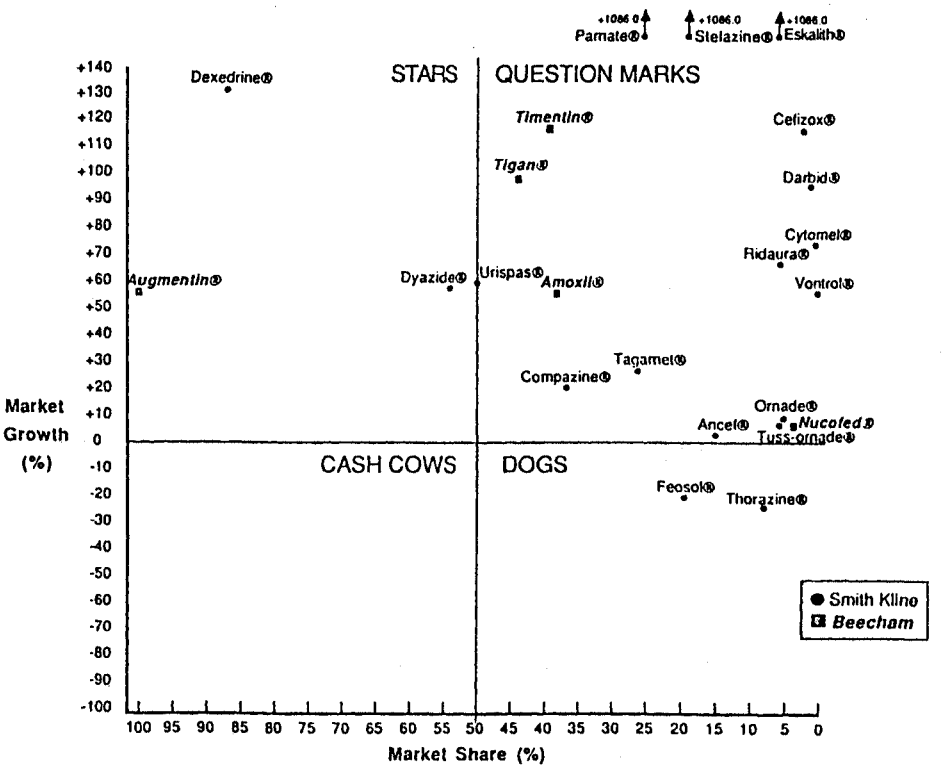


FIGURE 7-C

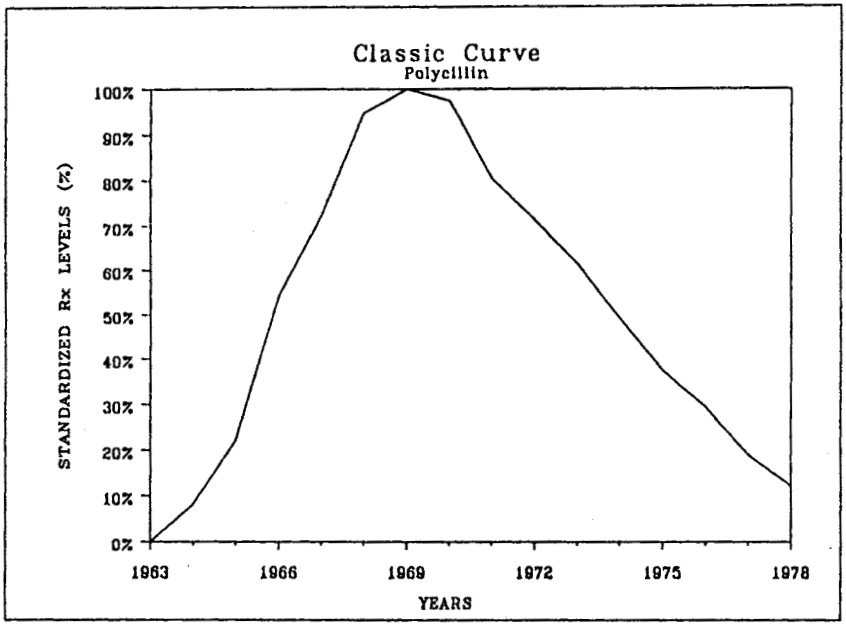


FIGURE 7-D

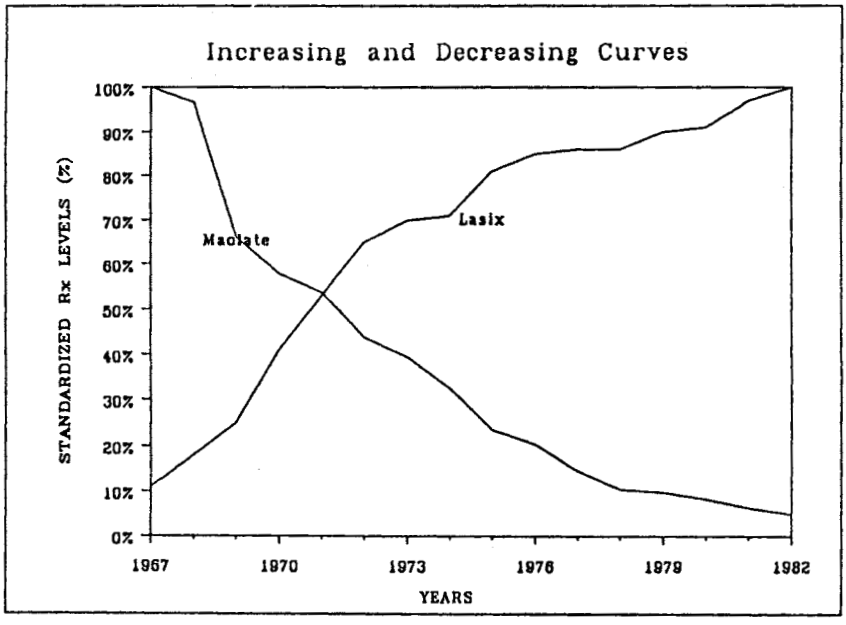


FIGURE 7-E

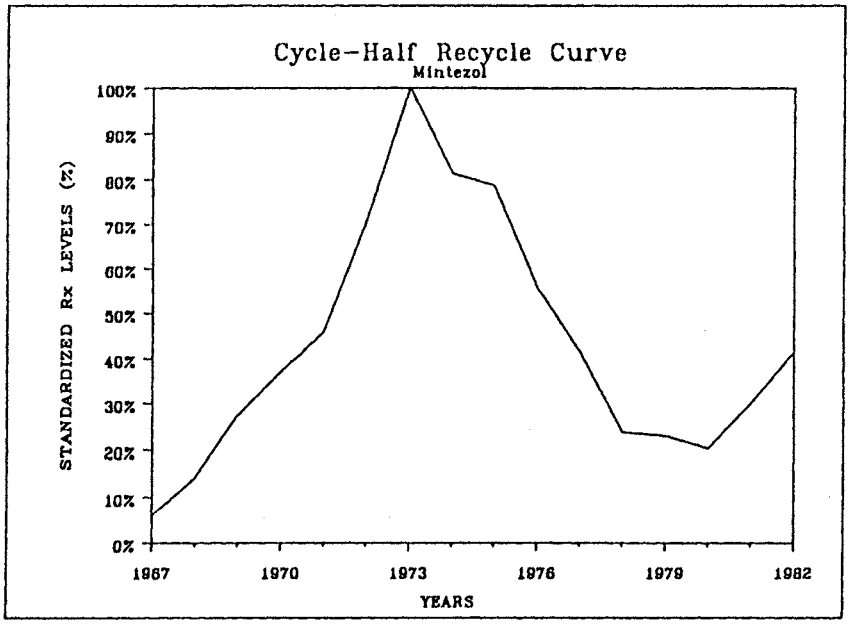


FIGURE 7-F

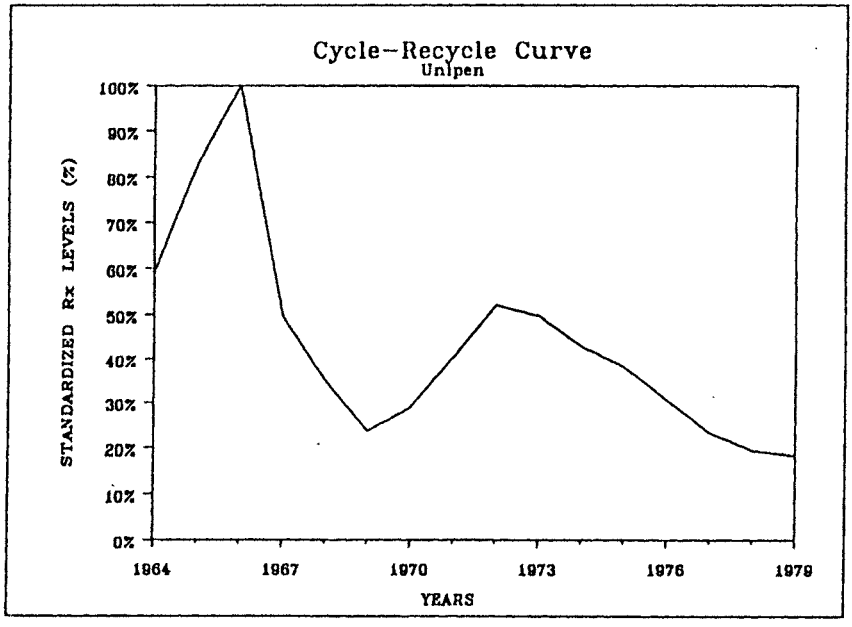
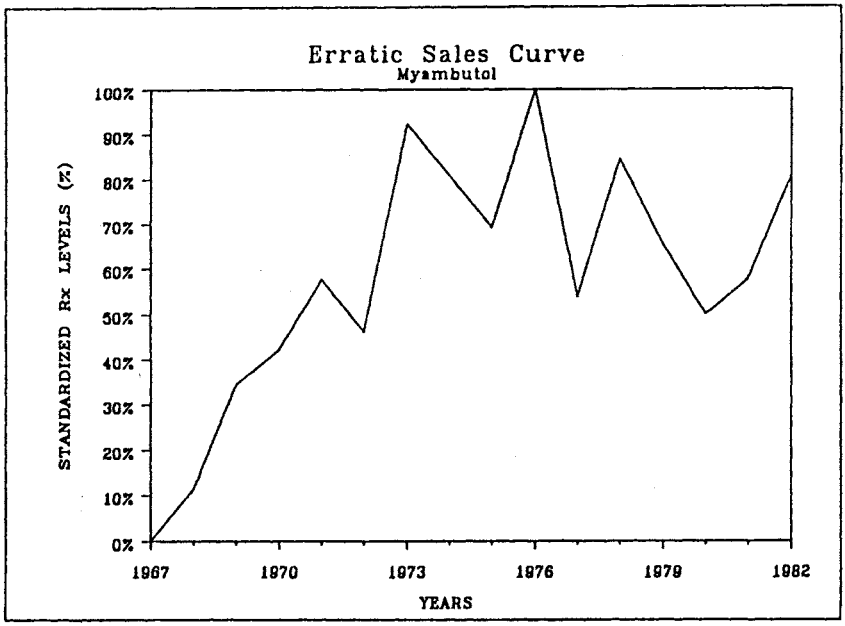


FIGURE 7-G



Drug Product Lives

In the years 1957-1958 a total of 79 new prescription drugs entered the U.S. pharmaceutical market. Of these, seven were no longer marketed ten years later in 1968. On the other hand, the following products were still included in the list of the 200 most prescribed drugs more than twenty years later in 1980: Darvon, Diabinese, Dimetane, Diuril, Ilosone, Kenalog, Orinase, Polarimine, Robaxin, Stelazine, Vistaril. In 1988 only Diabinese and Medrol remained on the list.

ANALYZING THE COMPETITION

It is time to return to the concept of marketing warfare.

In a free market economy, each company tries to exceed its competitors in performance. A competitor is like an enemy. To outperform its competitors, a company must know how it stands against each one of them with regard to "arms and ammunition"—skill in maneuvering opportunities,

preparedness in reacting to threats, and so on. To get adequate knowledge about the competition it faces, the company needs an excellent intelligence network.

Typically, whenever one talks in terms of competition, emphasis is placed on price, quality of products, distribution and other marketing variables. For the purposes of strategy development, however, one needs to go far beyond these marketing tactics employed by a competitor. Simply knowing that a competitor has been lowering prices, for example, is not sufficient. Over and above that, we must know how much flexibility the competitor has in further reducing the price. Implicit here is the need for information about the competitor's cost structure.

Perhaps the best way to define competition is to differentiate between natural and strategic competition. Natural competition refers to the survival of the fittest in a given environment. It is an evolutionary process that weeds out the weaker of the two rivals. Applied to the business world, it means that no two firms doing business across the board the same way in the same market can coexist forever. To survive, each firm must define how it is uniquely superior to other competitors.

Strategic competition, in contrast, relies on leaving nothing to chance. Bruce Henderson (Boston Consulting Group, 1981) has defined it as the "studied deployment of resources based on a high degree of insight into the systematic cause and effect in the business ecological system." Strategic competition requires (a) an adequate amount of information surrounding the situation; (b) development of a framework to understand the dynamic interactive system; (c) postponement of current consumption to provide investment capital; (d) commitment to invest major resources to an irreversible outcome; and (e) ability to predict the output consequences, even with incomplete knowledge of inputs.

The degree of competition in a market depends on the moves and countermoves of the various firms that are active in the market. Usually it starts with one firm trying to achieve a favorable position by pursuing appropriate strategies. Since what is good for one firm may be harmful to the rival firms, however, the latter then respond with counterstrategies to protect their own interests.

Competitive intelligence is the publicly available information on competitors, current and potential, which serves as an important input in formulating marketing strategy. No general orders an army to march without first fully knowing about the enemy's position and intentions. Likewise, before deciding on the competitive moves to make, a firm must be aware of the perspectives of its competitors. There are many sources of competi-

tive intelligence in the drug industry. Promotional activities may be monitored through promotional audits. Pricing practices are easily monitored from the field. Even drugs in research are easily identified well before they reach the marketplace. This is both a blessing and a curse of a highly regulated industry.

Industry economist Thi Dao has described the evolution of competition in the pharmaceutical industry as progressing from almost total emphasis on product differentiation to a current spectrum of competitive issues ranging from pure price competition to product innovation. (See Figure 7-1.) For the future it seems obvious that competition will have a strong economic component. Dao notes:

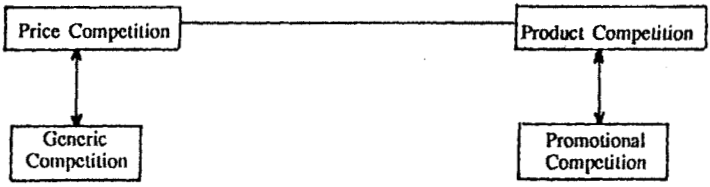
> To compete effectively in the future marketplace, pharmaceutical companies need more than just new medicines—they need new medicines that are cost-effective. Product competition based on cost-effectiveness will have a significant impact on the way companies do business and their collective and individual public image. At the industry level, the cost-effectiveness standard will preempt any need for governments to institute new price controls. For, as a mechanism by which medicines can be differentiated (by therapeutic benefits and/or quantified economic values), cost-effectiveness is, in effect, a form of economic regulation.
>
> And with this mechanism, product competition can take only one of the two following forms: first, if a new medicine is found to be more cost-effective than its competitors, the marketer can justify a higher price. Further, the medicine is likely to enjoy a leading market position because its cost-effectiveness will induce decision makers to grant it "medicine-of-choice" status. Second, if the therapeutic and safety benefits offered by the medicine are not sufficient to make it more cost-effective than existing competitors, its marketer will be forced to accept a lower price.

Analysis of the competition should proceed along lines similar to those used in self-analysis . . . and on a product-by-product basis. Once this has been accomplished one will have a clearer idea of where and how to compete and on what strategic basis, i.e., what changes in the marketing mix are possible given the corporate strengths and weaknesses as well as those of the competition. As Figure 7-2 demonstrates a broad view is necessary to evaluate competition completely.

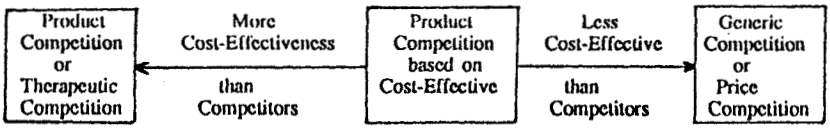
Some general strategic principles have been provided by Ries and Trout. (See Table 7-6.)

FIGURE 7-1. Views of pharmaceutical competition

PRESENT



FUTURE



Source: Thi Dao, Merck, Sharp and Dohme.

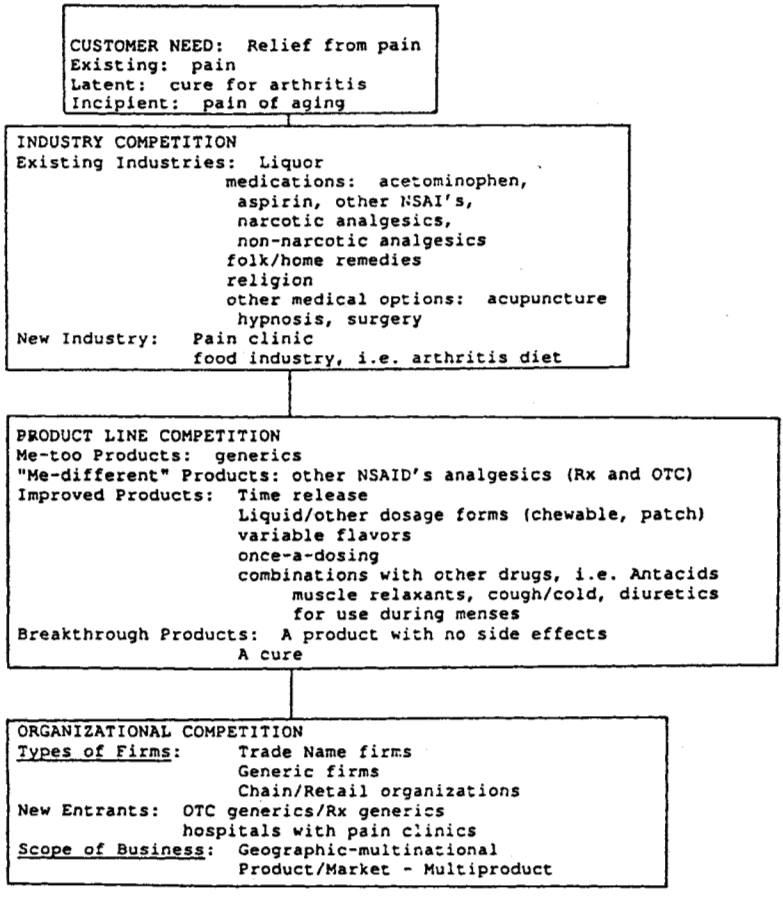
*ORGANIZATION AND CONTROL FOR STRATEGIC MARKETING**

A marketing company that places a great deal of emphasis on controlling its business environment is more likely to achieve its goals and objectives than is a company that just lets nature take its course. The marketplace is extremely complex and perpetually demanding; companies that cannot control their own activities have very little hope of surviving the competitive pressures for long. For this reason, most successful companies can point to effective internal controls that they regularly use as guides for their planning, production, distribution, and marketing.

A pharmaceutical marketing company is a highly complex organization

*Some of the materials in this section were written by Alfred A. Mannino for the previous edition.

FIGURE 7-2. Competitive analysis for Ibuprofen (hypothetical)



Source: Prepared by Patti P. Tucker.

that requires the application of many different business disciplines and the allocation of many different resources. Even a small company will become involved in the full range of marketing activities sooner or later: laboratory research, product development, production, packaging, financial planning, personnel administration, advertising, professional commu-

TABLE 7-6. Marketing strategies

Types of Strategy	Strategic Principles
Defensive (Role of the Leader)	Only the market leader should play defense Best strategy is to attach yourself Always block strong competitive moves
Offensive (Role of Number 2 or 3)	Main consideration is strength of the leader Attack a weakness in the leader's strength Attack on as narrow a front as possible
Flanking (Gamble, with big stakes)	Flanking moves should be made in an uncontested area Tactical surprise should be an important element Pursuit is as critical as the attack itself
Guerrilla (Role of the Small Firm)	Find a market segment small enough to defend Never act like a leader Be prepared to withdraw quickly

Adapted from: Al Ries and Jack Trout, *Marketing Warfare*, New York, McGraw Hill, 1986.

nications and, of course, sales. In this respect, the potential for organizational complexity, all pharmaceutical marketing companies are similar.

There is another point of similarity, one that is grounded in the utmost simplicity—a pharmaceutical marketing company will exist only as long as it continues to fulfill patient needs and investor desires. Fulfilling patient needs means contributing in some way to better health care; fulfilling investor desires means providing a reasonable return on investment.

This fundamentally simple fact of business life is often overlooked by the industry observer or company manager who becomes involved in the complexities of day-to-day operations; unfortunately, it is an oversight that can prove to be painfully expensive. If a company successfully meets both these standards, fulfilling patient needs and investor desires, it will assure its own continuity in the marketplace. If a company fails to meet either of these two standards, however, it will eventually cease to exist as a company; physicians just will not prescribe, and patients will not buy, products that do not contribute to better health care. By much the same token, investors will not be inclined to support a company that does not provide a reasonable return on investment.

The role of internal controls in a pharmaceutical marketing company is

an important one, important because controls are essential if a manager is to properly execute his responsibilities to his own personal goals, to his department's function, and to his company. By extension, it can also be inferred that internal controls are instrumental in helping a company meet the standards required for continued existence—that is, the fulfillment of patients' needs and the fulfillment of investors' desires.

Under ideal conditions a company would be able to control all aspects of marketing, thereby developing a new pharmaceutical product effortlessly, bringing it to the marketplace smoothly, and capturing universal awareness, total acceptance, and maximum sales volume immediately. Unfortunately, ideal conditions do not now exist and are unlikely to come into existence. There will always be the possibility of snags in the development process, there will always be competition, and there will always be problems with communications, awareness, and acceptance. The manager in a pharmaceutical marketing company, therefore, must simply adapt to whatever conditions are encountered and try to control what can be controlled.

Not all factors, of course, can be controlled. There are quantitative and qualitative aspects of marketing that offer varying degrees of opportunity and challenge. To a large measure, the quantitative aspects of marketing are directly controllable and the qualitative aspects are not, although it is sometimes possible to influence the qualitative aspects and thereby control them indirectly.

To clarify the point, consider the art of poetry. Essentially, the poet has four resources with which to work: words, rhyme, meter, and imagery. Of these four aspects of poetry, the first three are quantitative—they can be measured accurately and the poet can, consequently, control them with reasonable certainty. But the fourth aspect, imagery, is qualitative; it cannot be premeasured because its value (or weight or impact) depends on how the reader subsequently perceives it and reacts to it. The poet, therefore, cannot control the effect of imagery directly, but he can influence how it will be perceived by carefully selecting imagery that is universal and profound—and in this manner he exercises indirect control.

The same principle applies in marketing. A manager in a pharmaceutical marketing company can almost always establish direct control over the quantitative aspects of marketing, such as product characteristics (e.g., molecular structure, efficacy, and packaging) and corporate risks or resources (production costs, pricing levels, size and activity of the sales force). The qualitative aspects of marketing, however, such as public awareness and individual motivation of sales representatives, can be con-

trolled only insofar as the manager can influence them. This can usually be done by properly utilizing certain controllable quantitative aspects of marketing; increased advertising can raise public awareness, for example, and periodic evaluation of individual effort can improve the performance of sales representatives.

It should be apparent from what has been discussed so far that some factors are more controllable than others. The corollary—an important one—is that some factors are less controllable than others. Interestingly, these less controllable aspects of marketing are those that tend to cry out the loudest for the initiation of effective internal controls, primarily because they can subsequently determine the company's degree of success. It is a relatively simple matter, for example, to manage the size of the sales force because size is quantitative and, therefore, is directly controllable; all that needs to be done is to add or subtract qualified people. It is generally difficult, on the other hand, to manage the effectiveness of the sales force because effectiveness is qualitative in nature and is subject only to indirect control. Given these aspects of the sales force, size and effectiveness, most managers would agree that internal controls are potentially more valuable when they are applied to the less controllable of the two.

A pharmaceutical marketing company is a highly complex organization, a fact that need not cause anyone a great deal of concern because, although the word "complex" sometimes has undesirable connotations, there is really nothing undesirable or troublesome about complexity, as long as a certain degree of organization is applied. Biologic life, itself, is a highly complex matter, but the inhabitants of this planet have been able to manage well, thanks primarily to the structured organization that regulates the interactions of various life forms.

The basic organizational tool in a marketing company is a table of organization. Its purpose is to categorize the various business disciplines and resources clearly, establish levels of responsibility and authority, and delineate the paths of direction, instruction, and reporting. Properly applied, the table of organization can simplify the planning process, speed the flow and volume of work, and aid in the achievement of long-range objectives and short-range goals. In this sense, the table of organization serves as a sort of overall control mechanism and as such warrants some discussion here.

It is probably safe to say that no two companies are organized exactly alike. A company's size, scope of activities, and marketing objectives—along with numerous other factors, including the personalities of top man-

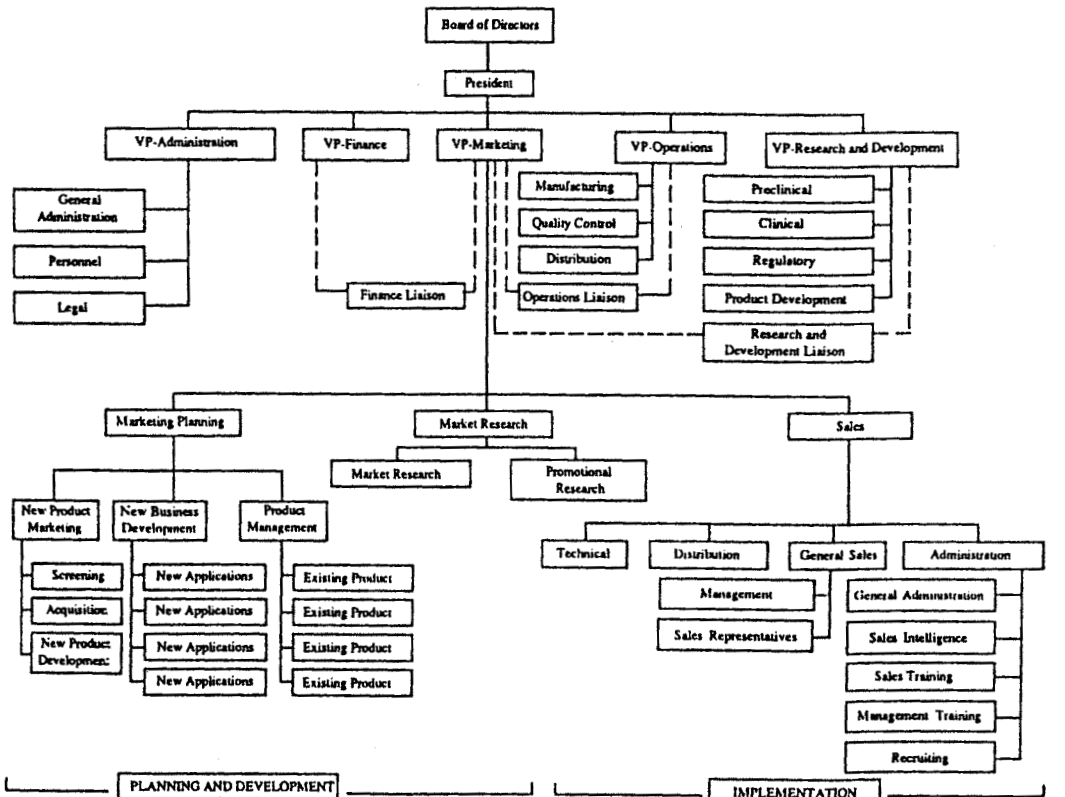
agement—all influence the form of the table of organization. It is therefore impossible to present a single organizational model and to suggest that it should apply to all companies. Instead it is better merely to outline a hypothetic model stipulating that, however logical it may appear, such an organizational structure may not actually exist anywhere in the world of marketing.

Figure 7-3 shows such a hypothetical table of organization for daily business operations. Notice that the company's business disciplines have been segmented into five different categories or divisions—finance, administration, operations, research and development, and marketing—and that the vice president of each of these divisions reports directly to the president, who in turn reports directly to the board of directors. In this table of organization the functions of the finance, administration, operations, and research and development divisions have not been thoroughly detailed, while the marketing division has been detailed to a greater extent. The marketing division is organized into three distinct departments: marketing planning, market research, and sales. The first two are essentially involved in planning and development, while the latter has the responsibility of actually implementing the plans in the marketplace. The casual observer might conclude that a pharmaceutical marketing company's efforts are centered on its sales staff, but this table of organization clearly shows otherwise. The planning and development activities are at least as critical as the sales activities, especially if proper internal controls are utilized.

One other point should be emphasized in this discussion of the daily organization of a company. Any division within a company may be operating in a vacuum, so to speak, thereby losing contact with what is happening elsewhere within the company. The marketing division, for example, could easily pursue its own promotional efforts for a new product and might introduce the product to the market months before the manufacturing division is ready to fill orders. Or, the research and development division could encounter obstacles in its work, thereby creating unexpected delays that would have an adverse effect on the marketing division. In order to ensure continuing communications and avoid potentially serious problems, the table of organization provides for top level coordination between divisions; there are established liaisons, and therefore vital control points, between the vice presidents of marketing and finance, of marketing and operations, and of marketing and research and development.

The organizational structure detailed in Figure 7-3 may be suitable for most daily business operations, but it falls short of providing the type of

FIGURE 7-3. Organization for day-to-day operation



control necessary for company-wide, special effort projects, such as the development of a new product from discovery to first sale. The reason for this is that the day-to-day table of organization shown is vertical in nature (the lines of responsibility and authority run vertically through each division), and does not allow for adequate coordination of activities horizontally between divisions. Some firms have an elaborate organization structure for gathering the internal and competition intelligence discussed above. An example is shown in Figure 7-4.

CASES IN POINT

Unprotected Assets

Expiration of patent and passage of the ANDA/patent extension law opened up a $10-billion window of opportunity for generics during the 1980s and provided considerable motivation for innovator pharmaceutical companies to bring new products to market, either through expedited internal R&D or external partnerships. The following table shows the number of products, sales volume of those products, percent of company product portfolios involved, and the companies' ranking in exposure to product line to generic competition that occurred during this decade.

Company	*Products Under Patent*	*Sales From Products Under Patent (dollars in millions)*	*Exposure Coming Off Patent in 1981-1990 % of Company Portfolio*	*Rank in Exposure to Generics*
Erbamont	*1*	*68*	*100*	*1*
Lilly	*11*	*961*	*52*	*2*
Merck	*22*	*1,055*	*47*	*3*
Bristol-Myers	*16*	*417*	*40*	*4*
American Home Products	*12*	*780*	*39*	*5*
Johnson & Johnson	*8*	*369*	*39*	*6*
Upjohn	*10*	*723*	*38*	*7*
Pfizer	*10*	*859*	*36*	*8*
SmithKline	*7*	*1,043*	*34*	*9*
American Cyanamid	*2*	*115*	*28*	*10*
Syntex	*8*	*485*	*26*	*11*
Warner-Lambert	*4*	*165*	*25*	*12*

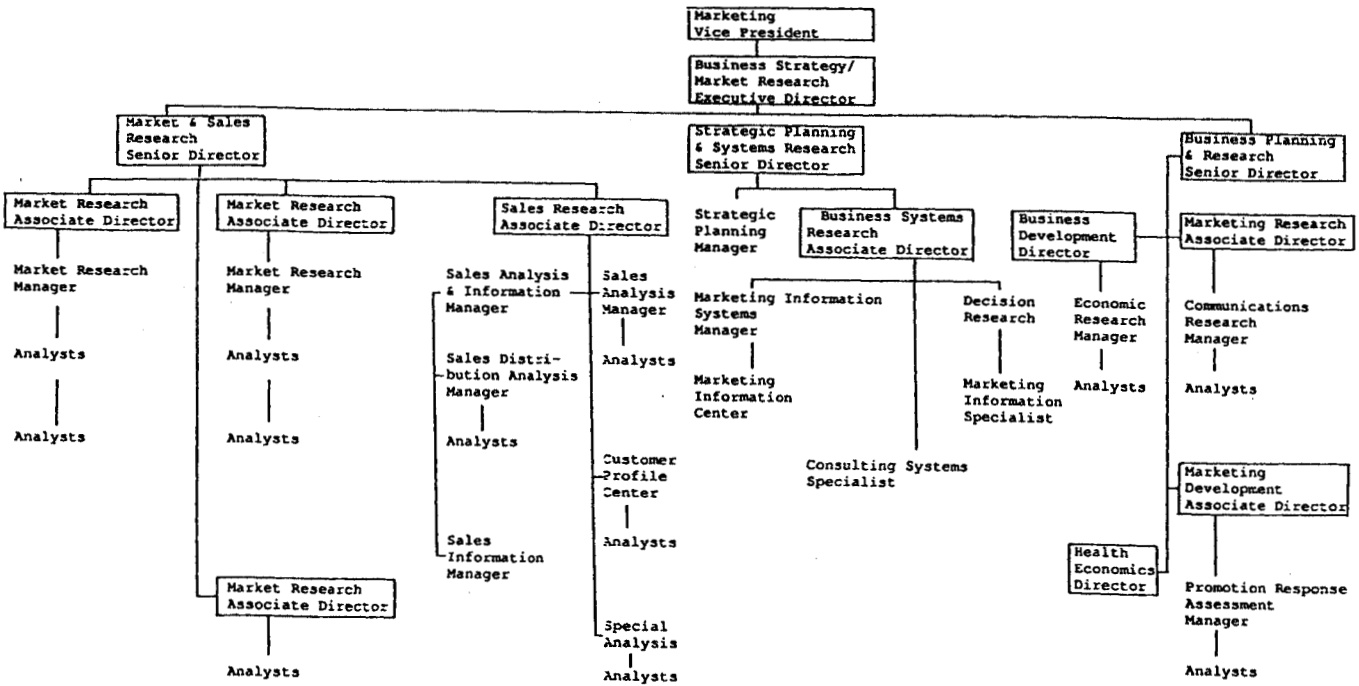
Company	Products Under Patent	Sales From Products Under Patent (dollars in millions)	Exposure Coming Off Patent in 1981-1990 % of Company Portfolio	Rank in Exposure to Generics
Marion	4	320	23	13
Schering-Plough	8	226	23	14
Glaxo	3	576	10	15
Squibb	6	408	5	16
Sterling	3	26	3	17

Source: Pharmaceutical Executive, *February, 1989.*

Assessing and Altering Strengths and Weaknesses

- *Glaxo and Roche combine sales staffs to compete with Lilly for cephalosporin business*
- *Marion enters OTC ulcer market with help from Schering Plough*
- *Boots raises U.S. presence by acquiring Flint Labs*
- *Warner-Lambert uses confection products expertise to produce Cholybar*
- *Roche weakness in OTC's eliminated them as a partner for Glaxo on OTC Zantac*
- *Merck admits interest in OTC switches, but will do so only through a new or acquired company, then reaches agreement with Johnson & Johnson*
- *Genentech hires Boehringer Ingelheim sales force to promote Activase*
- *Bristol-Myers and Squibb merge to gain "Critical Mass" and "Strategic Fit"*
- *SmithKline and Beecham merge*

FIGURE 7-4. Organization of the marketing function



Chapter 8

Pricing Strategy

Price, as defined in Chapter 1, is the "total cost components that markets must bear in order to use the products offered." A price represents the value of a drug product for both the buyer and the seller. In a free market both parties must feel that the product provides an equitable value for the dollars spent. A price contains all the terms of purchase: monetary and non-monetary, discounts, handling fees, credit and other interest charges, etc.

Price has had a complex and changeable role in the marketing mix for both prescription and non-prescription medications. Indications are that change will continue to be the rule in selecting pricing strategies.

Figure 8-1 shows the basic steps in developing a price strategy. It also lists some examples of factors affecting these strategy decisions. These broad elements will form the basis for discussion in this chapter. Much more detailed considerations are shown in Table 8-1, but these cannot be examined thoroughly here.

For prescription drugs the marketing literature on price as a marketing

FIGURE 8-1. Framework for developing a strategy

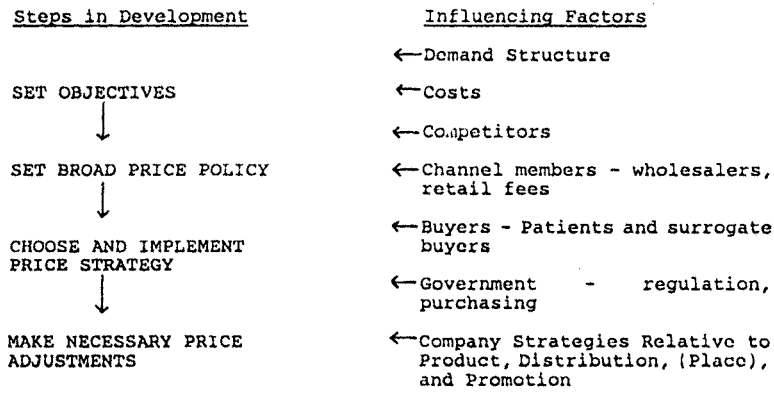


TABLE 8-1. Factors influencing drug prices

Demand Factors

1. Product characteristics defined by (a) acceptability, (b) efficacy, and (c) absence of side effects
2. The therapeutic qualities of a drug in relation to other products
3. Classes of physicians who are the most likely prescribers
4. Price schedules for related products
5. Daily dosage quantity and expected duration of patient therapy
6. Dosage or treatment costs in a health care program
7. Effects on related costs in a health care program
8. Extent and characteristics of probable users, considering age group, income levels, and so forth
9. Elasticity of demand with respect to price
10. Cross elasticities of demand with respect to price and product qualities
11. Elasticity of demand with respect to income
12. Probability and timing of appearance of new competing products
13. Projected volume at various prices
14. Duration and pattern of probable product life cycle
15. Extent of use of prepayment plans, insurance plans, and government programs in paying for health care and drugs

Supply Factors

1. Number and types of competing products
2. Number and types of competing companies
3. Rate of future prospective development of competing products
4. Research, production, and quality control requirements expressed in required investments and cost levels
5. Nature of distribution systems required for effective marketing
6. Size, forms, and strengths of products to be marketed
7. Expected shelf life of products
8. Patent position of the firm in relation to other products and firms
9. Other products produced by the firm and their prospective prices, costs, volume, and returns
10. Ease of imitation or improvements by others
11. Location of production in relation to markets served; domestic versus exports
12. Sources of raw materials
13. Differences in required associated services to the medical profession
14. Tax patterns
15. Government regulations and procedures required for certifying drugs
16. Sources and costs of capital
17. Types of scientific and technical capabilities required
18. Production and quality control supervision by regulatory agencies

Environmental Factors

1. Size of the economy
2. Percentage of income spent on health care
3. Nature and expectations toward health care systems

TABLE 8-1 (continued)

4.	Consumption habits and patterns with respect to the use of pharmaceuticals
5.	Standard of living in the economy
6.	Size and distribution of gross national product
7.	Characteristics of the political environment
8.	Role of government in payment for health care
9.	Role of government as regulator and inspector
10.	Rate of growth of the economy
11.	Economic instability or stability
12.	Patterns of price changes in the economy as a whole
13.	Import, export, foreign exchange regulations
14.	Antidumping regulations
15.	Laws with respect to patents
16.	Laws and administrative policies with respect to compulsory licensing
17.	Licensing regulations
18.	Comparative licensing regulations among different countries

Source: J. Fred Weston in *Issues in Pharmaceutical Economics*, Lexington Books, 1979.

variable is rather sparse. This must be due, in part, to the recurring criticism—official and grassroots—of the "high cost of drugs." Also, price strategy is one of the most difficult of the four "P's" to implement well.

David Luery of Total Research Corporation lists five situations in which a drug company's pricing strategy must be applied:

1. Setting a price for a new drug product
2. Forecasting share volume for a new product introduction
3. Setting and adjusting price policy for existing products
4. Setting product line pricing (How to price the 20 mgm. version relative to the 10 mgm. and 5 mgm. version)
5. Forecasting impact of generic competition on products without patent protection.

These are considered in the strategic steps which follow.

STEPS IN STRATEGY DEVELOPMENT

Setting Objectives

It is generally agreed that pricing objectives are likely to be generally oriented to profit or toward sales (volume), although, as Table 8-2 shows, much more specific objectives may be selected.

TABLE 8-2. Example price objectives

1.	Maximum long-run profits.
2.	Maximum short-run profits.
3.	Growth.
4.	Stabilize market.
5.	Desensitize customers to price.
6.	Maintain price-leadership arrangement.
7.	Discourage entrants.
8.	Speed exit of marginal firms.
9.	Avoid government investigation and control.
10.	Maintain loyalty of middlemen and get their sales support.
11.	Be regarded as "fair" by customers (ultimate).
12.	Help in the sale of weak items in the line.
13.	Discourage others from cutting prices.

Profit-based objectives typically set a return-on-investment figure or an actual dollar amount for a product, a line of products, or sales as a whole. Sales objectives may be set relative to the market (a percent market share) or a desired sales growth rate.

A company may pursue more than one pricing objective at the same time, such as maximizing market share and earning at least a specified net profit before taxes. A firm may also set different short-run and long-run objectives. For example, in the short run, it may want to secure an early recovery of cash; in the long run, it may seek to discourage the entry of competitors. The age of the product(s) is also a factor.

Setting Broad Price Policy

A broad price policy coordinates pricing decisions with the firm's target market, and marketing mix. It generates a coordinated series of actions, and a strategy that incorporates short- and long-term goals. The company outlines its broad price policy by placing individual price decisions into an integrated framework. For example, the firm would decide on the interrelationship of prices for goods within a product line, how often special discounts are used, how prices compare to competition, the frequency of

price changes, the method for setting prices for new products, and the pricing pattern selected for established products.

Choosing a Price Strategy

New Products

There are a variety of approaches to new-product pricing. We will briefly review a few of these.

Skimming pricing is the strategy of establishing a high initial price for a product to "skim the cream" off the upper end of the demand curve. (See Demand discussion below.) It is aimed at achieving profit-based objectives. It is usually accompanied by heavy promotion expenditures.

A skimming strategy may be recommended when the nature of the demand is uncertain, when a company has expended large sums of money on research and development of a new product, when the competition is expected to develop and market a similar product in the near future, or when the product is so innovative that the market is expected to mature very slowly. Other situations in which skimming pricing may be considered are:

- Preparations to which the consumer (payer) does not react very susceptibly to the price (= low price elasticity)
- Achieving short-term profits
- Quick amortization of research and development
- Making profits in the early phases of the products' life cycle (= reducing the risk that new, better preparations contribute to loss of profit)
- Avoiding the necessity of price increases
- Margin for price reductions
- High prices signalize high quality
- Limited production possibilities

In these circumstances, a skimming strategy has several advantages. At the top of the demand curve, price elasticity is low. Besides, in the absence of any close substitute, cross-elasticity is also low. These factors, along with heavy emphasis on promotion, tend to help the product make significant inroads into the market. The high price also helps in segmenting the market.

If there are doubts about the shape of the demand curve, and the initial price is found to be too high, the price may be slashed. But it is very difficult to start low and then raise the price later on. Raising a low price

may annoy potential customers, and further anticipated drops in price may retard demand at a particular price. For a financially weak company, a skimming strategy may provide immediate relief. This model depends upon selling enough units at the higher price to cover promotion and development costs. If price elasticity is higher than anticipated, a lower price will be more profitable and provide more relief.

Skimming is proper if competition can be kept out or minimized (through patent protection, brand loyalty, raw material control, or high capital requirements), funds are needed for early recovery of cash or further expansion, the market is insensitive to price or willing to pay a high initial price, and unit production and distribution costs remain equal or increase as sales increase (economies of scale are absent).

The decision on how high a skimming price should be will depend on two factors: (1) chances of competitors entering the market, and (2) price elasticity at the upper layer of the demand curve. If competitors are expected to bring out their own brands quickly, it may be safe to price rather high. On the other hand, if competitors are years behind in product development and a low rate of return to the firm would slow the pace of their research, a low skimming price would be useful.

Penetration pricing is designed to achieve sale-based objectives. It is the strategy of entering the market with a low initial price so that a greater share of the market can be captured. The penetration strategy is resorted to when demand seems to be elastic over the entire demand curve. High price elasticity of demand is probably the most important reason for adopting the penetration strategy. The penetration strategy is also used to discourage competitors from entering the market. When competitors seem to be encroaching on the market, an attempt is made to lure them away by means of penetration pricing, which requires lower margins. A competitor's costs play a decisive role in this, since a cost advantage over the existing manufacturer might persuade a firm to enter the market, however low the margin of the former may be.

Among situations suggesting a strategy of penetration pricing are:

- Preparations to which the consumer/payer reacts very susceptibly to the price (= high price elasticity)
- Achieving fast quantity growth
- Achieving high market share and thus strong market position by the time of competitors' entry
- Utilization of experience curves ("learning curves") and of magnitude advantages in production ("economies of scale")

- Low introductory prices reduce risk of a flop
- Hindering potential competitors to enter the market

Cost-plus pricing is where prices are determined by adding a predetermined profit to costs. It is the simplest form of cost-based pricing. In general, the steps for computing cost-pricing are to estimate the number of units to be produced, calculate fixed and variable costs, and add a predetermined profit to costs. The formula for cost-plus pricing is

$$\text{Price} = \frac{\text{Total fixed costs} + \text{Total variable costs} + \text{Projected profit}}{\text{Units produced}}$$

Although the cost-plus method is easy to compute, it has several shortcomings. Profit is not expressed as a percent of sales but as a percent of cost, and price is not tied to demand. Adjustments for rising costs are poorly conceived, and there are no plans for using excess capacity. There is little incentive for the firm to improve efficiency to hold down costs, and marginal costs are rarely analyzed.

Cost-plus pricing simply does not make sense for research intensive companies, for in such companies data show that not more than 30 percent of the costs can be allocated directly to individual products, the remaining costs and the profit margin have to be covered by contributions (i.e., the difference between the selling price and direct attributable costs) from total sales of the whole product range. The pricing problems for pharmaceutical products would be much reduced if society were satisfied with the drug therapies available. Problems arise from the intensity of research and the intentional division of labor. Research means that people have to pay today for research expenses which may bring better drug therapies tomorrow. As long as society is ready to pay higher prices for new and better drug therapies this allocation process can and must remain privately organized.

The consequences of this cost structure are that the manufacturer cannot use the cost-plus approach for a single product price = direct costs + overhead costs + profit margin. The research-based company's approach to pricing has therefore to be market-oriented. The manufacturer compares the benefits of his products (higher safety, fewer side-effects, higher efficacy, better patient compliance, etc.) with those of the drug therapies already on the market. The greater his additional benefits are, the higher he can price his products above the already marketed drug therapies—but he does not necessarily do so.

The activities of research-based pharmaceutical companies cover, besides other industrial functions, the following: production of new knowl-

edge (by research and development); the diffusion of new knowledge (by medical information and marketing); the manufacture of physical goods. The typical cost structure for research-based and non-research-based companies is shown in Table 8-3. The research-intensive companies can allocate directly to an individual product only a small fraction of their costs.

In *competition-based pricing*, the firm uses competitors' prices rather than demand or cost considerations as its primary guideposts. With this approach, the company may not respond to changes in demand or costs unless they have an effect on competitors' prices. A company may set prices below the market, at the market, or above the market, depending on its customers, image, overall marketing mix, consumer loyalty, and other factors.

Competition-based pricing is popular for several reasons. It is simple, with no calculations of demand curves, price elasticity, or costs per unit. The ongoing market price level is assumed to be fair for both consumers and companies.

Established Products

Strategy must continue over the life of a drug product. The product, over time, is likely to face competition from similar or generic products, from differing but therapeutically similar products, or face price pressure from other quarters. The strategic choices are three: maintain the price, lower the price, raise the prices.

TABLE 8-3. Cost structure of research-based vs. imitator firms

Cost Category	Per Cent of Sales	
	Innovator	Imitator
Production Costs:		
Direct and Indirect	30	30
Miscellaneous Costs	25	25
Profit Before Taxes	15	10
Research and Development	15	0
Scientific Information	15	15
Margin for Price Cuts	0	35
TOTAL	100	100

Source: Adapted from St. O. Slatter, *Competition and Marketing Strategies in the Pharmaceutical Industry*, Croom Helm, 1977.

Price maintenance is likely to be related if the market segment from which the largest portion of sales is drawn is not likely to be affected by competition or other factors *and* if the pricing objectives are being met.

Reducing prices may be a defensive measure (to meet, for example, generic competition), an offensive strategy (especially as costs decline and greater market share may be obtained at less cost), or dictated by market forces.

An increase in price may be sought for various reasons. First, in an inflationary economy, prices may have to be adjusted upward in order to maintain profitability. During inflation all types of costs go up, and to maintain profits at an adequate level, increase in price becomes necessary. How much the price should be increased is a matter of strategy that varies from case to case. Conceptually, however, price should be increased to such a level that the profits before and after inflation are approximately equal. The increase in price should also take into account any decline in revenue caused by shift in demand due to the price increase. Strategically, the decision should be based on the long-term implication of short-run cost increases. This indicates that in monopolistic situations, strategically, the price of a brand may be set high to increase revenues. In the 1980's a pattern has emerged wherein the owner of a patented, successful prescription drug will increase prices prior to expected generic competition, presumably to take economic advantage of its remaining "monopoly."

Making Price Adjustments

After a price strategy is implemented, it usually requires continuous fine tuning to reflect changes in cost, competitive conditions, and demand considerations. Prices can be adjusted through changes in list prices, added markups, markdowns, and rebates. It is important that price be used as an adaptive mechanism. Recently, some firms have successfully adopted strategies to reduce the impact of price in an otherwise price-driven market.

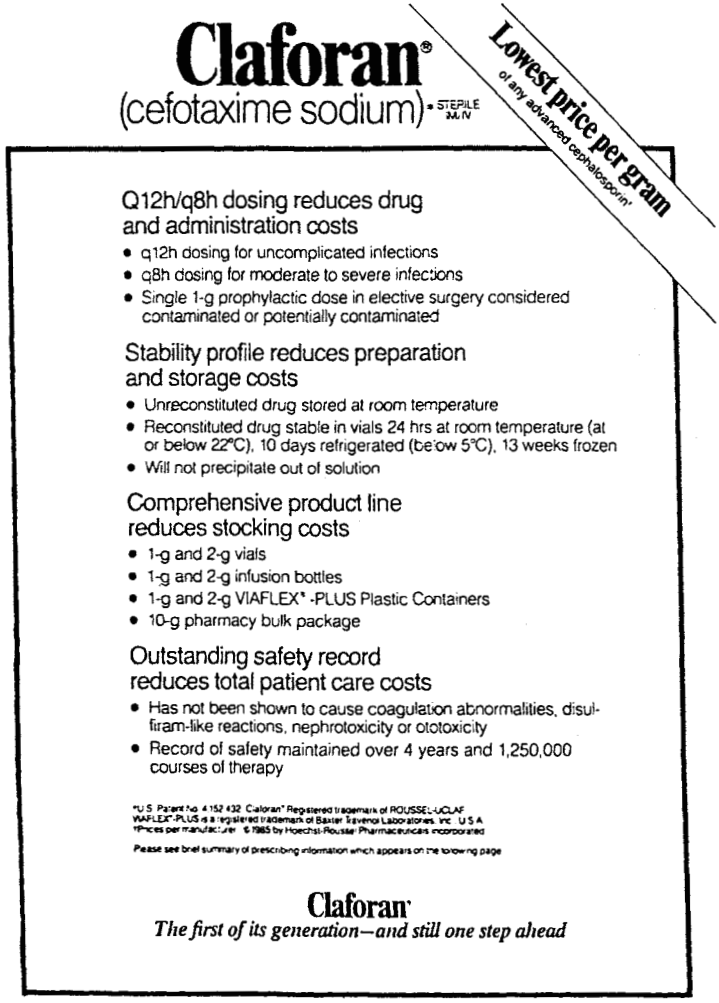
When it is not desirable and/or possible to fight price competition with strategic price changes (decreases), companies can employ other measures. One general example is the shift from price to cost in discussing the economic aspects of a product.

Cost can be described as: cost per day, cost per course of treatment, annual cost. Cost of drug therapy can be compared (always favorably) with the alternative cost of surgery as was done to good effect by SmithKline on behalf of Tagamet.

Cost can also be analyzed in terms of its direct and indirect components. An example is the claim that Hoechst's Claforan, which may directly cost more per patient day than do some of its competitors, is really

less costly when one considers the indirect costs avoided because of its lower incidence of side effects (see Figure 8-2). Similarly, several companies have compared the average length of stay (ALOS) in hospital for their product versus that of a competitor, showing a reduction of costly hospitalization.

FIGURE 8-2



CASES IN POINT

Merck Price Strategy

If another round of drug price hearings takes place on Capitol Hill this summer, it can be expected to reflect the major pricing strategy changes taking place in the industry. This column addresses two indicators of those changes: Merck's apparent strategy vis-à-vis Vasotec and an overview of strategy moves indicated by early 1986 price changes.

This is probably the first time that a major pharmaceutical company has introduced a product at a price substantially lower than that for an existing comparable—or superior, depending upon one's point of view—competitive product. Merck's Vasotec strategy seems to aim to use price as a means to gain as much market share as possible. The market share and price of a product will play a pivotal role in determining whether it is selected for the first formularies. That was illustrated when Tagamet was selected as the only product in its class for the California MediCal formulary.

Merck's rationale may be seen as proceeding along the following lines. First, as is well known, Merck has raised prices on virtually all of its pharmaceutical products by an average of 10 percent, up from its average 8 percent 1985 increase. In effect, it appears that Merck has decided to milk its existing generic and nongeneric product line—with the exception of Timoptic, which has also begun to face price competition from other companies—for all it's worth. If this assessment is correct, then Merck's pricing strategy with Vasotec becomes all the more clear: that is, to remove all potential barriers to the use of a new patented product in order to capture as much market share as possible.

It seems likely that Merck's sales force will use a direct marketing program to physicians that emphasizes using ACE inhibitors as a single-source therapy for hypertension. It also is likely that most physicians will find the argument therapeutically sound. In fact, their only objection might be price; physicians might prefer to use lower priced beta blockers instead of the "more expensive" new products. With Vasotec's price at a level comparable to that of the 50 mg strength of Tenormin, the Merck sales presentation can reassure physicians that Vasotec's price is comparable to that for beta blockers and thus there is no pricing barrier. Perhaps more important, the Merck presentation would also stress that, although Capoten is a good drug, Vasotec offers the convenience of once-a-day dosing at a price 20 percent lower than Capoten's. This would translate into estimated retail consumer savings of $4.50 to $5 per month. Assuming that one daily 10 mg dose of Vasotec is equivalent in efficacy to

two daily 25 mg doses of Capoten. Merck has a compelling argument for using Vasotec rather than Capoten.

What remains unknown is the price elasticity of demand for patented antihypertensive products. The developing marketing battle will provide some indication of the answer to this question. In a broader context, it clearly signals the beginning of a major change in pharmaceutical industry marketing practices.

Traditionally, new products have been introduced at a premium price – especially those that offer a therapeutic advantage over existing products. This is the first time a major company has introduced a better product at a price lower than that for existing therapy. There can be no doubt that Merck is intentionally using price as a marketing tool to capture market share. The company's success in achieving this end will determine whether Squibb cuts the price of Capoten and Capozide.

Five years ago, most physicians had never heard the words, "cost control." Today, many physicians have become cost conscious, and they have begun to pay attention to price as a factor when prescribing. Whether they will respond in this instance is unknown, but the risks seem great enough to make it prudent to remove Squibb stock from the recommended list. Squibb's shares are selling at about 16 times the 1986 estimate of $5.20 and are at virtually an all-time high.

It is assumed that the 5 and 10 mg strengths of Vasotec will capture more than 70 percent of Vasotec's new prescriptions and that the 20 mg strength will be used for moderate to severe hypertension and eventually, when approved for the indication, for congestive heart failure.

Source: John Curran in *Pharmaceutical Executive*, April, 1986.

Price Increases in Anticipation of Generic Competition

Initial analysis suggests a significant correlation between pricing strategies and the rate of generic penetration observed in recent years. Most products facing generic entry in the last five years followed a pattern of price increases of 8 to 15 percent or more annually in the period prior to generic entry. Older products facing initial generic competition in the middle to late 1970s had more moderate price increases and experienced lower generic penetration rates. Analyses indicate that under certain conditions more moderate pricing may lead to greater retention of market share than more aggressive price increases. The analyses also indicate, however, that such a strategy may not maximize revenues in all cases. Although high rates of price increase may lead to more rapid generic penetration, the study results suggest that companies in declining markets

may have been optimizing their revenues with aggressive pricing strategies.

Applying the same alternative pricing strategies to products in growing or even stable markets, however, produces quite different results. In these cases, more moderate pricing leads to significantly greater revenues over a longer term than aggressive price increases. Aggressive price increases in such markets result in a premature reduction of the brand's life cycle if generic competitors participate in a growing market.

Subclassifications exist within the basic profiles of products and markets. Consequently, companies need to consider other characteristics, such as the threat of a major new competitive entity, when evaluating a given product in terms of the predictive model. Matching an existing product against the profiles and characteristics developed with the study's analysis can provide pricing, promotional, and related marketing strategies that will help to maximize revenues for the product over the short term or longer term, depending upon a company's objective.

Alternative Pricing Strategies

The following table compares the revenues actually received by a representative pharmaceutical—Product X—with those revenues that would have been received under different pricing and generic-penetration scenarios. Generic entry began in 1985; "adjusted dollars" reflect an annual inflation rate factor of 7 percent. The market for X was already in decline.

Case I: Actual pricing and resultant sales.

Year	*1980*	*1985 (Entry)*	*1986*	*1988 (Estimated)*	*1980-86 (Cumulative)*	*1980-88 (Cumulative)*
Actual Dollars (thousands)	*100,000*	*122,500*	*87,500*	*60,500*	*724,000*	*857,000*
Adjusted Dollars (thousands)	*100,000*	*85,200*	*56,600*	*34,000*	*586,000*	*663,000*
Indexed Units (percent)	*100.00*	*55.73*	*35.15*	*18.38*		
Indexed Price per Unit (1980=100)	*100.00*	*219.53*	*248.63*	*328.82*		

Case II: Five percent annual price increases in five years before entry, market share loss reduced to 5.5 percent annually, generic entry reduced to half of actual (Case I) level.

Year	*1980*	*1985 (Entry)*	*1986*	*1988 (Estimated)*	*1980-86 (Cumulative)*	*1980-88 (Cumulative)*
Actual Dollars (thousands)	*100,000*	*91,800*	*83,900*	*69,100*	*668,000*	*812,000*
Adjusted Dollars (thousands)	*100,000*	*63,900*	*54,300*	*38,700*	*547,000*	*631,000*

Indexed Units (percent)	*100.00*	*71.97*	*62.62*	*46.77*
Indexed Price per Unit (1980=100)	*100.00*	*127.48*	*133.85*	*147.57*

Case III: No price increases in five years before entry, no market share loss, no generic penetration.

Year	*1980*	*1985 (Entry)*	*1986*	*1988 (Estimated)*	*1980-86 (Cumulative)*	*1980-88 (Cumulative)*
Actual Dollars (thousands)	*100,000*	*100,000*	*100,000*	*100,000*	*700,000*	*900,000*
Adjusted Dollars (thousands)	*100,000*	*69,600*	*64,700*	*56,000*	*569,000*	*685,000*
Indexed Units (percent)	*100.00*	*100.00*	*100.00*	*100.00*		
Indexed Price per Unit (1980=100)	*100.00*	*100.00*	*100.00*	*100.00*		

Source: Frank H. McKim and Paula C. Cramer in *Pharmaceutical Executive*, December, 1987.

FACTORS INFLUENCING PRICE STRATEGY

Demand

In theory, a firm can realize considerably enhanced revenues through price increases of products with relatively inelastic demand schedule. That same theory would suggest that prescription drugs should demonstrate inelasticity. Inelasticity depends, however, not only on the need felt by the consumer for the product, but also by the availability of substitutes. In the pharmaceutical industry, with the aid of outside influences, substitution has been institutionalized. (Even in the case of truly lifesaving therapy, total inelasticity does not seem to apply, as Genentech learned with TPA and Burroughs Wellcome found with retrovir.)

Elasticity of demand is a term frequently used to indicate the effect of price changes on the quantity demanded of a given commodity. The proportionality of the change is the means used to measure elasticity. As many as five classifications are used to describe various degrees of elasticity:

1. Perfectly elastic demand;
2. Elastic demand;
3. Unit elasticity of demand;
4. Inelastic demand;
5. Perfectly inelastic demand.

The most frequently encountered states are the elastic and inelastic in which price changes result in, respectively, greater than and less than proportionate changes in the quantity demanded. Unit elasticity represents exactly proportionate changes in quantity demanded corresponding with changes in price. Perfect elasticity is the situation in which any price change would result in an infinite change in the quantity demanded, while perfect inelasticity reflects the situation in which changes in price have no effect on quantity demanded.

It is possible to find potential situations in the prescription drug industry in which each type of elasticity might exist. The most frequent case, however, at least under present drug marketing conditions, would be that of inelasticity. Changes in price on prescription drugs do not normally result in proportionate inverse changes in the quantity demanded. During the course of rapid rise in price of quinidine some years ago, for example, there was little change in the number of units sold. The principal reason for the inelasticity of demand is the nature of the product itself. Prescription drugs are necessary to health, and within reasonable limits, will be purchased in spite of price rises. Further, there is little utility in purchasing more of a drug than is needed regardless of how low the price sinks.

Besides the nature of the product at least two other factors contribute to the price inelasticity. The physician's role as the decision maker in the choice of prescription drugs tends to make price a secondary consideration. Also the efforts of the pharmaceutical industry toward product differentiation, either through promotion or actual product changes, reduce the importance of price as a consideration in drug choice and consequently the elasticity of demand.

Probably the least likely type of elasticity to be found within the drug market would be perfect elasticity. It is highly improbable that any situation would exist in which any price change, either up or down, would affect the quantity demanded so dramatically. The main exception to this—and it is a major one —is in those market situations where products are completely interchangeable and purchased entirely on the basis of price. A company that loses a bid for a hospital's business has found itself in a totally price elastic situation.

Perfect inelasticity is possible within the industry, however, particularly when we consider the demand schedule for a single product. Given a product, the only one of its kind effective in life-threatening situations, it is highly unlikely that routine changes in price would have any effect on the quantity sold.

The case of elasticity of demand is infrequently encountered in the

pharmaceutical industry except in cases of products which are good substitutes for each other, and whose substitutability is well known to those who make the drug choice. Again, promotional and product development efforts are often aimed at minimizing this substitutability.

One characteristic of the market for prescription drugs which should be mentioned here is the influence of third-party payment on the nature of demand. It is possible to project considerable differences in the behavior of demand for product classes compared with individual products sold on a brand-name basis. It might be expected that the product class (e.g., antibiotics) would continue to exhibit a relatively inelastic demand schedule. The individual products might have quite elastic demand schedules, however, depending upon effectiveness of efforts to induce physicians to prescribe drugs by generic name.

Interestingly enough, federal and state programs to supply prescription drugs to certain groups of patients have almost completely opposite effects on the elasticity of demand for prescription drugs as a total class and the demand for individual, easily substitutable drugs. When one knows that a third party will foot the bill, cost considerations ("Should I see the doctor, or try to get something at the drug store?") become less important. Hence, the total demand for drugs by the groups affected will probably increase with less elasticity. In efforts to offset the effects of this increase, third-party payers have begun to build-in price elasticity by product in an effort to bring these prices down.

According to Weston (in Robert I. Chien, *Issues in Pharmaceutical Economics*, D. C. Health Publishers, Lexington, MA, 1979):

> A meaningful discussion of prices and pricing requires that the nature of prices be recognized. Prices of all products, but especially drug products, have a number of dimensions. The main dimensions of drug product prices are the following:
>
> | | | |
> |---|---|---|
> | "Quality" | = | efficacy + safety + clinical evidence + experience + information communicated to doctors and other professionals + reputation of manufacturer based on performance of prior products |
> | Nominal price | = | price to wholesaler − discounts to wholesaler − discounts and rebates to hospital or other distribution outlets |
> | (Actual) price | = | nominal price quality |

To understand the degree of price competition in the drug industry, it is necessary to view it within a dynamic framework. At a given point in time, prices are high in relation to their marginal costs. However, over time different forms of price competition emerge. Close substitutes enter markets, not protected by patents, and prices begin to decline. In other cases, improvements occur in competing drugs that sell for similar prices as existing drugs; hence, their quality-adjusted prices decline. Over time both the number and closeness of substitutes within a therapeutic market increase. As this occurs, the price elasticity of demand for each of the drugs increases, and prices begin to decline. There is thus a life cycle to therapeutic markets.

Drugs that are considered to be major innovations (i.e., to have large therapeutic gains and not having any close substitutes), can obtain a high market share despite a high relative price. However, drugs that are considered to be minor innovations are more likely to be introduced at low prices relative to other drugs in that market. Such pricing strategies are consistent with pricing according to the perceived elasticity of demand for that drug. The closer the substitutes (the case of a minor innovation), the greater the price elasticity of demand, hence, the lower the price to obtain a share of the market.

CASE IN POINT

Determining Price Elasticity

David A. Luery of Total Research Corporation has described the kinds of questions to be asked in determining price elasticities leading to price strategy moves.

PRICE ELASTICITY RESEARCH OBJECTIVES

Objective #1 Accurate Knowledge of Brand Self-Elasticities:

- *How will the sales of my product change as its price increases or decreases?*

  - *Just how price elastic is my product? Does a 10% price increase result in a 10% loss in unit sales? A 5% loss? A 15% loss? Or even a gain?*

- *How does my price elasticity change as I move along my price curve? Do I have particular "threshold points" (i.e., points of rapid change in elasticity) in my pricing curve of which I should be aware?*

- *How price elastic are the sales of my competitors' brands?*

Objective #2 Accurate Knowledge of Brand Cross-Elasticities:

- *How do the prices of my competitors affect the demand for my product?*

  - *Which competitors have the capability to really hurt me with price decreases? Which competitors can help me by raising their prices?*

  - *Which competitive pricing actions can I basically ignore, not worry about responding to?*

- *How do my prices affect the demand for the products of my competitors?*

Objective #3 Accurate Knowledge of Within-Brand Elasticities:

- *Within my own product line, which entries*

  - *Are relatively price elastic? These products will tend to flourish if I lower their prices; to flounder if I raise their prices.*

  - *Are relatively price inelastic? These products are candidates for larger price increases.*

- *How cross-elastic are the elements of my product line?*

Objective #4 Market Simulation:

- *In short, what will the unit sales for my brand(s) and my competitors' be under any conceivable pricing situation?*

Objective #5 Optimization:

- *Of all the pricing strategies that are within my command, which one will have the most favorable effect on my primary financial objectives (e.g., revenue, profitability)?*

Whose Price Sensitivity?

For ethical pharmaceutical studies, you will typically measure physicians' sensitivity to price:

- *How does price affect physicians' prescribing behavior?*

However, if use of the product category is largely consumer/patient driven for example, products whose effects are primarily cosmetic, patients' price sensitivity should be measured in addition to—or instead of—physicians' sensitivity.

- *How does price affect patients' likelihood of requesting a physician to initiate/or terminate therapy?*

If usage of the product category is primarily hospital based, it is necessary to measure prescribing physicians'' sensitivity and the sensitivity of key formulary committee members, typically the chief pharmacist or director of pharmacy.

Costs

Fixed and variable costs are the major concerns of a pricer. In addition, the pricer may sometimes have to consider other types of costs, such as out-of-pocket costs, incremental costs, opportunity costs, controllable costs, and replacement costs.

To study the impact of costs on pricing strategy, the following three relationships may be considered: (1) the ratio of fixed costs to variable costs, (2) the economies of scale available to a firm, and (3) the cost structure of a firm vis-à-vis competitors. If the fixed costs of a company in comparison with variable costs form a high proportion of its total costs, adding sales volume will be a great help in increasing earnings.

If the economies of scale obtainable from a company's operations are substantial, one should plan to expand market share and, in considering long-term prices, take expected declines in costs into account. Alternatively, if the experience is expected to produce a decline in costs, then prices may be lowered in the long run to gain higher market share.

If a manufacturer is a low-cost producer relative to competitors, it will earn additional profits by maintaining prices at competitive levels. The additional profits can be used to promote the product aggressively and increase the overall perspective of the business. If, however, the costs of a manufacturer are high compared to those of competitors, the manufacturer

is in no position to reduce prices since this may lead to a price war which it is bound to lose.

It is important to add that research and development costs must be recovered through the pricing strategy.

Competitors

As noted above, pricing based on the prices of the competition is comparatively simple. Once it is decided, whether the policy is to price higher, lower or the same as that of the relevant competition, the procedure is to monitor those prices and act accordingly.

The firm with a large market share will be in a position to initiate price changes without worrying about competitors' reactions. Presumably, a competitor with a large market share will have the lowest costs. The firm can, therefore, keep its prices low, thus discouraging other members of the industry from adding capacity and further improving its cost advantage in a growing market.

If a firm operates in a market where there are opportunities for product differentiation, it can have some control over pricing even if the size of the firm is small and there are many competitors in the industry. This may occur if one brand is considered to be different from other competing brands; whether the difference is real or imaginary, prescribers will not object to a higher price for their preferred brand. To establish product differentiation of their brand in the minds of prescribers, companies spend heavily for promotion. Product differentiation, however, offers an opportunity to control prices only within a certain range.

In an industry which is easy to enter, the price setter has less discretion in establishing prices; if barriers to market entry exist, however, the firm already in the industry will have greater control over prices. Barriers to entry may take any of the following forms:

1. Patents
2. Capital investment
3. Technological requirements
4. Nonavailability of essential materials
5. Economies of scale which existing firms are enjoying and which would be difficult for a newcomer to achieve
6. Marketing expertise

CASE IN POINT

Tylenol vs. Datril

What happened on Migraine Mountain documents the critical importance of timing. If you want to cover, you have to do it right away. If you wait, it may be too late.

The brand is Tylenol, an acetaminophen product marketed by Johnson & Johnson's McNeil Laboratories. Priced 50 percent higher than aspirin and promoted mainly to physicians and other health care specialists, Tylenol was headed up the sales charts.

The people at Bristol-Myers thought they saw an opportunity. So, in June 1975, Bristol-Myers introduced Datril with the "same pain reliever, same safety as Tylenol."

The difference is the price, said Datril ads which quoted $2.85 as the price of 100 Tylenol tablets and $1.85 for Datril.

One of Bristol-Myers' mistakes was to market-test the idea in its traditional test markets, Albany and Peoria.

Two weeks before the Datril advertising broke, Johnson & Johnson notified Bristol-Myers that it was cutting Tylenol's price to match Datril. Furthermore, Johnson & Johnson also issued credit memorandums to reduce prices on existing stocks in stores.

Hard-headed Bristol-Myers launched their attack anyway. They even advanced the break date of the television commercials so that they ran the day after they were notified of the Tylenol price reduction, apparently figuring it would take days for the price change to filter down to all the nation's 165,000 retail outlets.

Johnson & Johnson complained to the networks, the magazines, the Proprietary Association, and the Council of Better Business Bureaus.

The networks asked for copy changes. In the first revision, the "dollar lower" price was changed to "Datril can cost less, a lot less." Another protest from Johnson & Johnson brought deletion of "a lot less." Finally, both CBS and NBC refused to run the Datril spots at all, a bitter pill for Bristol-Myers to swallow.

The Johnson & Johnson response worked perfectly. Datril never achieved more than a 1 percent market share.

Tylenol, on the other hand, took off like a rocket. The momentum created by Tylenol's response lifted the brand to the top.

Partly because of the lower price and partly because of the publicity, Tylenol found itself on top of the analgesic market, reaching a high of 37

percent. At one point, Tylenol outsold Anacin, Bufferin, and Bayer combined.

Source: Al Ries and Jack Trout, *Marketing Warfare*, McGraw-Hill, 1986.

Channel Members

Each channel member seeks to play a significant role in setting prices in order to build sales volume, obtain adequate profit margins, establish a suitable image, obtain repeat purchases, and meet specific goals.

There often are conflicts among manufacturers, wholesalers, and retailers regarding price policies. The manufacturer wants to cover production costs and make a profit, establish a brand image, and have input into final selling prices. The wholesaler wants to cover selling costs and make a profit, be competitive with other wholesalers, and have input into final selling prices. Wholesale prices are based on the costs, goals, and strengths of individual wholesalers. The retailer wants to cover selling costs and make a profit, be competitive with other retailers, and control final selling prices. It sets prices based on objectives, method of operations, and cost considerations.

The impact of price increases on channel-member behavior should be evaluated. Usually, when manufacturers raise prices to channel members, the increases are passed along to final consumers. Of course, this is not always possible, especially if third-party reimbursement policies are a factor. (See Case in Point.)

To understand the reason behind drug manufacturers' willingness to engage price competition, it becomes necessary to reexamine the prescribing habits of physicians and the role of pharmacists. Apparently, drug manufacturers assume that at least some physicians are price conscious when they prescribe for their patients and that some pharmacists are willing to act as the patient's agent. This behavior among physicians and pharmacists will serve to increase price competition among drug firms. Pharmacists will use a low-priced drug rather than the original brand to fill a generic prescription. This is not universally true, but the proportion of generic prescriptions filled with low-priced drugs is much higher than the proportion of prescriptions that specify a brand accounted for by the low-priced brands. Substitution occurs. The pharmacist, in effect, acts as a price agent for the consumer.

Retail pharmacy has also fought and won battles to restrict the differential pricing practices of manufacturers to hospitals vs. retailers. This was accomplished through appeal to the Robinson-Patman Act.

The Robinson-Patman Act prohibits manufacturers and wholesalers from price discrimination in dealing with different channel-member purchasers of products of "like quality" if the effect of such discrimination is to injure competition. Covered by the Robinson-Patman Act are prices, discounts, rebates, premiums, guarantees, delivery, warehousing, and credit terms. Terms and conditions of sale must be made available to all competing channel members on a proportionately equal basis.

The Robinson-Patman Act was enacted in 1936 in order to protect small retailers from unfair price competition from large chains. It was feared that small retailers would be driven out of business due to the superior bargaining power of large chains with product suppliers. The Robinson-Patman Act required price differences to be limited to a manufacturer's cost savings in dealing with different retailers. The Robinson-Patman Act remains a major legal restriction on pricing.

Wholesalers, too, have exercised their channel influence. Hospitals have traditionally purchased directly from manufacturers because manufacturers were frequently willing to give hospitals a better price in return for contracts and exposure to physicians. In fact, differential pricing to hospitals was often seen as a marketing expense and sometimes treated as such.

With cost containment pressures, however, hospitals seem more willing to change their sources of purchases to wholesalers. Many hospitals feel that, although the purchase price might be slightly higher from a drug wholesaler, the actual cost is less because of reduced inventory levels—especially with the cost of holding inventory at 18 to 30 percent per year. Additionally, direct purchase administrative costs, including inventory, paperwork, and cost of physical space, are hidden expenses that may also justify purchase at a higher cost from the drug wholesaler, depending upon time and circumstances.

Many drug wholesalers now actively pursue the hospital market by using the same service approach used effectively with retailers—e.g., direct electronic order entry, management and inventory reports, and help in servicing manufacturers' bids and reduction of inventory.

CASE IN POINT

Price Policies Under Medicare

The drug industry's preference for instituting price increases at the beginning of the calendar year should be reexamined in the wake of the reimbursement pricing schemes of the Medicare outpatient drug benefit,

Purdue professor Stephen Schondelmeyer, PhD, observed during the planning of the program.

Noting that the Catastrophic Health Care bill called for price updating every six months, Schondelmeyer pointed out that schedule set up a de facto price freeze of at least six months, and possibly longer.

Although pharmacists "ostensibly" would be receiving reimbursement based on current median AWPs (published average wholesale prices), the prices would actually be AWPs from six months ago at best. The prices could be as out-of-date at 12 to 18 months.

Prices determined as of January 1, 1991 would go into effect in the reimbursement calculation on July 1 of that year. Thus, the pharmacy payments could lag the current published AWPs by six to 12 months. If the Health Care Financing Administration (HCFA) used surveys of usual and customary charges from the preceding six months to make its January 1 determinations, the pricing from July through December could be as far out of date as 18 months.

Being out of date on a single-source product by eight or nine months can mean pharmacies would be getting an AWP price between 7%-10% below the currently published price.

The price lag problem could be compounded if HCFA used survey data of usual and customary charges as its primary determinant of reimbursement levels. HCFA is required to use a "lowest of" payment procedure which could bring usual and customary payments into play.

Buyers

It is important to note that price/cost means different things to the various targets of pharmaceutical industry activity. The ultimate consumer frequently does not pay out-of-pocket for his/her prescription. The prescribing physician, it has been demonstrated, often does not know the relative prices of the drug product alternatives from which he/she chooses (Indeed, there have been major efforts to improve the physician's knowledge base and to assist him/her in making the best choice.)

Perhaps most interested in the drug price/cost issues are those institutions and agencies which pay for the medicines: hospitals, HMO's, and Medicaid, now Medicare.

Hospital purchasing in the past 10 years has rapidly shifted to a system of bid solicitation and group purchasing. The crisis in cost containment is again focusing on the costs of drugs and how drugs are purchased. Although figures are not provided, results of a survey by the Government Accounting Office suggested that changes in purchasing with emphasis on group purchasing could save significant amounts in health-care costs. One

example described a hospital that saved over $7,000 using group purchasing. An American Society of Hospital Pharmacists drug purchase survey showed that nearly 80 percent of the respondents were participants in a hospital purchasing group. Nearly 60 percent of the respondents expected the number of drug products used in their hospitals to decrease in the subsequent five years.

All hospital purchasing groups utilize bid solicitation to obtain competitive and favorable prices. Research has also shown that group purchasing has potential problems in that it requires better planning, more cooperation and information sharing, longer lead times, the determination not to sell out to a drug wholesaler who underbids to prevent the formation of a group, and individual hospital commitments not to purchase later from manufacturers who have lost a bid (a practice commonly known as "backdooring"). Many hospitals also participate in more than one group. This multiple-group participation presents a major dilemma for the pharmaceutical company, because estimated annual usages are frequently included in more than one bid solicitation. Although pharmaceutical marketers continue to tolerate this practice, it defeats the contractual implication of the bid solicitation and award process.

The hospital pharmacist has largely maintained control of drug purchasing. Because of the technical considerations of drug selection and purchasing, the purchasing agent has not assumed this role. This fact reinforces the importance of having a good business relationship between the purchasing pharmacist and the pharmaceutical sales representative. Without it, the chance of sales success in the hospital market is limited.

Due to the increased multisource availability of most frequently used drugs, pricing to hospitals has become increasingly competitive. As late as 1965, many hospitals were paying full retail price for most drugs purchased. Cost containment pressures and the advent of formularies and group purchasing have brought about radical changes in prices paid by hospitals for pharmaceutical products.

Prices offered to bid solicitations (individual hospitals or hospital groups) are usually based on such factors as estimated annual use and individual shipment quantity. Manufacturers have also been willing to price products at a lower level to teaching hospitals. The intent here is to acquaint new physicians with their drugs, with a view to cultivating future prescribing habits. Teaching hospital purchases are also generally greater than those of nonteaching hospitals.

Pharmaceutical marketers have also recognized that, in many cases, when a patient is given an oral drug in the hospital, that same medication will be continued at retail prices when the patient is discharged. Although audits have not been made to measure this retail spill-out, some estimates

have placed it as being more equal to hospital purchases of certain therapeutic classes of oral drugs. In the case of oral antihypertensives, a hospital patient start will frequently generate drug store refills for the rest of the life of the patient.

It is well to be reminded that the consumers of medication are not necessarily the buyers of that medication. Indeed, by the mid-1980's the proportion of prescription drugs paid for by a third party exceeded 50 percent. Those third parties, of course, have a great interest in and increasing influence on the prices of prescription medications.

In some cases of third-party purchasing of medications it has been possible to introduce economic principles to price discussions that would not be possible in dealings with a single paying consumer. Most of the concepts which will be mentioned are based on drug purchases as an investment—an investment in the health of the members or clients of the third-party organization.

One of the pharmaceutical industry's leading economists has provided an excellent overview of the nature of and relationships between various measures of drug "value" (*Drug Information Journal*, 1988, No. 3).

> In the Healthcare literature today, we encounter not only cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA), but also cost-utility analysis (CUA). When combined with survival data, utility values allow the researcher to estimate the number of life years gained weighted by their qualities of the "quality-adjusted life years" (QALY). . . .
>
> From the U.S. perspective, the growth of managed healthcare systems—those in which attempts are made to control costs by utilization review—has created an increasing demand for data to compare the "value for money" offered by different drugs in the same class. To gain acceptance into a formulary with a competitive price, a drug must be shown to be "cost-effective"; that is, when compared to a competitor, it can either reduce direct treatment costs and/or reduce indirect economic costs associated with lost productivity and/or improve patients' QOL. It should be pointed out that although healthcare providers (e.g., HMOs, PPOs, hospitals) and payers (e.g., Medicaid, employers) are most receptive to direct treatment cost-savings and QOL improvement are also well received because they are important to employers who want to keep their employees healthy and in the work force. Increasingly, patients themselves would also be interested in the effects of a drug on their quality of life. Although it is true that patients' current level of awareness may be low, companies' desire to bring the message directly to patients

has been expressed. When companies and the Food and Drug Administration come to some resolution regarding direct-to-consumer advertising in the future, it is very likely that consumer awareness will greatly increase.

To meet the needs of the market, pharmaceutical companies can rely on the techniques of CBA, CEA/CUA, or QOL assessments (see Table 8-4). . . .

Cost effectiveness evidence is likely to emerge as the driving force behind pharmaceutical competition in the future. If a new drug can be supported with cost effectiveness evidence, it can justify a high price and a leading market position. Otherwise, its viability in the market may be questionable unless it is competitively priced.

Government

The importance of the government in pricing decisions for pharmaceuticals is three-fold. There is the routine interest in price fixing and price discrimination which may affect any industry. In addition, the government is a major and growing purchaser of pharmaceuticals. Finally, the prices of health-related goods make great political material and the drug industry in the U.S., for example, has been the subject of price investigations by the Congress almost unremittingly, since the mid-1950's.

An illuminating example of government effects, both overt and subtle, on industry pricing is the relationship of the Waxman-Hatch Act and the Catastrophic Drug (Medicare Outpatient) Bill.

The thread of continuity tying the Waxman-Hatch law to the catastrophic coverage drug provision was Rep. Waxman, the cosponsor of the patent restoration/ANDA law, and one of the architects of the Medicare outpatient drug legislation. Over the past decade, Waxman has become the most important legislator on Capitol Hill on matters relating to FDA and the drug industry. As chairman of the House Energy and Commerce Committee Health Subcommittee, Waxman had jurisdiction on all health-related legislative matters coming through the House of Representatives.

Waxman has used his position to gain a thorough knowledge of the drug industry. His legislative initiatives in the drug area included the patent restoration/ANDA bill that bears his name, the Orphan Drug Act, and the drug export law. In oversight hearings, he also kept a close watch on FDA operations and developed a firm understanding of the agency's complex regulatory mechanism.

Waxman championed the interests of the generic segment of the U.S. drug industry, maintaining that American consumers of prescription drugs

TABLE 8-4. Price, cost, and benefit considerations

Differences Between CBA, CEA, and QOL

	CBA	CEA/CUA	QOL
Measurement of benefits of a drug	Money saved	Increased life years or QALYs	Improved quality of life
Measurement of costs associated with a drug	Money spent	Money spent	N/A
Net measurement	Cost-benefit ratio	Cost per live year saved	N/A
	Net benefit	Cost per QALY saved Net benefit	

Relationship Between Product Characteristic and Cost or Benefit Components

Product characteristics	Associated cost or benefit components
The drug	Its price
Efficacy	Treatment cost of condition
If works	Savings on cost otherwise incurred; improved quality of life
If fails	Additional cost due to treatment failure
Safety/side effects	Cost of treating side effects; patients' quality of life; cost associated with noncompliance
Dosage form	Cost of administration re IV, IM; cost re noncompliance
Dosing regimen	Cost of administration re IV, IM; cost re noncompliance
Delivery system	Cost of administration; cost re noncompliance
Legal status	Controlled substances require additional cost of administration
Indication	Nature of illness involves either mortality, lost productivity, or quality-of-life effects

Source: Thi Dao, *Drug Information Journal*, 1988(3).

benefit from a competitive generic industry. To the brand name segment of the drug industry he often appeared to be openly antagonistic.

In Waxman's activities involving the brand name drug industry, drug prices and the cost of pharmaceuticals to consumers consistently were his primary focus of attention. As indicated by the official title, Waxman's main objective in sponsoring the Drug Price Competition and Patent Term Restoration Act was to reduce the cost of pharmaceuticals to consumers

by making more low cost generic drugs available. After enactment of the law, Waxman followed up on the drug price issue in two major hearings, one in 1985 and the second in the spring of 1987, as the catastrophic care legislation was moving through the House.

In both of the hearings, Waxman asked Pharmaceutical Manufacturers Association (PMA) spokesmen and representatives of individual brand name companies to explain why pharmaceutical price increases were continuing at record high rates. The response from the industry on both occasions was the same: the price increases were necessary if industry is to continue funding research programs to discover medically important new drugs. At the 1987 hearing, for example, PMA President Mossinghoff told Waxman that the cost of bringing a new chemical entity to the market had reached $125 million, and that research and development costs were continuing to rise.

Another cause of continuing high rates of drug price increases paradoxically can be traced to the Waxman-Hatch law itself. The legislation achieved its primary goal of dramatically expanding the pool of multiple source drugs, reducing cost to consumers through generic substitution. The price competition, however, had secondary effect of putting sudden, intense pressure on the revenue streams of many research-based companies.

Faced with precipitous declines in market share because of generic price competition, those companies tended to respond in kind: where possible they raised prices to try to maintain revenues. For example, as a single source product neared the end of its patent term a company would sharply increase the price and keep it high, even after the patent expired, relying on sales and marketing to sustain volume. Prices of single source drugs with significant patent life remaining were also routinely raised to compensate for the actual or expected loss of revenue on a drug coming off patent. The defensive price increases may have offset the price reductions achieved through the competition introduced by the Waxman-Hatch law.

Given his continued involvement in drug price issues, it was no surprise that in 1987, as the catastrophic coverage bill began to gain momentum, Waxman stepped forward as a leader in the effort to add an outpatient drug benefit provision to the legislation. The law provided both an opportunity to extend drug benefits to the elderly, and a new approach to the drug price question.

Waxman saw a possible connection between a catastrophic coverage initiative and the addition of an outpatient drug benefit.

Some estimates suggested that the government would become the purchaser of as much as 30 percent of all pharmaceuticals in the U.S. With

that buying power, the government has the leverage to change the structure of the drug industry in the same way that the hospital and medical products industries were changed by the implementation of the prospective pay system.

The Pharmaceutical Manufacturer's Association, representing brand name drug companies, was put in a difficult position. The drug benefit was supported in Congress because of its popularity with the elderly, and to oppose the law would create an image problem for the industry. The law was also good for business, at least in the short run, because it would result in a significant expansion of the market for prescription drugs.

On the other hand, PMA recognized that the new business would be with a single, notoriously difficult customer, the federal government. With the DRG experience still fresh, the association did not want to take any action that could eventually result in government intervention in the workings of the industry.

The procedure for reimbursement of multiple source drugs forms the cornerstone of the Medicare drug benefit, and the program will bring about a market change in the pricing of this class of prescription product.

The basic principle of the Medicare reimbursement system is competition at the retail level among pharmacists, and this competition should be most pronounced in the case of multiple source products. Under the payment limit formula for multiple source drugs, pharmacists will be compensated most liberally when they can obtain inventory at a price below the reimbursement limit for a particular product. In turn, manufacturers of multiple source products are expected to adjust their prices so that their products are attractive to pharmacists working under the payment limitations of the Medicare program.

At the manufacturer level, this should result in a clustering of most supplier prices near the median average wholesale price level with individual suppliers vying to position products a shade below the price of other manufacturers or offering discounts to bring the actual acquisition cost down to or below the median. Many generic suppliers already price their products in this pattern as a result of Medicaid and other third-party programs.

Because of the Medicare reimbursement system and the number of generic suppliers, innovator companies will face again the question of whether to compete on a price basis in order to retain a share of the market. To do so, however, will oblige innovator companies to break with traditional marketing strategy when a product loses patent protection. Conventional wisdom has been to increase prices to maintain dollar volume to compensate for lost market share.

In early 1989 the PMA Newsletter (2/20/89) quoted Waxman on prices.

> "We are in the midst of a new era of prescription drug prices," he said, an era when manufacturers "believe there is no limit on what they can charge." Waxman predicted "continuing rapid price increases."
>
> But the Medicare Catastrophic Act, he said, has brought "a new awareness of drug pricing." Regular reports to Congress will "record" rising costs. Data generated by the new law will supply early warning signals not now available. And "if price hikes persist, there will be prompt congressional action."
>
> The Catastrophic Act drug benefit did not become effective immediately after enactment, he said, to allow "time for mid-course corrections to prevent price hikes later." Congressional "concerns about cost," Waxman predicted, will continue until the drug benefit is fully phased in.

There is often a tendency to underestimate the importance of price in the marketing mix. Many firms simply apply a standard markup to sales anywhere in the world. This may not guarantee the proper flow of funds needed to carry on the other activities that are necessary to bridge the gap between production and consumption. Pricing in the international context is more complex than in the domestic arena because of:

1. a different degree of governmental intervention,
2. a greater diversity of markets,
3. price escalation in exporting, and
4. the changing relative price value of currencies.

According to Klaus von Grebmer, economist for Ciba-Geigy:

> The markets in which drug manufacturers are currently operating may be said to fall into three categories: "free market economies" (criteria: price competition, supply and demand mechanisms), "mixed market economies" (criteria: indirect market control) and "regulated markets" (criteria: state control, cost curbing). . . .
>
> There are three different approaches to interventions which are used either separately or in combination: regulation of the overall consumption; direct or indirect price interventions. The total consumption is controlled in Germany (for example) where any increase in drug consumption is collectively agreed upon at the beginning of the year. If the total consumption is higher than this agreed ceiling,

> physicians are individually advised whether they have over-prescribed in terms of quantities or drugs which are too expensive. With this budget approach, the quantities of drugs as well as their prices are indirectly controlled. This may induce the physician to prescribe the cheaper drugs of the nonresearch-based companies. . . .
>
> The quantities are indirectly controlled in those countries where the state defines, either in a positive way the drugs whose costs are refunded totally or partially by the System (positive lists) or in a negative way those drugs whose costs are not refunded (negative lists). . . .
>
> Another means of influencing the amount of drug consumption is through the introduction of prescription fees for the consumer. This mechanism works only for a short time, either because consumers become accustomed to it or because inflation reduces the real amount of this fee over time.

The U.S. is in many ways behind other countries in the degree of government involvement in drug prices. But changes certainly lie ahead. As one industry consultant (Roger Green, *Medical Marketing and Media*, February, 1991) has observed: "We need to look at our counterparts across the ocean, East and West and wonder: 'How do these people function under government price control?' We are about to find out—through first hand experience."

Green was referring to legislation passed in 1990, the Prudent Pharmaceutical Pruchasing Act, for the purpose of controlling the prices that state Medicaid programs pay for prescription drugs. The legislation *directly* affected 10 to 15 percent of prescription drug sales but indirectly will affect pricing practices on virtually all prescription medications. Certainly major insurers will want to follow the lead of the Congress in seeking rebates for their drug payments, thus greatly increasing the percent of prescription affected.

As Green notes: "[The legislation] made drug pricing a make-or-break skill as critical as the mastery of product development, positioning, and promotion."

Chapter 9

Distribution

In the first chapter we used the following definition for "Place" in the marketing mix: The distribution channels and physical distribution practices that make it possible, easy or difficult for markets to use the product. In this chapter we will explore these issues. It should be noted that, for prescription drugs in the U.S. and most developed countries, many of the distribution options in consumer goods marketing are not available. Pharmacies, hospitals, and health professionals are, by law, the end points in the channels of distribution. (OTC drugs offer an interesting contrast, however.) As a consequence of this legal restriction, much of the present chapter is devoted to the role of the wholesaler.

"PLACE" CONSIDERATIONS IN THE MARKETING MIX

Marketing is defined as an exchange process. In relation to distribution, exchange poses two problems. First, goods must be moved to a central location from the warehouses of producers who make heterogeneous goods and who are geographically widespread. Second, the goods that are accumulated from diversified sources should represent a desired assortment from the viewpoint of customers. These two problems can be solved by the process of sorting, which combines concentration (i.e., bringing the goods from different sources to a central location) and dispersion (i.e., picking an assortment of goods from different points of concentration). There are two basic strategic questions that need to be answered here. Who should perform the concentration and dispersion tasks—the manufacturer or intermediaries? Which intermediary should the manufacturer

select to take the goods close to the customer? These questions are central to distribution strategies.

In addition to the above, there are other strategy-related matters. The focus of other strategic questions is on the scope of distribution (i.e., how widespread distribution may be), use of multiple channels to serve different segments, modification of channels to accommodate environmental shifts, resolution of conflict among channels, and use of vertical systems to institute control over channels.

The channel-structure strategy refers to the number of intermediaries which may be employed in moving goods from manufacturers to customers. A company may undertake to distribute its goods to customers or retailers without involving any intermediary. This comprises the shortest channel and may be labeled a direct distribution strategy. Alternatively, goods may pass through one or more middlemen, such as wholesalers and/or agents. This is an indirect distribution strategy.

Channels of distribution may be evaluated on such primary criteria as cost of distribution, coverage of market (penetration), customer service, communication with the market, and control of distribution networks. Occasionally such secondary factors as support of channels in the successful introduction of a new product and cooperation with the company's promotional effort also become evaluative criteria. To arrive at a distribution channel which will satisfy all these criteria requires simultaneous optimization of every facet of distribution, something which is usually not operationally possible. Consequently, a piecemeal approach may be followed.

Cost of Distribution

A detailed cost analysis of distribution is the first step in evaluating various channel alternatives on a sales-cost basis. This requires classification of total distribution costs under various heads and subheads. Table 9-1 gives an illustration of such a cost classification, based on general accounting practices; the information on each item should be conveniently available from the controller's office.

The question of evaluation comes up only when the company has been following a particular channel strategy for a number of years. Presumably, the company will have pertinent information to undertake distribution cost analysis by customer segment and product line. This sort of data allows the analyzer to find out how cost under each head varies with sales volume, e.g., how warehousing expenses vary with sales volume, how packaging and delivery expenses are related to sales, etc. In other words, the purpose here is to establish a relationship between annual sales and

TABLE 9-1. Examples of distribution costs related to function

1. Direct Sales
   Salaries
   Commissions
   Training
   Returned Goods

2. Sales Discounts and Allowances
   Cash
   Quantity

3. Credit Extension
   Bad-Debt Losses
   Credit-Rating Services
   Legal Fees
   Financial Fees
   Financial Costs of Accounts Receivable

4. Market Research
   Salaries: Administrative
   Clerical
   Surveys: Distributors
   Consumers
   Industry trade data

5. Warehousing & Handling
   Salaries: Administration
   Wages: Warehouse services
   Depreciation: Furniture, Fixtures
   Insurance
   Repair & maintenance
   Unsalable merchandise
   Warehouse responsibility
   Utilities

6. Inventory Levels

Obsolescence markdown
Financial cost of carrying inventories

7. Packing, Shipping, & Delivery
Salaries:
Wages: Truck drivers and
maintenance men
Packers
Shipping clerks
Truck operators and repairs
Depreciation:
Packing supplies

Freight: Factory to warehouse
Warehouse to customer
Factory to customer
Outside trucking service

8. Order Processing
Order forms
Salaries: Administration
Wages Order-review clerks
Order processing

9. Customer Service
Salaries: Administration
Customer service representatives
Clerical
Stationery & supplies

10. Returned Merchandise
Freight
Salaries
Returned-goods processing:
Material labor
Forms & supplies

different types of cost. These relationships are useful in predicting the future cost behavior for the established dollar-sales objective, assuming present channel arrangements are continued.

Coverage of Market

An important aspect in predicting future sales response is the penetration which will eventually be achieved in the market.

One measure of the coverage of market (or penetration of market) will be the number of customers in a group contacted or sold, divided by the total number of customers in that group. Another measure may be the penetration in terms of geographical coverage of territory. But these measures are too general. Using just the ratio of customers contacted to the total number of customers does not give a proper indication of coverage, because not all types of customers are equally important.

A desired level of penetration for each subgroup should be specified; e.g., 90 percent of the large, 75 percent of the medium, and 50 percent of the small drugstores may be penetrated. These percentages can be used for examining the effectiveness of an alternative channel.

Customer Service

Level of customer service differs from customer to customer for each business. Generally speaking, the sales department, with feedback from the field force, should be able to designate the various services that the company should offer to different customer segments. If this is not feasible, a sample survey may be planned to find out which services the customers expect and which services are currently being offered by competitors. This information can be used to develop a viable service package. Then the capability and willingness of each channel alternative to provide these services may be matched to single out the most desirable channel. This can be done intuitively. A more scientific approach would be to list and assign weights to each type of service, then rate different channels according to their liability to handle these services. Examples of most frequently provided services of drug wholesalers are shown in Table 9-2.

Communication and Control

Control may be defined as the process of taking steps to bring actual results and desired results closer together. Communication refers to the information flow between the company and the customers. To evaluate alternate channels on these two criteria, the communication and control

TABLE 9-2. Services most frequently provided by pharmaceutical wholesalers

Store Fixturing Programs
Pharmacy Computer Hardware
Third Party Claims Processing
Co-Sign Loans for Retailers
Arrange Financing for Pharmacist
Site Selection
Pharmacy Computer Software
Host Support for Computers
Financial Management Reports
Private Label Programs
Point of Sale Scanning/Computer Hardware
Ad Support Programs
Product Price Labels
Shelf Price Updates
Price Updates
Product Movement Reports
Inventory Reports
Plan-O-Grams
Dating On Opening Inventory
Co-op Advertising Programs
Point of Purchase Aids
Store Remodeling Programs
Point of Sale Software

objectives should be defined. With reference to communication, for example, information may be desired on the activities of competitors, new products from competitors, the special promotional efforts of competitors, the attitudes of customers toward the company's and competitor's services, and the reasons for success of a particular product line of the company. Each channel alternative may then be evaluated in terms of its willingness, capabilities, and interest in providing the required information. In the case of wholesalers, the communication may also depend on the terms of the contract. But the mere fact that they are legally bound by the contract may not motivate them to cooperate willingly. Finally, the information should be judged for accuracy, timeliness, and relevance.

*THE DRUG WHOLESALER**

The pharmaceutical wholesaler typifies the kinds of strategic considerations necessary in drug distribution.

The casual observer of marketing channel practice may wrongly assume that wholesaling is a low growth, unnecessary function that adds an unjustified cost factor to the price paid by retailers and consumers. Easily (but mistakenly) ignored is the value added by wholesale distribution in terms of the utilities of time, place, access, and appropriate quantity.

A functional approach may be used so that channel management is understood with reference to the "physical flow of the goods, the flow of ownership or control, the flow of information, and the flow of money." This distinction "makes it possible to determine the precise role of each agency or facility in the channel of distribution" (R. Cox and T. F. Schutte in *Marketing Channels*, L. C. Boone and J. C. Johnson, eds., Tulsa, PPC Books, 1977).

The customary argument for wholesaling is presented in terms of several basic principles of marketing. Among these are reduced transactions, concentration-dispersion, market proximity, and specialized service. A familiar illustration of an economic justification for the wholesaler's role is the estimate that 600 million transactions annually would be required if 50,000 pharmacies ordered directly each month from 1000 manufacturers.

If this illustration is extended to the extreme of daily ordering on a direct basis, some 13 billion transactions would result, an obvious impossibility. This may be contrasted with the introduction of 250 wholesalers to the model. Assume that 1000 manufacturers deal weekly with this group of distributors, who then serve the 50,000 pharmacies daily. If 260 working days in a typical year are used as a multiple, the result is 26 million transactions. (See Figure 9-1.)

A similar reduction is achieved in order processing, invoicing, and all associated costs, with the genuine advantage of fewer opportunities for error. Computerization of this process overcomes the difficulties of human order takers and depersonalizes inventory control for maximum economic benefit.

Wholesaling, then, concentrates merchandise appropriately by assembling an assortment from diverse manufacturers, and disperses the right amount to the indicated point of sale in the quantity required. This concen-

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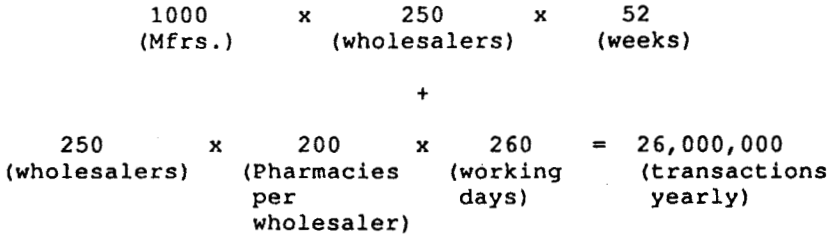
*This section was adapted from the chapter by John T. Fay, Jr. in the Third Edition of this book. At that time Dr. Fay was with the McKesson Organization.

FIGURE 9-1. Role of wholesalers in transaction reductions



tration-dispersion function is often characterized by the terms "sorting" or "breaking bulk." Local availability in response to demand is an important factor in the value added by sorting.

Market proximity in an economic sense refers to local availability and the utilities of place, timeliness, and possession. Next-day delivery from wholesalers is possible virtually everywhere in the United States, and same-day delivery can be achieved in many urban markets. For reasons of cost efficiency, however, there is a trend toward fewer deliveries per week from wholesalers to the pharmacies they serve.

Siecker has provided an interesting example that recognizes this trend and relates it to turnover improvement. He noted that two-thirds of the funds in a typical pharmacy are tied to the purchase and resale of inventory, and he then emphasized the problems of ordering too frequently "because scarce dollars are supporting lazy stock." His example continued with the following:

> If a pharmacy were designed to operate on a two-week order cycle . . . the theoretical inventory turnover would exceed 17 for the year. Obviously, it would be tough to make that figure. But what if 10 turns was a realistic figure for this model? Compare that with the norm of about four turns per year, and suddenly thousands of dollars could be extracted from lazy inventory, easing the cash flow crunch, allowing more flexibility on promotional purchasing and improving return on investment.

CONCENTRATION OF PURCHASING POWER

An extension of this reasoning leads to the primary supplier concept. More pharmacists now recognize the benefits that can be obtained by ordering less often from a single wholesaler—a concentration of the pur-

chasing pattern. Similarly, wholesalers are seeking out the best-managed pharmacies in a given market in order to concentrate and improve their customer base.

Some attrition is unavoidable during periods of growth. Improperly managed, underfinanced businesses at both the wholesale and retail levels leave the market to the strongest competitors. One result of this change is a measurable increase in the effectiveness of competition, sharpened and focused by market forces.

Increasing recognition of the primary supplier concept and its decided advantage changes this service ratio. From the former average of 300 pharmacies in a typical wholesaler's customer base, movement toward a smaller base is apparent. Much the same pattern can be observed in the United Kingdom and other countries in which computerization and consolidation have accelerated the survival of the fittest in drug marketing.

Addressing the 1980 year-end sales conference of Bergen Brunswig Corporation, Chairman Emil P. Martini, a pharmacist, described the primary supplier commitment as "causing major changes in the entire economics of the business." Martini argued further that "cost-plus selling and cost-plus-a-fee are quickly eliminating the traditional adversary buyer-seller relationship.

The relationship between price and place in the marketing mix can be exemplified by the wholesaler's strategic moves.

Innovation in pricing by wholesalers is a logical response to competitive intensity in a growing market. It can be estimated reliably that some 25% of wholesalers now offer cost-plus pricing (percentage or fee), and that the practice enjoys increasing application and understanding. Acceptance of this strategy has been facilitated by computerized order entry with invoices in pick sequence, shortened payment terms for customers, and more realistic delivery schedules.

Wholesalers include the following as important influences on their choice of pricing: the method of order entry, frequency of delivery, and the amount of service involved. Daily delivery remains the norm but the trend is toward a reduced schedule. Payment terms for most customers are twice monthly, with a few firms moving to weekly payment.

Pricing decisions are considered by many to be more important in the determination of marketing strategy than any other factor. Price is certainly a major influence on policy at all levels in the distribution channel. An accurate assessment of wholesale pricing is that: "price competition is more direct and more intense for wholesalers than at other levels of distribution. A wholesaler has many rivals, including the manufacturer who sells direct, the functional middlemen, and other wholesalers in the same

or broader lines. Wholesale prices fluctuate much more than do retail prices or manufacturers' prices because wholesalers operate on narrower margins and are less able to absorb increases in cost, even over a short period of time" (Baumback, Lawyer and Kelley, *How to Organize and Operate a Small Business*, New York, Prentice-Hall, 1973).

This observation about price fluctuation can be supported by two other considerations. Because wholesale markets are well organized, response to supply and demand factors is particularly sensitive. Competing wholesalers react quickly to changes in the market. Also important is a factor that is often overlooked: a relatively slight change in price to the wholesaler involves large dollar amounts because of the quantities purchased.

Price is an important determinant of the relationship between manufacturers and wholesalers in the pharmaceutical industry. It has been argued that drug wholesalers are now less inclined to be "price-takers" (accepting manufacturers' suggested retail prices and discounting from list) and more inclined to be "price-makers" (adding a charge based upon an increasing variety of services to product cost, largely computer-based).

Because wholesalers distribute the products of hundreds of competing manufacturers, the relative amount of support extended to particular lines is a variable factor. The manufacturer's policy is seen as favorable or not by wholesalers with reference to exclusivity in distribution, gross profit, dollar volume, turnover, and credit terms, among other considerations.

Formerly, a typical reaction of wholesalers to manufacturers who chose to bypass them and sell directly to retailers and hospitals was resentment expressed in lack of sales support. This is understandable when the wholesaler's margin is a function of manufacturers' policy and "suggested" resale prices under the restrictions of list less pricing at wholesale.

As wholesalers apply innovative pricing strategy that frees them from dependence on list prices and shifts them from the position of price-taker to price-maker, the conventional resentment toward direct sellers is tempered by the increased sales that result from pricing their lines competitively. A policy favoring wholesale distribution is then more important than pricing or stipulated margins.

It is significant that many of the top 20 companies are direct sellers by inclination and policy, but the wholesalers' market share for all of these lines is increasing according to the general trend. Order minimums for retailers are a factor of importance.

Conversely, a manufacturer fully committed to wholesaling, such as Burroughs Wellcome, Lilly, Searle, and SmithKline should expect and receive greater support from his wholesaler than that provided to direct sellers. Among the companies that have made this commitment are Ar-

mour, Astra, Boehringer Ingelheim, Dorsey, Endo, Fisons, Hoyt, Knoll, Mead Johnson, Norwich-Eaton, Ortho, Pennwalt, Riker, and others. Although these firms distribute to independent pharmacies exclusively through wholesalers, there are usually differences in policy for chain stores, hospitals, and government agencies. On occasion, these variations have been a source of friction between wholesalers and manufacturers. An examination of this and other kinds of relationships within the distribution channels follows.

*RELATIONSHIPS WITHIN THE DISTRIBUTION CHANNELS**

The pharmaceutical industry, as with many others, has suffered from superficial analysis of its channels or distribution. Such analysis may result in glossing over the ways in which more than a dozen major industry components impinge upon the activities of each other. A better understanding of the industry can result from viewing the channel as an open system. In this view, input (of many kinds) is received from the environment, operations or series of operations are performed by the channel on that input, and the transformed input is returned to the environment. These transformations, including addition of time, place, possession and form utility, are necessary for the product to be complete.

Louis Stern, in his book *Distribution Channels, Behavioral Dimensions* (Houghton-Mifflin, 1969), developed a description analysis of commercial channels.

Using Stern's typology (with one addition) nine marketing flows are identified:

1. Ownership (taking title to the goods);
2. Physical Possession (includes warehousing, but taking title is not necessary);
3. Sorting (breaking bulk and preparing for redistribution);
4. Promotion (e.g., advertising, personal sales, sales promotion);
5. Negotiation (discussion or conference aimed at reaching agreements, concluding transactions, etc.);
6. Financing (supplying money for or managing the money of another institution);

*This section adapted from a series of articles in *Medical Marketing and Media* by Mickey Smith, Kenneth Roberts and Darego Maclayton.

7. Risking (assumption of possible loss, connected with ownership of goods);
8. Ordering (requesting the product to be supplied);
9. Payment (supplying what is due for goods and/or services rendered).

These marketing flows have been identified in Figure 9-2 in the following fashion:

Flow	Direction	Code
Manufacturer	⟶	Consumer
Ownership		A
Physical Possession		B
Sorting		C
Promotion		D
Negotiation		E
Financing		F
Risking		G
Ordering		H
Payment		I

It is not possible to examine in this chapter every cell in Figure 9-2, however, the multitude of relationships is dramatically displayed. This is in spite of the necessity of eliminating a number of types of transactions. Returns, for example, are not covered. Word of mouth is not included as promotion. Services of facilitating agencies such as advertising firms, truck lines, etc., are missing. Even so, more than 200 types of relationships and functions are displayed for prescription drugs alone.

It is fairly obvious that the drug industry is one of many complex relationships. It is well to remember that this industry is part of an even larger system, the health care system. It may be well to test the drug industry against the characteristics of a system—in this case a social system. In such a system the behavior or change of state of members system influences (a) the state of the system, and (b) each other's states and relations. Every concrete act thus originates in a unit or member and has effects on the state of the system and its other component units.

In order for a social system to operate sufficiently:

1. The structural variables, which define the parties in the system and prescribe behavior for these parties, must permit behavior to be predicted by system constituents;
2. Functional variables must be of such a nature as to allow the system

FIGURE 9-2. Channel functions and responsibilities

		Manu-fact.	W/S	M.D.	R.Ph.	Con-sumer	Inter. Con.	3rd Party	Fed. Agency	PMA	NWDA& FWDA	AMA, etc.	APHA, etc.	Consumer Unions
		1	2	3	4	5	6	7	8	9	10	11	12	13
Manufacturer	1		ABCD EF	ABCD EFG	ABCDE FG	D	ABCDE	DE	E	E	E	E	E	E
Wholesaler	2	CDEGHI		ABCD EFG	ABCDE FG		ABCDE FG	E	E	E	E		E	
Physician	3	DEGHI	DEGHI		GHIDE	ABCDE FG	EHI	EFG	E			E		E
Pharmacist	4	DEGHI	DEGHI	ABCDE FG		ABCDE FG	ABCDE FG	EFG	E	E	E		E	E
Consumer	5			EGHI	EGHI		EGHI	EFGHI						E
Intermediate Consumer	6	EGHI	EGHI	ABCE FG	ABGE FG	ABCDE FG		E	E	E	E	E	E	E
Third Party	7	E	E	EI	EI	E	EI		E	E		E	E	E
Federal Agency	8	E	E	E	E		E	E		E	E	E	E	E
PMA	9	E	E		E		E	E	E	E	E	E	E	E
NWDA & FWDA	10	E	E		E		E	E	E	E			E	
AMA, etc.	11	E		E			E	E	E	E			E	E
APHA, ASHP, NARD	12	E	E		E		E	E	E	E	E	E		E
Consumer Unions	13	E		E	E	E	E	E	E	E		E	E	

A: Ownership
B: Physical Possession
C: Sorting
D: Promotion
E: Negotiation
F: Financing
G: Risking
H: Ordering
I: Payment

to satisfy desires of its components while simultaneously fulfilling the task of the system as a whole. These variables are:

a. Pattern maintenance—the tendency of the system to maintain structure in terms of its parties and their expected behaviors;
b. Goal attainment—activities necessary to satisfy needs of the total system through interaction with the task environment;
c. Adaptation—activity needed to provide resources for goal attainment;
d. Integration—mutual adjustment of the components in relation to their contribution to effective system functioning. This requires a channel leader.

A channel system's performance will be enhanced if roles are well defined, conflict managed and/or resolved, power used judiciously, and communications kept open.

Smooth functioning of the channels of distribution within the pharmaceutical industry relies in large part on general agreement concerning the roles of the respective parties in the channels. Agreement concerning the roles can go a long way toward preventing unpleasant surprises, disappointment, and inefficiency.

In addition to roles, organizational character (defined as being a product of "its method of work, its natural allies, its stake in the course of events, the predispositions of its personnel, and the labels which have become attached to it") also assists in lending stability and predictability to industry relationships.

The specific channel member (e.g., wholesaler or retailer) possesses a definite self, distinctive character, and ways of acting and perceiving different from other such organizations. It behaves in accordance with specific roles or sets of prescriptions defining what its behavior should be. The other firms in the distribution channel are able to anticipate its behavior, and similarly, it can foresee the behavior of dependent channel members.

This is of course an idealized relationship. It is patently impossible for each organization in the drug industry to have ready knowledge of the organizational character of all others (although some companies—Lilly, McKesson, and Walgreens have developed such a recognized character.) Too, in many cases the character of one organization is known to another organization only through one or a few representatives. Thus the Syntex detailman is the Syntex organization in the experience of the pharmacies in his territory.

The concept of organizational roles also presents problems. This is particularly true since smooth industry functioning is most likely to occur when all parties have a mutual perception of the roles of all organizations in the system. This obviously does not come about quickly, but rather is the result of long-term and increasingly successful performance in a particular role. Other members of the industry, through experience, tend to prescribe behavior in accordance with their concept of what is correct behavior and attempt to enforce sanctions if there are deviations.

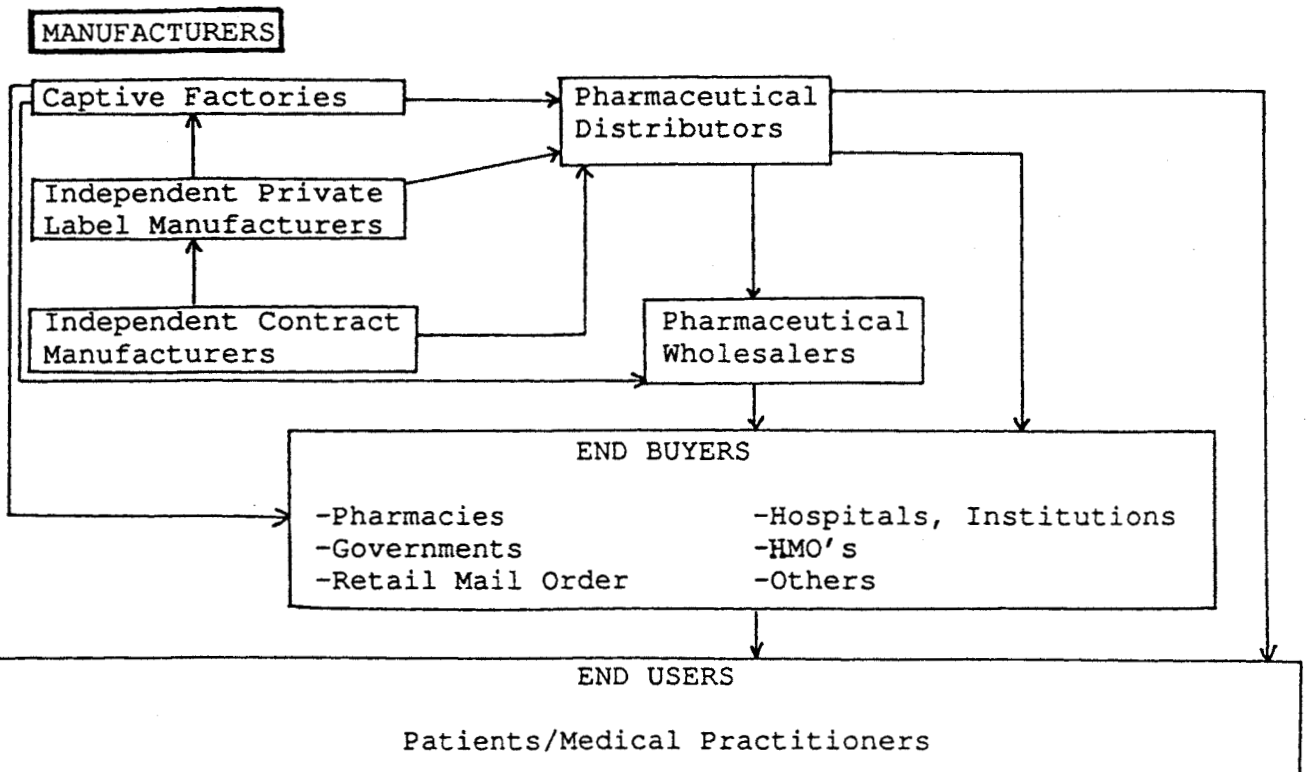
In spite of the importance of historical developments, evaluation is also an important factor in role perceptions. Thus the super drugstore was originally opposed by almost all segments of the drug industry, whereas its role in the industry is a pivotal one today. To a certain extent the same may be said of generic pharmaceuticals, whose distribution channels are shown in Figure 9-3.

In considering the importance of role identification in the pharmaceutical industry it appears to us that a major source of difficulty is a lack of consensus, the degree of agreement among industry members about behavior pertinent to a given situation. The principal area of lack of consensus in the drug industry appears to be the role of the retailers. A second area of "discensus" is differences in motivation of the retailers and the manufacturers' desires for such motivation. If retailers, particularly small retail businesses, have reached earning levels which satisfy personal aspirations, they are likely to be apathetic to efforts by manufacturers to effect changes which increase volume.

The prescription drug industry is a great industry by almost any standard. Its products, in spite of their often cited problems, are remarkably effective. The costs of the drugs to the ultimate customer have remained remarkably stable. Perhaps most important of all the distribution system has been beautifully effective. Of all the components of the health care system, pharmaceuticals have been the most accessible. There are pharmacists in almost every hamlet and they have made a way of life of having any prescription drug when it is needed. Whereas one might have to travel miles to obtain cobalt therapy, orthodontist services, or even a pediatrician, the odds are, in any town of more than 1500 people, that any prescription drug will be available.

Surely, this accomplishment is something of which all members of the drug industry might be justifiably proud. Justifiably one might expect a great deal of mutual pride. Yet "conflict" is probably the word which best describes the current industry state of affairs.

FIGURE 9-3. Sources and distribution of generic pharmaceuticals



CONFLICT IN THE CHANNELS

There are obviously many and compelling reasons for the members of distribution channels to cooperate. Sometimes, there are also reasons for conflict. A certain amount of conflict will always be present. Indeed, some conflict is a necessity of a competitive marketplace. However, when conflicting objectives outweigh cooperating objectives, the efficient distribution of drugs will almost certainly be impeded. This is especially true in the case of OTC drugs whose distribution is particularly complex. (See Figure 9-4.)

Many years ago, in one of the first treatments of conflict in modern distribution channels, Palamountain described three types of conflict in distribution:

1. Horizontal—among similar competitors, e.g., independent versus chain pharmacies;
2. Intertype—among different methods of distribution, e.g., drugstore versus food store;
3. Vertical—between different structural levels in the same distribution channel (Palamountain, *The Politics of Distribution*, Harvard Press, 1955).

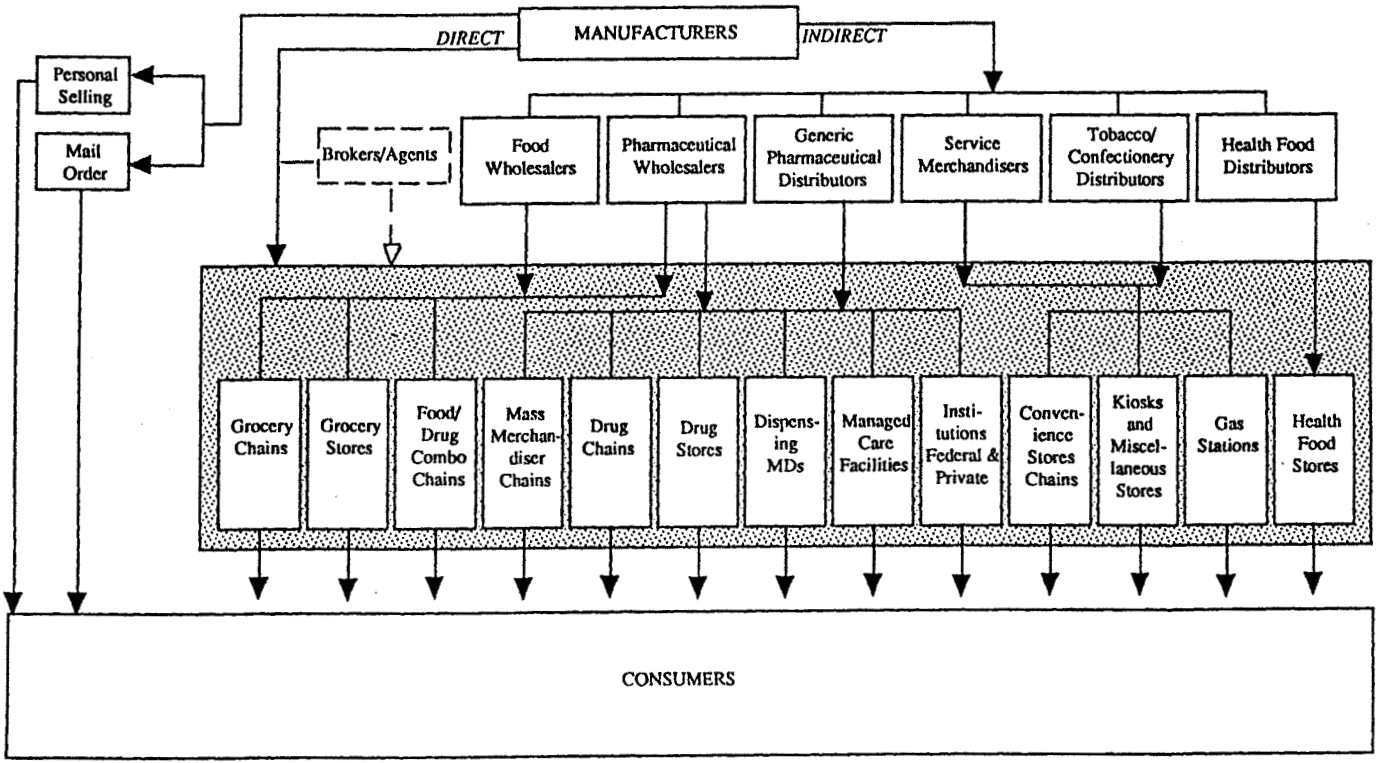
In our discussions we have dwelled and will dwell somewhat more upon vertical conflict, partly because it tends to affect the entire industry and partly because it is more interesting, since, as Palamountain says, "it is so directly a power conflict."

One may draw a sharp distinction between external conflict and competition. Competition achieves a working accommodation. There is rivalry, but not hostility. However, firms which do not compete in the customary fashion may be regarded as "inimical to the interests of the in-groups." External conflict tends to be a conflict over values while internal conflict (competition) will be limited to means. To the independent pharmacists, then, it must have been troubling to learn that their ally, the manufacturer, would not stand firm with them against the growth of chains. More recently the rising legitimacy of the "generic house" in the buying habits of some pharmacists must also have given the brand name defenders disappointment.

The effect and effectiveness of national advertising and promotion of both prescription and nonprescription drugs must be considered as potential causes of conflict. The possible effects are several.

If physicians and patients are pre-sold on a drug, much of the pharma-

FIGURE 9-4. OTC distribution system by channels, intermediaries, and outlets



cist's discretionary decision-making power is nullified. This may be resolved, particularly if the producer makes it known that he feels it is the pharmacist's duty to stock the product. When he does not do so or does not push the product, conflict is almost inevitable.

Also related to promotion is the obvious or apparent (in terms of relative number of pages) fact that the producer of the product sees the physician as the prime target of his promotion. This is a particularly sticky problem for the drug industry. To the manufacturer it must seem incongruous that the retailer should be concerned with the amount of promotion directed at him. Understanding, not necessarily acceptance, of this position can only come from understanding of the profession-businessman conflict which goes on (perhaps kept alive artificially) within pharmacy.

What is the meaning of the substitution controversy in the context of conflict and power? What is at stake basically is the selection function. As long as product selection rested with the physician, dominance in the channel rested with the manufacturer through his ability to influence that selection. (The retailer-pharmacist never really got into that type of influence.) Legalized substitution shifts substantial amounts of power to the retailer. Conflict is inevitable in this effort by the retailer to attain power. It is even greater in the case of therapeutic substitution, where patent protection may be compromised.

One may identify seven causes of channel conflicts. They will each be reviewed in turn.

1. Roles. The roles of each of the channel members are normative models of conduct. In order to achieve the marketing task each member must behave in a fashion which can be integrated with the needs of the entire channel system. Attempts to change roles, which pharmacy has been doing, or failure to fulfill a role, will bring conflict.

2. Issues. In this discussion an issue is a scarce resource desired by two or more parties. The resource may be a drug, as when there is a shortage of influenza vaccine, or compensation or sales territory. Shelf facings constitute an issue.

3. Perception. Because of frame of reference, predispositions, prejudice, attitudes, or values, different members of the channel may perceive reality differently. Differing perceptions provide differing bases for action, and because of this the action may cause conflict.

The pharmacist perceives himself (or at least in public pronouncements claims to perceive himself) as a professional. There is some real question of the perception of the pharmacist by the manufacturers and wholesalers who almost certainly see the community pharmacist as a retailer.

Similar perceptual differences may also exist with regard to other chan-

nel members. Is the manufacturer a creator of products which essentially sell themselves? Is he the retailer's benefactor? Or is he merely a supplier to a professional who is doing the main task?

4. Expectations. This cause of conflict is similar to "self-fulfilling prophecy." In some ways this means that conflict begets conflict. As a rather farfetched example we take the case of many pharmacists who expect that manufacturers will not advertise in their journals and consequently do not read the journal ads. Subsequent readership studies reveal this lack of readership making it poor business to advertise in the journal.

Perhaps more realistic is the pharmacist who believes that the manufacturer favors the physician in terms of attention and promotion. The pharmacist may then be harsh in his treatment of the detailman—his only personal contact with most firms. Little wonder if the detailman, in turn, confirms the pharmacist's beliefs by avoiding the unpleasant contact.

5. Decisions. Conflict arises here when two or more organizations wish or attempt to control decision making in the system. Examples here include disagreement between manufacturers and wholesalers over who shall set prices to retailers.

6. Goals. If goals between firms and channel segments conflict, other conflicts result.

7. Communication. One observer pointed out more than 25 years ago "the people who manufacture the goods and the people who move the goods into the hands of the ultimate consumer do not share the same business philosophy and do not talk essentially the same language" (Wittreich, *Harvard Business Review*, June, 1962). Without a common language, communication is difficult and some parties will not take the trouble. This is partly a function of terminology, but how many manufacturing executives regularly read the journals of their retailers and vice versa? A great deal of conflict in the channel may result from the exchange act between channel members.

Suppliers may emphasize the customer aspect of a retailer rather than the channel member aspect. As a customer, the retailer is somebody to persuade, manipulate, or even fool. Conversely, under the marketing concept, the view of the retailer as a customer or channel member is identical. Under this philosophy he is someone to aid, help, or serve . . .

To view the retailer as simply the opposing principle in the act of exchange may be channel myopia but this view exists. On the other hand, failure to recognize this basic opposing interest is also a conceptual fault.

If one starts at the Kefauver Congressional hearings of the 1950's and 1960's where the pharmaceutical industry presented a relatively united front, the years since are certainly rife with tension building events. A

partial list would include: newfound strength of the FDA, new third-party programs such as Medicaid, more vocal consumer groups, new nonpharmacy leaders in the proliferation of chains, and many more. Little wonder that conflict has resulted. Mutual recognition of a stake in survival of the channel remains to be fully demonstrated, although there are signs of rapprochement.

Nearly all of the major generic causes and types of conflict seem to be at work to some degree in the drug industry. What are the players doing in the face of this conflict? Some, of course, are simply grousing about their problems. Others, however, engage in overt behavior. Some of this behavior is pathological, and feeds the fire of even greater conflict. Other activity, however, is aimed at resolving the conflict.

EXERCISE OF POWER

Power is both a cause of and response to, conflict. We are interested primarily in the latter. When conflict occurs a natural reaction is to attempt to relieve the source of the conflict. There are several methods by which this may be attempted:

1. Threats. In general, economic-in-nature threats tend to produce counterthreats rather than positive results unless the imbalance of power makes these impossible. Bergen Brunswig's discontinuance of the Flint line in 1974 provides a good example.

2. Coalitions. Efforts to increase power within a market segment may take the form of coalitions. Recurrent calls for "one voice" for pharmacy arise at least in part from this idea. The National Pharmaceutical Council allowed, at its inception, many firms to share the burden of fighting the practice of illegal substitution.

3. Symbols. Increased flow of symbols is a frequent response to real or expected conflict. In the pharmaceutical industry each component has used this approach at one time or another. The wholesaler is "full service," the manufacturer talks "quality," the retailer preaches "small business," "profession," or "service." Chains promote "low prices."

4. Legal Actions. In some, perhaps many, cases in the pharmaceutical industry, the response to conflict is a resort to legal power. Legal action was sought years ago to stop substitution. The Portland case by retailers against differential pricing to hospitals also applies.

Power in the pharmaceutical industry resides mainly with the drug manufacturers. There are pockets of power elsewhere, of course, but for those who would demur, we suggest asking their physician to prescribe 160 mg

of tetracycline four times a day or 350 mg of chlorothiazide in the morning.

Our interest in this power stems not from any condemnatory position, but rather in the hopes of discovering some direction for the formulation of the type of industry relationships into an organized behavior system. It is important to identify the center of power because an organized behavior system, with its mutually beneficial cooperative interaction, depends on a "control group" within the system which projects a plan of operation and attempts to induce participation on its own terms.

If the pharmaceutical industry is not behaving as an organized system, then this theory would tell us that it is because some member or members do not expect the benefits, they expect them in vain, or the control group is not functioning. We hold that achievement of organized behavior system status for the pharmaceutical industry must await:

1. Definition and mutual acceptance of the roles of each party;
2. Constructive and accepted use of power and influence of the industry;
3. Resolution of existing conflicts.

Roles

Discussions of the pharmaceutical industry return again and again to the role of the pharmacist. Is he retailer or professional? What can the manufacturer expect from him?

A role is a set of prescriptions defining what the behavior of a channel member should be. It has been pointed out that channel members who occupy channel positions (e.g., retailer) may come and go, but the set of specifications for role performance remain fairly stable over time.

In fact, however, the drug industry may not yet have come completely to grips with the specification of role performance for each of its members. The role of the retail druggist is a particularly thorny problem. In the view of many, community pharmacy is filled with would-be professionals and would-be businessmen who are not making a great deal of progress in either direction. If one channel member is confused about his own role this confusion tends to spread, but it need not necessarily be counterproductive. It is conceivable, then, that the community pharmacist might be able to occupy more than one role at once. Whether one or all of these roles will be acceptable to the channel partners is by no means sure.

As channel members interact in carrying out the marketing tasks, they develop conceptions about their own roles and the roles of other position occupants. As a member increasingly plays a successful role, the other

channel members come to regard the position-occupant's behavior as customary. Therefore, they prescribe behavior for the channel member in accordance with their conception of correct behavior and overtly enforce their prescriptions by means of sanctioning behavior.

NWDA President Martin, back in 1974, noted that the discounts given by the manufacturer and passed on to the retailer had come to be expected. "We've spoiled the hell out of our retail pharmacy customers," Martin said in a speech to the National Wholesale Druggist's Association.

> We've given away what little profit we had in the form of deeper and deeper discounts—bleeding ourselves to death, to keep a competitor from getting the order. We've spoiled the hell out of our suppliers by accepting across-the-board margins on entire lines, when we knew damn good and well we were losing money on the slow movers. And all too frequently we have knuckled under, without a whimper, to unreasonable and destructive terms of sale. We've deceived the hell out of each other, too, by insisting that our problems are created by others—our customers, our suppliers, or the Government—when we ourselves are at least partly to blame for the economic illnesses endemic in the wholesale drug industry today.

The ability to exercise sanctions springs from power. What are the sources of power in the pharmaceutical industry?

POWER AND INFLUENCE

The manufacturers of prescription drugs must have a great deal of power. They changed the entire character of one profession—pharmacy. They completely trained another profession to write medical orders to conform to the characteristics of their products. These are not the only kinds of power available to members of the pharmaceutical industry, however. There are a number of power bases, each of which finds some application in the drug industry.

Rewards. Power based on rewards springs from belief by one party that a second party has the power to grant certain rewards. This power is made stronger when rewards actually accrue. Wider margins, promotional allowances, and franchised sales are all examples of rewards which result in delegation of power. Trips by pharmacy students to major drug companies and free prescription blanks provided by pharmacists to physicians fit this category.

Coercion. Coercion is certainly a corollary of reward in that a form of

coercion may be the threat of removal of privilege or special consideration. A wholesaler may adopt this approach to bring the recalcitrant manufacturer into line by threatening to discontinue carrying his products. Dropping the pharmacist from direct accounts by the manufacturer or removing favored customer status by the wholesaler are coercive.

Expertness. A third power base springs from expertise: an example of this expertise is the advice provided to drug retailers by drug wholesalers in such areas as layout, location, and modernization. The current struggle by pharmacists to be recognized as the drug expert arises in part (and perhaps unconsciously) from a wish or need for marketing power. Management services such as those provided in the Lilly Digest certainly lend an aura of expertise.

Legitimacy. Power is legitimate when granted by law, or when it is simply ascribed by the subordinate. Patent laws, the Durham-Humphrey Amendment, and anti-substitution laws all fit this category.

Identification. Finally, power may arise when one party or group occupies a position which is attractive to channel members. If, for example, National Pharmacy Week had ever achieved any real degree of success, one might have expected individual manufacturers or groups of manufacturers to have attempted to become identified with it.

Power is exercised in a variety of ways, depending upon who is exercising it. The manufacturer, for example, may use his promotional power to force assistance within the channel. He may use legal means, suggestion (premarked packages), or negative means (e.g., refusing to sell). He may also use "negative cooperation" as we note below.

The retailer may exercise power in other ways, among them:

1. Building a franchise with the consumer, perhaps through private brands;
2. Concentrating purchasing power as, for example, through co-ops;
3. Specification buying—to date largely a hospital practice;
4. Vertical integration—so far primarily back to the wholesale level of the channel.

Neither of these lists of power alternatives is exhaustive. Nor do we for a moment believe that the end of imaginative new means of gaining and exercising power has been seen. Strange (in today's atmosphere) bedfellows may yet appear in drug marketing channels.

Stated another way, the proper exercise of power is in bringing about the cooperation necessary to make the industry function as an organized behavior system. Power, intelligently exercised toward this end, may result in the resolution of the industry's internal conflicts.

It is perhaps obvious that a manufacturer will want to use that channel or those channels which together with the other components of his marketing mix will yield him the greatest profit or otherwise achieve his goals and objectives. This means that the dollars expended and the return dollars generated in the market must be compared for each channel alternative; that is, the principles of a cost-revenue trade off must be constantly applied. Ideally this would be done on a marginal or incremental basis with the further proviso that in a similar vein channel expenditures be compared with all other marketing mix expenditures in terms of their dollar returns. Such a framework requires, of course, that all data are known and available. But even the difficulties on the cost side pale in comparison to the vagaries of information about demand and customer reaction patterns. Sometimes, the firm must at least make some educated guesses about these complex relationships.

As an alternative to working with specific data to illustrate the strategic problem of channel choice, we will merely try here to identify the major factors involved. Among these are (1) the nature of the products and markets being served, (2) the existing channels for such products, (3) the financial resources of the manufacturer, (4) the kinds of assistance needed in the channel, and (5) the forms of cooperation received from channel outlets.

A thorough analysis of the product including whatever information is available concerning the buying habits and behavior of customers is obviously an essential consideration. If, in the case of OTC products, customers prefer to buy in several retail outlets, the manufacturer must get the goods there. If his volume is large enough to each outlet he may be able to sell direct to the retailers involved. The existing channels of distribution for comparable products may provide additional clues for the manufacturer. He may or may not find it desirable to depart from tradition.

The financial resources of a manufacturer obviously affect his choice of channels. It is easy to see that a manufacturer in a relatively poor financial position is likely to be dependent upon middlemen. The establishment of a sales force and the provision of company-owned wholesaling facilities are typically undertaken only by those who can finance them. Even then, if the economies or other advantages to be derived do not match these provided by the independent wholesale middlemen, such direct channels will not be used.

The various selling and promotional aids which are necessary in the channel also play an important role in determining the channel relationships that emerge. The more control a firm feels that it needs over the

ways by which the final resellers dispose of its products, the more direct is the channel of distribution likely to be. There is a trend for manufacturers of many consumer products toward providing an increased amount of assistance to their channel members.

At the retail level it starts with simple point of purchase display materials and extends to include cooperative advertising and promotional allowances generally; it may go so far as to involve sending out missionary salesmen or detailmen to further encourage the retailer to sell and promote the manufacturer's product the way he prefers it to be done.

In choosing his channel arrangement, a manufacturer must take factors into consideration. If a channel member refuses to participate in a cooperative venture by doing little or nothing, the manufacturer may be forced to bypass him and choose another alternative. Without such cooperation, the manufacturer's entire marketing program may be in jeopardy. It should be pointed out that in one way or another such cooperation is purchased by the manufacturer. Indeed, all the benefits in the way of availability, promotion, and other services that a middleman may offer are obtained at a cost to the manufacturer—the manufacturer must weigh the benefit against the cost.

CASE IN POINT

McKesson

How technology may be utilized to revamp the operations of a wholesaler, making it worthwhile to adopt indirect channels, is illustrated by the case of Foremost-McKesson, the nation's largest wholesale distributor. In the 1970s the company found itself in a precarious position. Distribution, although one of the company's most pervasive business functions, did not pay. It merely took manufacturers' goods and resold them to small retailers through a routine process of warehousing, transportation, and simple marketing that offered thin profits. In 1975, the company earned a tiny 5.9 percent on equity, and its profit growth of 2 percent per year meant slow liquidation because of inflation. As a matter of fact, the company came close to selling off drug wholesaling, its biggest business. Instead, however, its new chief executive decided to add sophisticated technology to Foremost's operations, in order to make the company so efficient at distribution that manufacturers could not possibly do as well on their own. It virtually redefined the function of the middleman. Having used the computer to make its own operations efficient, it devised ways to make its data processing useful to suppliers and customers in a way that

made Foremost become, in essence, part of their marketing teams. Since the company computerized its operations, Foremost has turned around dramatically. Profits that had grown at an average of 2 percent per year for five years until 1976 have since grown at 20 percent per year. Foremost earned $69.9 million on sales of $4.2 billion in its fiscal year ending March 31, 1981. Here are the highlights of Foremost's steps in reshaping its role:

- *Acting as middleman between drugstores and insurance offices by processing medical insurance claims.*
- *Creating a massive "rack jobbing" service by providing crews to set up racks of goods inside retail stores, offering what amounts to a temporary labor force that brings both marketing know-how and Foremost merchandise along with it.*
- *Taking waste products as well as finished goods from chemical manufacturers, and recycling the wastes through its own plants – its first entry into chemical waste management.*
- *Designing, as well as supplying, drugstores.*
- *Researching new uses for products it receives from manufacturers. Foremost found new customers, for example, for a Monsanto Co. food preservative, from among its contacts in the cosmetics industry.*

Source: *Business Week*, December 7, 1981.

APPENDIX

*Institutional Marketing, Distribution and Procurement of Pharmaceuticals Through Drug Wholesalers**

The advent of Medicare and Medicaid in 1965 increased government's role in providing health care benefits to indigent and elderly citizens. These two programs were founded on the philosophy that health care was a right of all Americans. The health care industry took this philosophy to heart. Expansion of services and their associated costs occurred in all segments of the health care delivery system. The hospital segment was responsible for the majority of the cost increases experienced. Expenditures for health care grew 15 percent per year while the concurrent gross national product grew less than 10 percent per year.

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*Reprinted by permission of the National Wholesale Druggist's Association.

During the 1970's, federal and state governments and private sector payers became increasingly alarmed by the rapid rise in health care delivery costs. The pharmaceutical industry—particularly product manufacturers*—were often the focus of attention, due in great measure to their financial success and visibility in the stock market.

Pharmaceutical manufacturers' success was primarily due to their ability to market innovative new products. However, another significant reason for their success was aggressive marketing to hospitals as well as retailers.

During this same period, a few drug wholesalers began working directly with large hospitals and hospital buying groups to develop a "prime vendor" relationship. This contractual relationship provided an opportunity for the wholesaler to supply the majority of pharmaceutical and related products to these institutions for a specified period of time. In return, the drug wholesaler agreed to specific prices and value-added services.

Changes in Medicare, Medicaid, and other third-party programs were initiated in an effort to curtail the rate of health care cost increases. The federal government's initiatives culminated in the passage of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. This act radically altered the federal government's method of Medicare reimbursement.

Medicare reimbursements to hospitals were now to be made on a prospective rather than retrospective basis, as was the case prior to the act's passage. A system of diagnosis related groups (DRG's) was instituted. Under the DRG program, Medicare reimbursement is set at the time of the patient's admission according to a specific diagnosis group categorization formula. If the hospital incurs expenses greater than this fixed amount, it suffers a loss. Conversely, patient admissions treated for less than the DRG-specified amount provide the hospital with a profit.

Once considered a profit center, the hospital pharmacy under a prospective reimbursement system is now considered a cost center. The cost of warehousing pharmaceuticals in the hospital contributed significantly to this change in perception. Hospital buying groups and individual hospitals turned to the prime vendor purchasing system as a method to reduce this cost by shifting the physical inventory and management burden to drug wholesalers.

As the prime vendor concept grew in acceptance, drug wholesaler sales to these institutions grew dramatically. With the shift to the prime vendor system, the relationship between hospitals, hospital buying groups, and

*Throughout this document, manufacturer refers to either the actual manufacturer or labeler of the product.

the pharmaceutical manufacturers changed. Direct purchasing lost appeal. However, the advantages for both the hospitals and manufacturers of the bid system of purchasing pharmaceuticals supported its continuation.

In an effort to maintain competitive advantages, manufacturers continued to use low bid pricing to hospitals. The potential to influence physician, medical resident, and interns' prescribing habits continued to be a strong force in their marketing strategies. Competition between multisource, pharmaceutical manufacturers often resulted in hospital bid prices that were significantly lower than prices normally charged to the drug wholesalers or direct purchasing retailers.

The low bid price at which drug wholesalers sold products to these institutions minus their normal, higher purchase price, yielded a difference. This difference was then "charged back" to the manufacturer.

Therefore, a chargeback can be defined as wholesaler debit memo to manufacturers. They are used when a vendor establishes a special price for a specified item during a specific period of time for qualified institutions and the item is supplied out of the wholesaler's regular inventory. Since the wholesaler purchases the item at the regular price, chargebacks provide a mechanism by which the vendor can reimburse the wholesaler for the difference between the wholesaler's current product cost at invoice date of sale to the hospital and the special or contract price.

Under the chargeback system, the drug wholesaler is responsible for documenting hospital contract sales and reporting the information back to the manufacturers. The report includes the following information: DEA number, NDC number, item description size, date filled, invoice number, quantity, unit cost, contract cost, extended chargeback, contract number, total item record count, total credit due, and debit memo number. It should be noted that the wholesaler's fee for service is not a part of the chargeback process, but a separate amount added to the product net bid price.

In light of the fact that a significant number of manufacturers contract with hospitals or hospital buying groups, a major portion of the prime vendor hospital sales are conducted on a chargeback basis. The reporting requirements outlined above add tremendously to a distributor's administrative costs. Another factor which significantly contributes to this administrative burden is the insistence of some manufacturers that a hospital will be serviced under only one designated group contract, even if the hospital is a member of several buying groups. The distributor must not only keep track of all needed information, but further, he must track which buying group contract each manufacturer will honor for each hospital.

Initially, chargeback claims were sent in hard copy (paper) from drug

wholesalers to manufacturers. They, in turn, would check the claim against contract specifications and, barring any discrepancies, send a credit or payment for the chargeback to the wholesaler. As chargeback volume grew, the paper-based manual processing system began to bog down. Slow processing and increased outstanding dollar amounts of chargeback claims became a significant accounts receivable problem for the prime vendor drug wholesaler. In an effort to resolve these difficulties, several drug wholesalers and manufacturers developed computer transmission of chargeback claims.

In 1983, prompted by industry-wide concerns about the amount of outstanding chargeback monies and the length of time it was taking to process chargeback claims, the NWDA Board of Directors approved and funded an ad hoc committee to address these issues.

Composed of manufacturers and wholesalers, the Ad Hoc Committee on Chargebacks was asked to study the problem and report its findings to the NWDA membership. In the spring of 1985, the committee's findings were reported in a paper entitled "The Problems and Opportunities Presented by the Marketing and Distribution of Specially Priced Ethical Pharmaceuticals by Manufacturers Through Drug Wholesalers."

Concurrently, the NWDA Business Systems and Pharmaceutical Marketing Committees developed an electronic chargeback reporting system. In addition to an industry standard for chargeback documentation, the committees developed chargeback reconciliation and bid award notification formats. These electronic standard formats were tested by several drug wholesalers and pharmaceutical manufacturers. They then were presented to the industry in 1984 and 1985. Implementation of these standards resulted in greater accuracy and speed of information transfer between drug wholesalers and manufacturers. A resultant reduction in chargeback processing time was quickly evident. After implementation of electronic processing, the range of average processing times was reduced from 30 to 120 days to 30 to 60 days. In some rare cases it was dropped to as low as two to five days.

In March of 1985, NWDA sponsored a Hospital Marketing Conference. It was attended by sales, marketing, bids administration, data processing, and financial management executives from drug wholesalers and pharmaceutical manufacturers. The conference provided an opportunity for those in attendance to review, discuss, and propose possible resolutions to many of the problems identified in the ad hoc committee's report. This first conference also brought the realization that many of the issues/problems could best be addressed through a three-party exchange—drug wholesalers, pharmaceutical manufacturers, and hospitals/groups.

In February of 1986, NWDA sponsored the NWDA Hospital Marketing Symposium, which brought together the wholesaler, manufacturer, and hospital/group executives. Symposium registrants re-examined known issues/problems, identified new issues/problems, and in certain instances, proposed solutions. With the hospital/hospital buying group representatives as active participants, all parties were able to gain a better understanding and awareness of the entirety of the pharmaceutical product bid purchasing system.

Nine major issues/problems were identified during the symposium. They were:

1. administrative complexities due to multiple group membership by hospitals
2. eligibility of buying group members
3. lack of standardization in bid solicitation
4. the need for procedures to handle returned goods within the chargeback process
5. determining product cost in the chargeback claims process
6. reducing turnaround time on chargeback credits from manufactures to wholesalers
7. lack of standardization in the hospital/group contract with prime vendor drug wholesalers
8. lack of standard time frames throughout the process
9. the lack of standardization in hospital usage reporting

The outcome of this symposium was a call for NWDA to recommend a more effective and efficient system of institutional marketing, distribution, and procurement of ethical pharmaceuticals through drug wholesalers to the benefit of all parties.

Chapter 10

Product

"Product," to refer to the definition used in Chapter One, is: the benefits or positive results that markets derive out of doing business with the company using the products you offer in the way you offer them.

People do not buy drills, it is said, they buy holes. Similarly, patients do not want medication—they want relief from pain, a longer life, or better function. Those who prescribe or dispense to those patients want those things as well as their own professional needs to be satisfied.

Ultimately, it is the product strategies which eventually come to dominate the overall market strategy of the company. In this chapter we will discuss product strategies from the several aspects listed below. The new product strategy will receive the most attention—as it does in the industry.

Aspects of Product Strategy

- Product-Scope Strategy
- New Product Strategy
- Product Positioning Strategy
- Product Repositioning Strategy
- Product Elimination Strategy
- Diversification Strategy

PRODUCT-SCOPE STRATEGY

The product-scope strategy deals with the perspectives of the product mix of a company (i.e., the number of product lines and items in each line that the company may offer). The product-scope strategy is determined by making a reference to the business mission. (See Chapter 6.) Presumably, the mission defines what sort of business it is going to be, which helps in selecting the products and services which are to become a part of the product mix.

The product-scope strategy must be finalized after a careful review of all facets of the business since it involves a long-term commitment. Addi-

tionally, the strategy must be reviewed from time to time to make any changes called for because of shifts in the environment. Product-scope strategy is also related to market-scope strategy. The strategies alternatives discussed briefly here are:

- Single Market
- Multimarket
- Total Market
- Single Product
- Multiple Products
- System of Products

Single Market

A variety of reasons may lead a company to concentrate its efforts on a single segment of the market. For example, a small company, in order to avoid confrontation with large competitors, may find a unique niche in the market and devote its energies to serving this market. The single-market or niche strategy is often born of necessity. Lacking the resources to fight head-to-head battles across the board with larger, entrenched competitors, the winners typically seek out niches that are too small to interest the giants or can be captured and protected by sheer perseverance and by serving customers surpassingly well. Two examples are Serono Labs and Adria.

Single Product

A business may have just one product in its line and try to live on the success of this one product. There are several advantages to this strategy. First, concentration on a single product leads to specialization, which helps in scale and productivity gains. Second, management of operations is much more efficient when a single product is the focus. Third, a single-product company may become so specialized in its field that it can stand any competition.

Innovative imitation may not only gain a foothold into a fruitful market, but may go a long way toward preventing a decline. Ortho Pharmaceuticals, for example, might have been content to remain in the "prophylactics and diaphragm" business. Instead, defining their "market province" to be control of conception, they were ready with their own version of the oral contraceptive early in the development of this market.

Despite its obvious advantages, the single-product company has one drawback: if changes in the environment make the product obsolete, the single-product company can be in deep trouble.

The single-product strategy has an additional drawback. It is not conducive to seeking growth or market share. Its main advantage is profitability.

If a company with a single-product focus is not able to earn higher margins, it is better to seek a new posture. Companies interested in growth and/or market share will find the single-product strategy to be of limited value.

Multimarket

Instead of limiting business to one segment and thus putting all its eggs in one basket, a company may opt to serve several distinct segments. To successfully implement the multimarket strategy, it is necessary to choose those segments with which the company feels most comfortable and in which the company is able to avoid confronting companies that serve the entire market. This strategy accepts the premise that it is possible to differentiate between such markets as: prescription and OTC, hospital and drugstore, brand name and generic, etc. Strategy is then formulated accordingly.

Multiple Products

The multiple-products strategy amounts to offering two or more products. A variety of factors leads companies to choose this strategic posture. A company having a single product has nowhere to go if that product gets into trouble; with multiple products, however, poor performance by one product can be balanced out. In addition, it is essential for a company seeking growth to have multiple product offerings.

While not all products may be fast-moving items, they must complement each other in a portfolio of products. (See Chapter 7.) The multiple-products strategy is directed toward achieving growth, market share, and profitability. Not all companies will prosper simply by having multiple products. This is because growth, market share, and profitability are the functions of a large number of variables, only one of which is having multiple products.

Total Market

A company using the total-market strategy serves the entire spectrum of the market by selling different products directed toward different segments in the market. The strategy evolves over a great number of years of operation. As the market grows and different segments emerge, leading competitors may attempt to compete in all the segments. This may be done by employing different combinations of product, price, promotion, and distribution strategies. These dominant companies may also attempt to enter new segments as they emerge.

The total-market strategy is risky. For this reason only a very small number of companies in an industry may follow this strategy. It requires a top management commitment to embracing the entire market. Additionally, a company needs an ample amount of resources to implement this strategy. Finally, only companies in a strong financial position may find this strategy attractive.

System of Products

The word "system" as applied to products is a post-World War II phenomenon. Two related forces have been responsible for the emergence of this phenomenon. These are the popularity of the marketing concept that businesses do not sell products but customer satisfaction, and the complexities of the product itself which call for the use of complementary products and after-sales services.

Offering a system of products rather than a single product is a viable strategy in a number of ways. It makes the customer fully dependent on the company, which in turn gains monopolistic control over the market. Additionally, the system-of-products strategy blocks the way for the competition to move in. With such benefits this strategy is extremely useful in seeking growth, profitability, and market share.

The successful implementation of this strategy requires a thorough understanding of customer requirements, the processes and functions the consumer must perform when using the product. Effective implementation of this strategy broadens both the company's concept of its product and the market opportunities for it, which in turn help meet the product/market objectives of growth, profitability, and market share.

NEW PRODUCT STRATEGY

New products continue to be the life blood of the research-intensive pharmaceutical industry. They may be new in the sense of new chemical entities, new to an individual firm's product line, or a new name for an existing (especially OTC) product. However, new products are usually necessary for sustained profitability and growth.

Top management can effect the implementation of new-product strategy: first, by establishing policies and broad strategic directions for the kinds of new products the company should seek; second, by providing the kind of leadership that will create the environmental climate needed to stimulate innovative drive in the organization; and third, by instituting review and monitoring procedures so that the manager is involved at the

right decision points and can know whether or not work schedules are being met in ways that are consistent with the broad policy direction.

New product strategies can focus on imitation of existing products, modification and improvement of existing products, or truly new products. The latter will receive the most attention here, but all of these are widely employed in the drug industry.

Product Imitation

True product imitation is, of course, the heart of the generic drug industry. Indeed, the FDA requires the imitation to be identical, at least insofar as its bioequivalence is concerned. A sort of quasi-imitation exists in the form of new, patented drug products that are molecular analogues of existing products, but which offer no therapeutic advantages. (The FDA, in fact, makes such a judgement on each new product. See Table 10-1.)

This strategy particularly suits companies with limited resources. Many companies, as a matter of fact, develop such talent that they can imitate any product, no matter how complicated. With a limited investment in research and development, the imitator may sometimes have a lower cost, which gives it a pricing advantage in the market over the leader.

The imitation strategy may also be adopted on defensive grounds. Being sure of its existing product(s), a company may initially ignore new developments in the field. If the new developments become overbearing, however, they may cut into the ground held by the existing product. In such a situation, a company may be forced into imitating the new development as a matter of survival.

It should be noted that truly innovative imitation attempts to improve upon the original article, and as such tends to lend its own contribution to better pharmaceuticals. On balance the gains to be realized by this type of competitive activity seem to outweigh the problems created by the numbers of available drugs.

The pioneer in the field has a strong talking point when referring to his need to recover his research and development costs plus a fair profit in a short period. All of his advertising, no matter how actively oriented toward promotion of his brand name, tends to contribute to the primary demand for the product type, and thus aid his competitors. Further, by the very fact that he is first, he must take some stand as to products and policies. The followers, then, are free to deviate from this stand and, if these deviations are good from a marketing point of view, to profit by it.

TABLE 10-1. FDA rating and classification system for new drugs

Chemical Type

Number	Classification	Number	Classification
1	**New molecular entity** The active moiety is not yet marketed in the U.S. by any drug manufacturer either as a single entity or part of a new combination product.	4	**New combination** Contains two or more compounds which have not previously been marketed together in a drug product by any manufacturer in the U.S.
2	**New salt** The active moiety in the U.S. by the same or another manufacturer but the particular salt, ester, or derivative is not yet marketed in the U.S. by any drug manufacturer either as a single entity or as part of a combination product.	5	**Already marketed drug product** The product duplicates a drug product (the same active moiety, same salt, same formulation, or same combination) already marketed in the U.S. by another firm.
3	**New formulation** The compound is marketed in the U.S. by the same or another manufacturer, but the particular dosage form or formulation is not.	6	**Already marketed drug product by the same firm** Used primarily for new indications for marketed drugs.

Type	Classification	Type	Classification
A	**Important therapeutic gain.** Drug may provide effective therapy or diagnosis (by virtue of greatly increased effectiveness or safety) for a disease not adequately treated or diagnosed by any marketed drug, or provide improved treatment of a disease through improved effectiveness or safety (including decreased abuse potential).	M	**Drug already marketed in a foreign country.**
		R	**Drug is subject to specific** unique conditions of approval (i.e., additional studies) outlined in appropriate or approval letter for NDA.
		T	**Important problem in** toxicity, i.e., carcinogenic in animals.
B	**Modest therapeutic gain. Drug** has a modest, but real potential over other available marketed drugs - i.e., greater patient convenience, elimination of an annoying but no dangerous adverse reaction, potential for large cost reduction, less frequent dosage schedule, useful in specific subpopulation of those with disease (i.e., those allergic to other available drugs), etc.	U	**Drug is likely to be used in** children.
		D	**Special situation. Drug has** decreased safety or effectiveness compared with alternative marketed drugs, but also has some compensating virtue (i.e., provides treatment for patients who do not respond to or are intolerant of alternative drugs)
C	**Little or no therapeutic gain.** Drug essentially duplicates in medical importance and therapeutic usage one or more already marketed drugs.	P	**A very important feature of** application is the packaging
		S	**Application is sensitive by** virtue of wide publicity, congressional interest, unusual request from firm, etc.

Product Improvement/Modification

An existing product of a company may reach a stage which requires that something be done to keep it viable. The product may have reached the maturity stage of the product life cycle because of shifts in environment, thus ceasing to provide an adequate return. Or new-product, pricing, distribution, and promotion strategies employed by competitors may have reduced the status of the product to a "me-too" category. At that stage management has two options: either to eliminate the product or to revitalize it by making improvements or modifications. Improvements or modifications are achieved by redesigning, remodeling, or reformulating so that the product satisfies customer needs more fully. This strategy seeks not only to restore the health of the product, but also sometimes to help in distinguishing it from those of competitors.

There are a number of reasons for "molecule manipulation" within a firm's product line. Sometimes an expiring patent may move a firm to search for a slight but patentable modification of a successful product (Chlor-Trimeton and Polaramine). Sometimes, however, slight modifications bring about completely new uses for the compound. The levo-form of Lilly's propoxyphene (an analgesic) was found to have antitussive properties, for example. Often, efforts are made to provide a full spectrum of analogues active in different types of conditions, or at least sufficiently different to be promoted for these differing conditions. Tranquilizers in a series are often handled in this manner. Further, it has been shown that the introduction of a new product by a firm having an older one already a success usually exerts an incremental effect on sales, rather than cutting into the market share of the established product. Finally, in the understandable rush to be first, some firms may market the first product possible, with the acknowledged aim of replacing it with another at a later time.

Structural modifications are not, of course, the only means of changing the character of existing products. Another method is finding new uses for them.

*New Product Development**

New product development and marketing in the pharmaceutical industry, perhaps as in no other industry requires the close and efficient cooperation of the research and the marketing functions in the firm: The interface between basic research whence come (one hopes) the breakthrough chem-

*Much of the material in this section was adapted from Richard E. Faust's chapter in the Third Edition of this book.

ical compounds and marketing, charged with the creation of a successful promotion/price/distribution plan, is the site of action of drug development. Drug development is the process by which a chemical entity is transformed into a drug product.

The success of a pharmaceutical firm is the result of more than just the efficiency of its research and development (R&D) laboratories, however, because the input of research is essentially information that is used by manufacturing and marketing to make and to sell products. For the pharmaceutical firm to be successful, these three key functions must operate in an integrated and productive manner.

All regulatory and pricing policies that make it difficult for marketing to compete successfully will also affect the research process indirectly. Consequently, the technoscientific success of the pharmaceutical company is dependent upon the integration of key functions and the proficiency of research to create, manufacturing to make, and marketing to sell new and improved products.

More attention is being given to the development of the total corporation through managed creativity applied to every business function. In addition to new and improved products and processes, corporations may seek growth and efficiency through new distribution channels and customers, new financial and administrative practices, and new marketing strategies. Close interaction with and collaboration between R&D and marketing is therefore needed to support various corporate development plans and objectives.

Unquestionably, investing in long-range R&D requires an act of faith by top management. In spite of all the elaborate models available for identifying market opportunities, establishing research priorities, and forecasting return on investment, research investment still requires the judgment of top level managers. There is little doubt, however, that the success of a major new drug product can have a profound impact on a firm's sales and profit profile, and it is this possibility that often encourages continued investments in R&D in many firms. The introduction of Tagamet, the new drug for the treatment of ulcer disease contributed significantly to a near doubling in sales and profit for the SmithKline Corporation for the nine months ending September 30, 1978, as compared to the same period a year earlier. Merck went through a dry spell with no significant new drug being introduced from 1965 to 1975. The firm continued to invest heavily in research that developed important new products that provided an excellent revenue stream in the 1980s.

The nature of the "research planning" function varies considerably within pharmaceutical firms but, in general, it focuses on the allocation of

research resources involving project selection and monitoring. It may also encompass such activities as those associated with generating R&D budgets and forecasting output, personnel administration, and organizational development.

Research functional or operational plans are often designed to convey the status of research activities and commitments, to present a profile of the use of research resources, and to generate a picture of outputs both in the near and long term. Most research plans seek to create a balance between programs yielding near-term results (1 to 5 years) and those providing rewards further out in time (5 to 10 years). In addition, the major research-oriented firms invest in more exploratory or basic programs that may be termed "new horizon research," in which the payback may not occur for at least 15 to 20 years. The contents of a typical strategic or functional research plan may be outlined as follows:

I. Introduction: A statement of the orientation of the plan, its relationship to previous and related plans, and current information being developed in research.
II. Objectives: A statement of research objectives and their relationship to corporate and business objectives.
III. Research Environment: An overview of research and how it is affected by competitive R&D trends, political-legislative pressures, various major scientific and technological factors, and socioeconomic forces. Strategies to respond to these dynamic environmental elements are presented.
IV. Research Resource Analysis: An analysis of research personnel, expenses, and facilities, including recent growth patterns, current allocations, and present needs.
V. Drug Development Project Analysis
    A. Drug development projects (year 1 to 5)
    B. Drug development projects (year 5 to 10): The compounds projected in the pharmaceutical business plan are analyzed using a "one-pager" format that encompasses such information as the project objective, sales projections, patient status, development timetable, and competitive products.
VI. Exploratory Research Activities
    A. Overview of exploratory effort: Perspectives on magnitude of the effort, emerging trends and changing patterns, and commentary on research activities that have an impact on broad areas, such as aging.

B. Important research areas and activities: A review of current important and emerging research efforts and integrated programs aimed at generating significant new products and product leads beyond those of the current project planning period.

VII. Support for Marketed Products: A summary of research efforts aimed at developing new dosage forms and indications, as well as special clinical and other studies that support current products.

VIII. Research Operational Improvement Strategies and Goals: An elaboration of research actions, plans, and strategies aimed at improving operations and the probability of success over the planning board; an assessment of broad trends, patterns, and considerations to aid in evaluating research output and contributions to corporate success.

IX. Research Requirements and Resource Projections: A profile of personnel, funding, and facility needs during the next 5 years, including perspectives on alternative output patterns influenced by the magnitude of budget and personnel increases.

X. Planning Highlights and Summary: An overview and summary of planning goals, operating strategies, and achievements projected for the near, mid, and long term.

A strategic business plan is designed to convey the thrust of the business operation. The areas covered usually include an analysis of environmental forces and other factors that influence the success of the enterprise and indirectly impact on R&D. The contents of a typical pharmaceutical strategic business plan may be outlined as follows:

I. Description and Purpose of the Business: A statement of the basic business growth strategy and goals of the marketing area that presents a picture of the business and its general plans for the planning period, usually 5 to 10 years.

II. Environmental Analysis: An overview of the environmental forces affecting the business, such as increased substitution, more generic prescribing, efforts to reduce health care costs, inflation, patent expirations, concern for "orphan" drugs, increased competition, and various governmental regulations.

III. Critical Issues: Many plans contain a description of important issues that will affect the success of the business over the planning period. These issues and concerns will vary with the firm, but they might include such topics as

A. The impact of various special regulations, such as Drug Efficacy Study Implementation (DESI) and Controlled Substances Act (CSA) on the product line.

B. The patent status of marketed products.

C. Inventory current research programs and commitments to improve allocation of resources.

D. Establish mechanisms for research program review to ensure consistency with business objectives and goals. These various action strategies in a business plan are similar to those found in a typical research planning document. They illustrate dramatically the need for close collaboration between R&D planners and those marketing personnel responsible for generating the business plan.

IV. Strategies and Programs: Once critical operational areas have been identified, strategic plans usually describe how the business intends to meet these challenges and to ensure growth and profits. Because one critical issue usually centers on the flow of new products from research over the planning period, various strategies are often mentioned that are designed to improve research productivity and to enhance the functional interface between research and marketing groups. Under a plan to "improve research productivity," one might find such action strategies as the following:

A. Improve criteria for product candidate selection for development and evaluate compliance to criteria throughout development.

B. Improve the priority-setting process and communication of priorities for research and product development programs.

C. Inventory current research programs and commitments to improve allocation of resources.

D. Establish mechanisms for research program review to ensure consistency with business objectives and goals. These various action strategies in a business plan are similar to those found in a typical research planning document. They illustrate dramatically the need for close collaboration between R&D planners and those marketing personnel responsible for generating the business plan.

V. Resource Requirements: This section of the planning document presents a detailed analysis of the projected output over the planning period, including sales from existing and new products and dosage forms. The resources needed (e.g., facilities, capital, and personnel) for this are also projected over the planning period. Often probabilities are used to forecast output and, in some cases,

an "optimistic," "pessimistic," and "most likely" forecast is presented that is also closely connected to research productivity.

It is obvious that the impact of marketing on the R&D process varies with the stage of the process. (See Table 10-2.) As we move from the exploratory end of the R&D spectrum to the point at which leads are identified and a decision is made to pursue an IND and an NDA, the goals of projects become better defined and the role of marketing increases. At any point either inadequate marketing inputs or attempts to exert excessive control over the research process can create major problems. Difficulties may also arise when research programs are too unstructured and are not in tune with marketing strategies and the near-term concern for increased revenues and profits. Once projects are formalized, marketing needs to

TABLE 10-2. Parallel courses in new product development: Bridging the gap between basic science and marketing research

Stage	Basic Science	Marketing Research
Idea generation	-Component synthesis -New dosage forms -New delivery systems	-New product/service ideas
Screening	-Animal studies of pharmacology, therapeutic activity, and toxicology	-Ratings of product potential and company strengths -Market profile of disease prevalence, population/epidemiological trends, and competition -Competitive strategies -Product life cycles
Business and medical analysis	-Added animal studies and Phase I, II, and III human studies	-Decision makers' reactions to the product concept and suggestions for product development -Quantification of market potential to the product concept, and marketing strategies -Positioning studies, evaluation of promotional themes, segmentation analysis -Sales force training and deployment studies -Subjective patient evaluations and preferences

Development	-Completion of clinical studies -Dosage form, delivery system research	-Naming studies -Packaging studies -Marketing tactics research - ad copy testing, pricing studies
Test marketing		-Experimental evaluation of product performance and marketing strategies /tactics
Commercial-ization	-Phase IV studies	-Evaluation of marketing tactics implemented, progress toward sales goals, model validation -Documentation of product life cycles -Development of strategies for later stages of the product life cycle and competi-tive counterstrategies

Source: Robert N. Zelnio and Juliet G. Zimmerman in *Pharmaceutical Executive*, July, 1984.

monitor progress and to provide important insights concerning (1) the nature of the clinical studies to be undertaken and the desired claim structure for the product, (2) dosage forms to be developed, and their characteristics, and (3) the timing of the NDA submission.

Marketing should also exert considerable influence on research activities in support of existing products, including broadened claims, new dosage forms, and overall defensive efforts. Because of the decline in the evolution of new chemical entities over the past two decades, there has been more emphasis on defensive projects, those aimed at prolonging the life cycle of currently marketed products. Even in the large research-based firms, as much as 20 to 25 percent of the R&D budget may be directed to such defensive activities.

In some firms a formal statement of marketing interests and opportunities in various therapeutic categories is developed by marketing specialists, and is presented to research scientists as a guide to research decision making in the selection of R&D programs and projects. The marketing overview usually includes such information as market definition and potential, patient prevalence, current sales data and projections, leading marketed products, prescribing patterns, and competitive trends. In some cases marketing experts may provide specific suggestions to research such

as those on Table 10-3, noting potential sales for products that might be developed.

Project selection decisions are often influenced by a number of important considerations in addition to the size of the research budget. It should be noted that many research, manufacturing, and marketing concerns must be considered that influence project selection decisions. Consider, for example, the following factors for a firm wishing to develop a market position in antibiotics, essentially a new area for the firm that has a couple of exciting research leads.

1. Do we have specific objectives in the antibiotic field with regard to market position by a targeted date? Can we obtain commitment of resources (e.g., people, funds, facilities) to obtain these objectives? Should our emphasis be near term (2 to 3 years) or long term (5 to 10 years)?
2. What are the risks and uncertainties associated with the effort? What are the financial implications of these uncertainties?
3. What is the nature of the competition in terms of marketed products and current development efforts? What are their strengths, weaknesses, and abilities?
4. What other known antibiotics are actively being developed? What are their potential market advantages and disadvantages?
5. What are the competitive advantages of the products we are considering to develop? What is the expected market life cycle? Are there possible follow-up products?
6. What are the pricing structure and profit trend with antibiotics?
7. Who are the customers (e.g., physicians, third-party payers, government) and what value is each looking for? How will value differences affect our market positioning and opportunities?
8. Can we market antibiotics more successfully with a dedicated sales group or through our existing field force? Are special promotional efforts needed?
9. How will products be produced? If agents are manufactured by us, where? How much investment is needed? Do we have adequate in-house technical expertise to manufacture? What are the new material requirements? Do we need specialized facilities?
10. What is the patent position for each of our potential market entities? Are areas of litigation of concern?
11. What is the R&D cost to support our strategy? Do we have the internal technical and scientific expertise to support the needed research effort? How will a move to antibiotic research impact other research projects and programs?
12. If we accomplish our objectives, what is the likely response of our

competitors? How will we respond to them and what will be the impact on our market share and profitability?

In addition to the interactions between marketing and research that occur during the drug development stage in the category of project management, most firms have new product coordinators in marketing who are concerned with developing market plans for existing products and who have, in addition, a vital interest in new products moving toward NDA approval. Because these products, when approved, are assigned to the product planning function, personnel in this area seek to become involved during the latter stages of the drug development cycle. The job description

TABLE 10-3. Market potential of possible new products

	Fifth Year Sales Potential ($)
Single-entity hypotensive agent, with new mode of action, effective for mild to severe hypertension without significant side-effects (e.g., prostaglandin, ionophore).	150 million
Centrally acting hypotensive agent with a significant reduction in the incidence of sedation and sexual dysfunction occurring with current products.	75 to 100 million
A cardiospecific beta blocker with once- or twice-a-day dosage marketed within the near future.	70 to 80 million
A uricosuric potassium-sparing diuretic with hypotensive activity free of ticrynafen-like hepatic toxicity.	50 to 75 million
An agent with hypotensive activity that is effective in treating patients with severe hypertension but with a much lower incidence of side-effects than agents currently available.	20 to 25 million
A new class of hypotensive agents with minor improvements in side-effect profile of existing products.	10 to 20 million

Source: Adapted from Statement of Marketing Interests and Opportunities, Project Management Department, Hoffman-La Roche, 1981.

for a product coordinator at a representative company may be described as follows:

The basic function of a product director is to plan for and manage the development of assigned, existing, and new pharmaceutical products as individual businesses by assessing marketing needs and opportunities, developing marketing strategies and responsibility, and directing the application of marketing resources in an optimal manner consistent with the goals of the firm. In this capacity he directs the product- or project-related activities of each member of the marketing teams, composed of the following personnel:

- Advertising manager
- Product sales manager
- Sales planning manager
- Professional services physician
- Professional services writer
- Professional services manager
- Medical affairs physician
- Proofreader
- Marketing research analyst
- Copywriter
- Career development associate
- Other specific team members (as appropriate)

The principal functional responsibilities of the product director are the following:

- Develop annual, intermediate, and long-range marketing and business strategies and plans for the business.
- Manage and recommend to the marketing board strategies and plans relative to pricing, distribution, labeling, trademarking, and packaging associated with assigned products.
- Establish and achieve all quantifiable product, project, and personnel objectives.
- Develop unit and dollar sales projections to ensure appropriate planning to meet the anticipated needs of the marketplace and achievement of profit plans.
- Recommend and develop appropriate new dosage forms strategy and plans for assigned products to maximize opportunities.
- Conduct team meetings, foster communications among team members and departments, and issue appropriate and timely minutes.

- Work with sales management to achieve national and regional sales strategies and plans.
- Direct selected projects that will impact across product lines and influence future business policies of the firm.
- Ensure, through leadership and direction, that the planning, developing, implementation, and monitoring of marketing programs conform with and fully support the product plan.
- Initiate and maintain appropriate linkage between the product and project teams and other functional resources, such as distribution, drug regulatory affairs, finance, law, materials management, product development, packaging development, production, manufacturing, facilities planning, research, public relations, public policy, business development, and strategic planning.
- Communicate and actively participate with research and project management to ensure that product research and development plans are implemented that fulfill agreed-to strategies for assigned products and therapeutic areas.
- Coordinate to achieve mutually satisfactory resolution of any actual or potential conflicts identified between assigned product marketing strategies or programs and existing local, state, or federal laws and regulations.
- Monitor social, political, economic, regulatory, and legal trends affecting the pharmaceutical industry and assigned markets, and react with recommendations.
- Consult with and engage outside support, consultants, and agencies to ensure the continuous generation of new, innovative, and creative ideas for product and project objectives.
- Establish budgets, budget mix, and monitor expenditures by specific media and target audiences for products or projects.
- Anticipate and apprise management of changes in the marketplace and initiate modifications to the marketing plan based on evolving market dynamics.
- Exercise final team approval on promotional copy and field communications related to assigned products.
- Assume responsibility in concert with appropriate department heads to assist team members in the informal training process relative to team interactions and activities.
- Participate and interact with broad chartered committees, such as FDA production committee, product coordinating committee, project teams, and product management review committee.

- Coordinate the response to FDA relative to assigned marketed products with drug regulatory affairs and others.
- Input into project management to maximize potential marketing opportunities prior to issuance of the transfer document.
- Review and comment on selling emphasis programs.
- Recommend appropriate allocation of sales efforts for the pharmaceutical line to the sales department and marketing board for the current planning period.
- Launch new products.

CASES IN POINT

Merck Invests in Basic AIDS Research

In 1986, P. Roy Vagelos, the intense chief executive of Merck & Co., fired off an unusual order to his research troops: Merck would immediately join the race by scientists around the world to thwart the epidemic of acquired immune deficiency syndrome.

Scientists at the pharmaceutical company usually wait for so-called basic research on disease to bubble up from universities before exploring drug applications. Suddenly, they were thrust onto new ground: Their laboratories were expected to make discoveries in basic research of an extraordinarily complex ailment. . . .

Dr. Vagelos, though, says he is "damn optimistic" Merck will find a blocker drug. While a vaccine to combat AIDS is perhaps more than a decade away, he says, "an effective therapy to treat those already infected will be developed first, conceivably within five years."

Merck's AIDS research clearly evolved as his personal campaign. A highly competitive man not given to small talk, Dr. Vagelos, 50 years old, was trained as a physician and was formerly Merck's top scientist. He has said he wants Merck to develop drugs against every major disease category before he leaves office. And he has told company managers he wants Merck to be among the first in finding an effective therapy for AIDS, which ravages the immune system. . . .

"Enzyme inhibition is the strength of Merck," says Dr. Vagelos, adding that it is "the main strategy" he promotes for finding new drugs.

Source: *Wall Street Journal*, February 16, 1989.

Gold Medal Drug Development

One group of pharmaceutical consultants argues, persuasively, that the drug development team should be prepared to turn off the drug development process for products that don't "qualify" for the "Product Olympics." A product qualifies by demonstrating characteristics that screen out weaker competitors. A "target package insert" should be designed and studies conducted as early as possible to validate assumed and required advantages.

Examples?

Glaxo's labetolol found an important market niche because targeted clinical trials demonstrated unique alpha-blocking properties important in the black patient market. Ives' Sectral, on the other hand, has unique sympathetic nervous system stimulant properties, but the company did not demonstrate them in the clinical trials that led to market approval.

Source: Jay Kranzler, Norman Selby, Dinah Taylor, Felix Weber in the *Pharmaceutical Executive*, March, 1989.

PRODUCT POSITIONING STRATEGY

The term "positioning" refers to placing a brand in that part of the market where it will have a favorable reception compared to competing products. Since the market is heterogeneous, one brand cannot make an impact on the entire market. As a matter of strategy, therefore, the product should be matched with that segment of the market where it is most likely to succeed. The product should be so positioned that it stands apart from competing brands. Positioning tells what the product stands for, what it is, and how the customers should evaluate it.

Positioning helps in differentiating the product from competitive offerings. Positioning is achieved by using marketing-mix variables, especially through design and communication efforts. While differentiation through positioning is more visible in OTC products, it is equally true of prescription drugs. With some products positioning can be achieved on the basis of tangible differences (e.g., product features); with many others, intangibles are used to differentiate and position products.

The desired position for a product may be determined by use of the following procedure:

1. Analyze product attributes which are salient to consumers.
2. Examine the distribution of these attributes among different market segments.
3. Determine the optimal position for the product in regard to each attribute, taking into consideration the positions occupied by existing brands.
4. Choose an overall position for the product (based) on the overall match between product attributes and their distribution in the population and the positions of existing brands).

Approaches to a positioning strategy take many forms. Among these are:

- Attribute positioning
- Price/quality positioning
- Use/application positioning
- User positioning (See Figure 10-1)
- Product class positioning
- Competition positioning

PRODUCT REPOSITIONING STRATEGY

Often a product may require repositioning. This can happen if (1) a competitive entry has been positioned next to the brand with an adverse effect on its share of the market, (2) preferences have undergone a change, (3) new preference clusters have been discovered with promising opportunities, or (4) a mistake has been made in the original positioning.

Costs and risks of repositioning are high. The technique of perceptual mapping is one that may be gainfully used to substantially reduce those risks. Perceptual mapping helps in examining the position of a product relative to competing products. It helps in:

- Understanding how competing products or services are perceived by various groups in terms of strengths and weaknesses.
- Understanding the similarities and dissimilarities between competing products and services.
- Repositioning a current product in the perceptual space of decision-maker segments.
- Positioning a new product or service in an established marketplace.
- Tracking the progress of a promotional or marketing campaign on the perceptions of target segments.

PRODUCT ELIMINATION STRATEGY

Marketers have believed for a long time that sick products should be eliminated. It is only in recent years that this belief has become a matter of strategy. It is believed that a business unit's various products represent a portfolio and that each of these products has a unique role to play in making the portfolio viable. If a product's role diminishes or if it does not fit into the portfolio, it ceases to be important.

When a product reaches the stage where continued support can no longer be justified because its performance falls short of expectations, it is desirable to pull the product out. Poor performance may be characterized by any of the following:

1. Low profitability
2. Stagnant or declining sales volume or market share which would be too costly to build up
3. Risk of technological obsolescence
4. Entry into a mature or declining phase of the product life cycle
5. Poor fit with the business unit's strengths or declared mission

Products which are not able to limp along must be eliminated. They are a drain on a business unit's financial and managerial resources, which can be used more profitably elsewhere.

Three alternatives in the product-elimination strategy are harvesting, line simplification, and total-line divestment.

Harvesting refers to getting the most from the product while it lasts. It may be considered as controlled divestment whereby the business unit seeks to get the most cash flow it can from the business. Usually, harvesting strategy is applied to a product or business whose sales volume and/or market share are slowly declining. An effort is made to cut the costs associated with such a business to help improve the cash flow. Alternatively, prices are increased without simultaneous increase in costs. Harvesting leads to a slow decline in sales. When the business ceases to provide positive cash flow, it is divested.

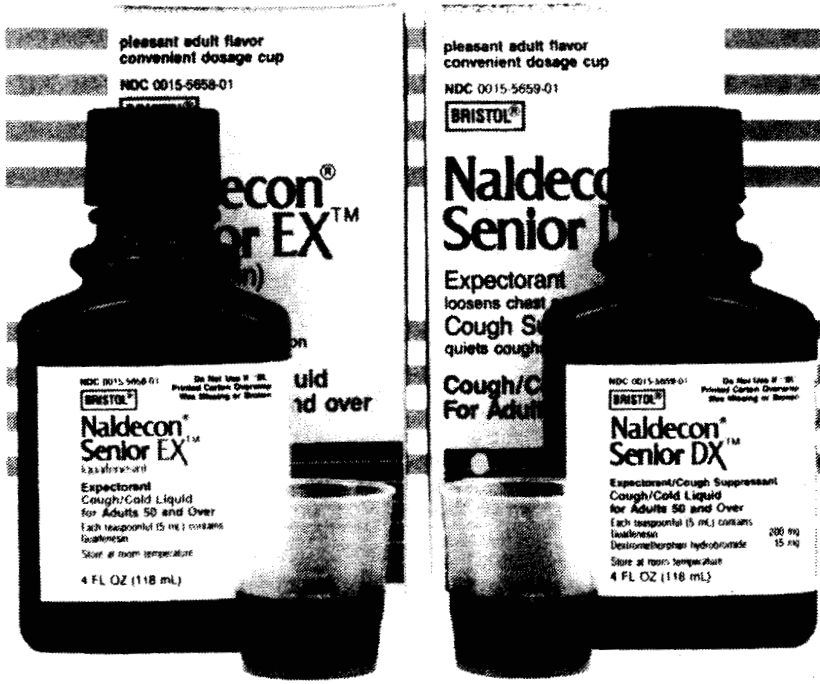
Ideally, harvesting strategy should be pursued when the following conditions are present:

1. The product is in a stable or declining market.
2. The product has a small market share, and building it up would be too costly; or it has a respectable market share that is becoming increasingly costly to defend or maintain.

FIGURE 10-1

Finally, cough relief enters a new age

Introducing...



■ To Encourage Loose, Productive Coughs

Each teaspoonful (5 mL) contains	
Guaifenesin	200 mg

■ To Discourage Dry, Hacking Coughs

Each teaspoonful (5 mL) contains	
Guaifenesin	200 mg
Dextromethorphan hydrobromide	15 mg

Naldecon® Senior

3. The product is not producing especially good profits or may even be producing losses.
4. Sales would not decline too rapidly as a result of reduced investment.
5. The company has better uses for the freed-up resources.
6. The product is not a major component of the company's business portfolio.
7. The product does not contribute other desired features to the business portfolio such as sales stability or prestige.

Line-simplification strategy refers to a situation where a product line is trimmed to a manageable size by pruning the number and variety of products or services being offered. This is a defensive strategy which is adopted to keep the falling line stable. It is hoped that the simplification effort will help to restore the health of the line. This strategy becomes especially relevant during times of rising costs and resource shortages.

The implementation of line-simplification strategy can lead to a variety of benefits: potential cost savings from longer production runs; reduced inventories; and a more forceful concentration of marketing, research and development, and other efforts behind a shorter list of products.

Despite the obvious merits, simplification efforts may sometimes be sabotaged. Those who have been closely involved with a product may sincerely feel either that the line as it is will revive when appropriate changes are made in the marketing mix, or that the sales and profits will turn up once temporary conditions in the marketplace turn around.

Divestment is a situation of reverse acquisition. It may also be a dimension of market strategy. But to the extent that the decision is approached from the product's perspective (i.e., to get rid of the product which is not doing well even in a growing market), it is an aspect of product strategy. Traditionally companies resisted divestment for the following reasons, which are principally economic or psychological in nature:

1. Divestment means negative growth in sales and assets, which runs counter to the business ethic of expansion.
2. It suggests defeat.
3. It requires changes in personnel, which can be painful and can result in perceived or real changes in status or have an adverse effect on the entire organization.
4. The candidate for divestment may be carrying overhead, buying from other business units of the company, or contributing earnings.

With the advent of strategic planning, divestment became an accepted option for seeking faster growth. More and more companies are now will-

ing to sell a business if the company will be better off strategically. These companies feel that divestment should not be regarded solely as a means of ridding the company of an unprofitable division or plan; rather, there are some persuasive reasons supporting the divestment of even a profitable and growing business.

Divestment of businesses which no longer fit the corporate strategic plan can occur for a number of reasons. For example:

- There is no longer a strategic connection between the base business and the part to be divested.
- The business experiences a permanent downturn, resulting in excess capacity for which no profitable alternative use can be identified.
- There may be inadequate capital to support the natural growth and development of the business.
- It may be dictated in the estate planning of the owner that a business is not to remain in the family.
- Selling a part of the business may release assets for use in other parts of the business where opportunities are growing.
- Divestment can improve the return on investment and growth rate both by ridding the company of units which are growing more slowly than the basic business and by providing cash for investment in faster-growing, higher-return operations.

DIVERSIFICATION STRATEGY

Diversification refers to seeking unfamiliar products or markets, or both, in pursuing growth. Every company is best at certain products; diversification requires substantially different knowledge, thinking, skills, and processes. Thus, diversification is at best a risky strategy, and a company should choose this path only when current product/market orientation does not seem to provide better opportunities for growth.

The term "diversification" must be distinguished from integration and merger. Integration refers to accumulation of additional business in a field through participation in more of the stages between raw materials and the ultimate market, or through more intensive coverage of a single stage. Merger implies a combination of corporate entities which may or may not result in integration. Diversification is a strategic alternative which implies deriving revenues and profits from different products and markets.

Diversification strategies might include internal development of new products or markets (including development of international markets for current products); acquisition of an appropriate firm or firms; a joint venture with a complementary organization; licensing of new product tech-

nologies; and importing or distributing a line of products manufactured by another company. The final choice of an entry strategy in most cases involves a combination of the aforementioned alternatives. This combination is determined on the basis of available opportunities and of consistency with the company's objectives and available resources.

There are various modes of diversification. We examine concentric diversification and use it as an admittedly imperfect lead to discussion of switching products from prescription to non-prescription status.

Concentric diversification bears a close synergistic relationship to either the company's marketing or its technology. Thus, new products that are introduced share a common thread with the firm's existing products either through marketing or production. Usually, the new products are directed to a new group of customers.

While a diversification move per se is risky, concentric diversification does not lead a company into an entirely new world, since in one of the two major fields (technology or marketing), the company will operate in familiar territory. When a firm enters the OTC market for the first time, the technology should be familiar if the consumer marketing strategies are not. Figure 10-2 shows, in very general steps, the development of a marketing plan for the launch of a new OTC product.

It is beyond the scope of this book to discuss in detail the marketing of OTC drugs. Because of the relatively recent burgeoning interest in the switch of substantial numbers of drugs from prescription to non-prescription status, that phenomenon will be addressed briefly, from the company strategy perspective.*

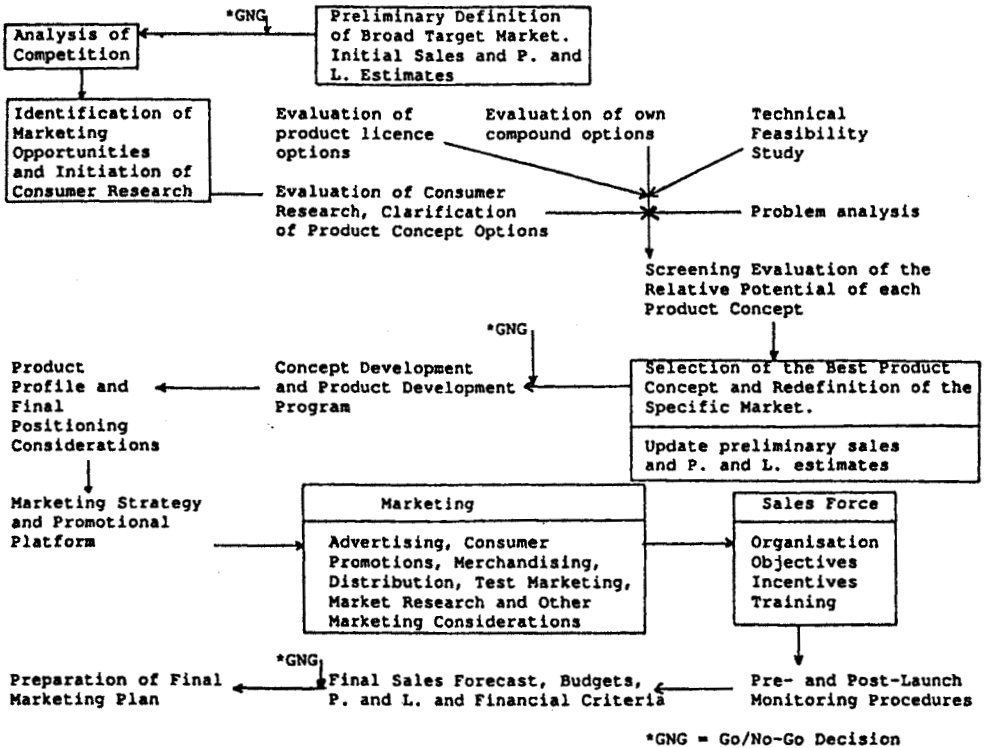
On the prescription side, the feelings are liable to be primarily negative. That division loses a product and it risks the alienation of physicians who are thought likely to resent the reclassification of former prescription drugs to wider availability.

A potential positive aspect on the prescription side of the pharmaceutical house is the fact that a long-standing successful prescription item can be gracefully pushed aside in order to make way for a product of new research developed in the laboratories. If it were not for the availability of the OTC outlet the product manager for the previous Rx item or the marketing director might oppose the introduction of a new drug thought likely to cannibalize a successful old one.

On the OTC side the situation will be reversed with more pluses than minuses. The marketing department on the OTC side will welcome the possibility of building a product with brand name loyalty, recognition, and longevity. The patent runs out on new drugs after a finite period of

*This section draws heavily from the work of Dr. William Rosenberg.

FIGURE 10-2. Development of OTC marketing plan



Source: Promotional brochure, IMS America, System 200

time but successful brand names can go on forever, frequently with a new formula. Coca-Cola® is an example of this but there are other well known brand name OTC drugs which have long outlived a variety of prescription items that have come and gone during their stay on the market.

Also the move towards OTC means a considerably wider market for the drug than did the prescription limitation. In 1983, Micatin was available only on prescription. In that year combined hospital and drugstore sales were $1.25 million. In 1984 Micatin was available for the first time as on OTC agent and sales increased 172 percent to $3.4 million. During that same time sales of the comparable Lotrimin/Mycelex remained on prescription-only and remained flat. The fact that Johnson & Johnson had econazole as a backup drug as a prescription-only antifungal while Schering-Plough and Miles had nothing with which to replace clotrimazole may have been at least partly responsible for the difference in these two decisions.

There is not universal acceptance of former Rx drugs on the OTC side of a pharmaceutical company, either. The change in type of agent means a considerably different way of doing business for many of the participants there. For instance, the research laboratories on the OTC side are frequently composed primarily of formulators and not pharmacologists. They may feel uneasy with the new agents with which they have to deal.

Likewise, the consumer research and marketing forces will find that new agents present both opportunities and challenges. The remarkable success of Sudafed introduced by Burroughs Wellcome to the OTC market is an example of the fact that there is a significant group of informed consumers who are able and willing to purchase a new group of agents which they recognize as different and possibly more effective than those that have had the major push of prior OTC promotion.

The same can be said for the initial success of ibuprofen in an intensely competitive analgesic market.

The result of all of this may well mean the emergence of new factors as important in the strategy of marketing OTC drugs. For one thing, it seems that companies which were formerly not considered important factors in the OTC market have the potential of becoming so.

Upjohn is a company, for example, with good name recognition among an educated consumer class. They have the added benefit of prior use of the name, Motrin, in years of television commercials. Thus, the shift of Motrin, finally, to OTC is a natural phenomenon.

The question of provider recognition is an important one. The nature of the OTC drug market is such that frequently the consumer is surprised to find out that a number of favorite items all come from the same company. He frequently does not associate an entire stable of home health remedies

that come, for example, from American Home Products or Beecham. The nature of those corporations is such that many of them have acquired their lines through purchase of formerly independent single product companies. It is, thus, not surprising that the name of the product is pushed forward ahead of the name of the provider.

It may well be, however, that some company will find an advantage in promoting its own corporate identity or perhaps an identifiable kind of brand name that could carry over from one product to another. For instance, a consumer who recognized some brand of nutritional supplement, laxative, analgesic, product for dry skin, or the like might well look with favor on a recognizable sister product for one of the other indications.

That sort of advertising was common in days before prescription and OTC were so sharply separated in 1938 by the Food and Drug law. An example is the Squibb ads in the 1930's *Saturday Evening Post* that tried to convince consumers who were going out to purchase aspirin, mineral oil, boric acid or whatever else was the OTC agent of the time that they could look with confidence if it bore the familiar 3 Squibb columns. It might well be that the time is ready for a return to that type of image. (The red "Lilly" would be easy to incorporate into such a campaign.)

A further prospect for the future is the possibility of the innovative coordination of advertising of prescription and related non-prescription drugs. Thus, if there are related items that differ in strength or form or even indication it may be perhaps possible to pick up some positive associations at the prescription side of the consumers' experience with the expectation that this would carry over further to the OTC side.

H.I. Silverman, in a 1987 speech to the Proprietary Association, forecast a number of developments at the prescription/OTC interface:

1. The prescription to OTC switch will continue.
2. Line extensions will proliferate.
3. Exceptionally useful ethical OTC's will be developed.
4. New delivery systems will provide a new dimension.
5. New packaging concepts will attract new users.
6. New and more realistic dosages and therapeutic combinations will result in new product claims and product growth.
7. New evolving diagnostics will add to the OTC armamentaria.
8. Preventive medicine is new—encompassing a potentially enormous market—and it will enjoy a startling growth.

An elaboration of each is valuable to a discussion of product strategies.

1. *Switch continues*—especially in oral health and control of use of tobacco. Special niches will be found in areas of heavy consumer demand.
2. *Line extensions* work. They are comparatively easy to accomplish and add sales volume. The best ones also offer customer benefits. Some examples are Drixoral plus analgesic, Unisom II.
3. Certain *exceptional ethical OTC's* (non-legend, but not promoted to the consumer) will be developed. Many current OTC's had *ethical* OTC histories: Maalox, Robitussin, Sudafed. This requires special care in dealing with the partners in the distribution system.
4. *New delivery systems*—edible whips, patches, once-a-week controlled release, pumps—all offer exceptional scope in designing OTC products. (See Figure 10-3.)
5. *New packaging* will include compliance aids, easy open tops (such as Pharmacia uses outside the U.S. for its Azulfidine arthritis patients), unit dose packs.
6. *New dosage concepts* and perhaps new combination products should appear and result in market expansion.
7. *Diagnostics*, already a factor in home testing, should be refined and additional products developed. Pregnancy tests are a good example of the evolutionary nature of this category.
8. *Preventive Medicine* may yet be embraced by the pharmaceutical industry as it already has been by the consumer. With or without the manufacturer or the retail pharmacists, the customer has already chosen aspirin to prevent heart attacks, calcium to prevent osteoporosis, lecithin to delay Alzheimer's Disease. Medical rationale notwithstanding, the consumers have spoken: they want to help take care of themselves.

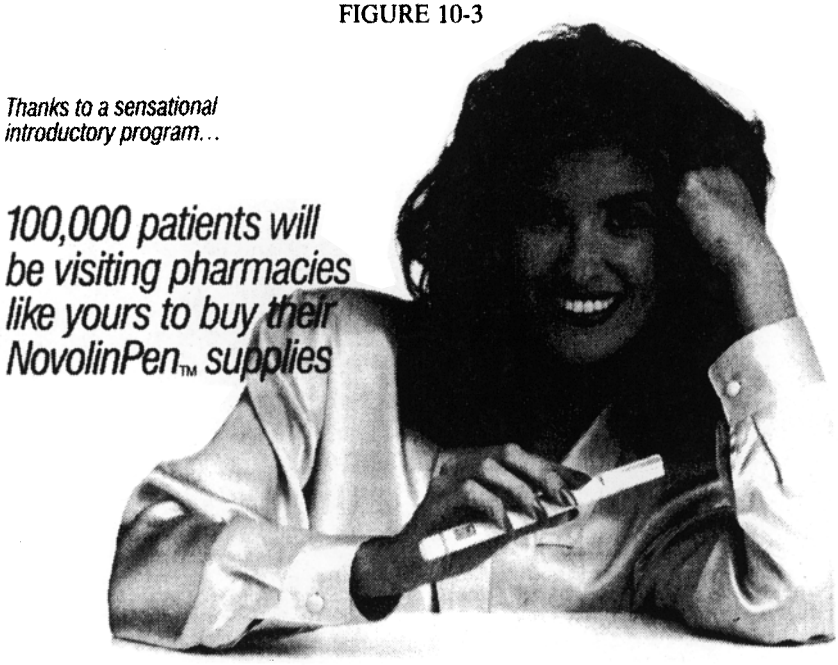
CASES IN POINT

Merck and Johnson & Johnson to Form Venture for Over-the-Counter Medicines

Merck & Company and Johnson & Johnson, two of the nation's biggest health care companies, said they will join forces to develop and market new over-the-counter medicines in the U.S.

The two companies, whose headquarters are several towns apart in central New Jersey, said they will form a 50-50 venture, called Johnson & Johnson Merck Consumer Pharmaceuticals Co. The new business will market medicines, such as an anti-ulcer treatment called Pepcid, that

FIGURE 10-3



They'll need Novolin® PenFill® insulin cartridges and PenNeedle™ disposable needles for their new NovolinPen™ Dial-A-Dose Insulin Delivery System

During the NovolinPen™ introduction, physicians nationwide will distribute over 100,000 complimentary Dial-A-Dose Insulin Delivery System units to insulin-using patients as part of the NovolinPen™ National Lifestyle Survey.

Patients in your area will be enthusiastic about NovolinPen™. It's insulin therapy at its simplest. They'll be heading from the doctor's office to their pharmacy to purchase the Novolin® PenFill® insulin cartridges and PenNeedle™ disposable needles they'll need.

And...in addition to the National Lifestyle Survey this exciting introduction also includes an extensive advertising and direct mail campaign, a Novolin® PenFill® consumer rebate program, and a public awareness campaign.

Be ready for this dynamic traffic, sales, and profit-building program. Display the NovolinPen™ window sticker and put up the counter easel with the Novolin® PenFill® patient rebate coupons and product information brochures.

And to meet your customers' needs, order your supply of:

*Novolin® **R** PenFill®**
Regular Human Insulin Injection (semi-synthetic)

*Novolin® **N** PenFill®**
NPH Human Insulin Isophane Suspension (semi-synthetic)

*Novolin® **70/30** PenFill®**
70% NPH Human Insulin Isophane Suspension &
30% Regular Human Insulin Injection (semi synthetic)

*PenNeedle™**
Disposable needle for use with NovolinPen™
Insulin Delivery System

For more information, call 1-800-727-6500.

NovolinPen™ Dial-A-Dose Insulin Delivery System

and pharmacists
Patients will love NovolinPen™

SQUIBB NOVO

*Novolin® PenFill® cartridges and PenNeedle™ disposable needles are the only accessories designed and authorized for use with the NovolinPen™ Insulin Delivery System

The diabetes care specialists

268 826 June 1988 Printed in U.S.A.

currently are sold or being developed by Merck as prescription drugs, the companies said in a joint statement.

While the joint venture probably won't gain government approval to market any new medicines for several years, the marriage is expected to cause a stir in the very competitive consumer health-products business, where annual sales total $9 billion. "The venture combines Merck's preeminent research and development operation with Johnson & Johnson, one of the country's foremost marketers of consumer health-care products," said Neil Sweig, an analyst with Prudential Bache Securities Inc. "On paper, at least, its's a very compelling deal."

Several industry executives said they had been expecting Merck to find a partner that could sell some of Merck's prescription products to consumers since Merck had mentioned such plans at a meeting with securities analysts last fall. But the choice of Johnson & Johnson surprised some.

"The rumor was that Merck was going to pick a little company hungry for new products," said a marketing manager at a Johnson & Johnson competitor. "The question when the two giants get together is, who's going to wear the pants?"

Rogaine and Progaine

A brilliantly conceived tie-in between a prescription and a non-prescription product is Rogaine-Progaine. The latter product, a shampoo "for thinning hair," is itself nicely positioned. When combined with the synonymous prescription product, Rogaine, the potential for synergy seems inescapable. (See Figure 10-4.)

Too Much Success for Accutane

Since its launch in 1982, Accutane, noted as the medication that revolutionized the treatment of severe acne, carried warnings that its use by pregnant women may lead to malformed babies. Roche distributed patient information brochures which explain that a woman of child bearing age should not take Accutane unless it has been confirmed that she is not pregnant and is practicing an effective form of contraception.

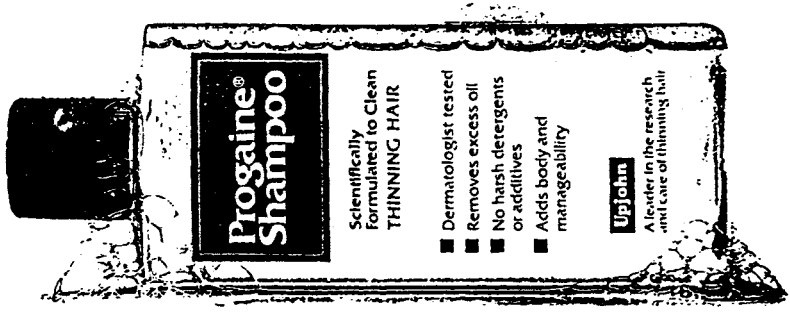
At the time of the product's launch, Roche estimated the potential number of Accutane users at 360,000 nationwide. According to industry figures, there were 892,000 prescriptions written for the brand in 1987.

In April, 1988, Roche representatives met with FDA's dermatologic committee and proposed several steps the company could take in its marketing to stop the drug's use by the wrong patients. "We've even gone so far as to suggest that Roche will offer to pay for pregnancy tests and

FIGURE 10-4

THINNING HAIR SHOULD BE CARED FOR UNDER IDEAL CONDITIONS.

INTRODUCING THE IDEAL CONDITIONS.

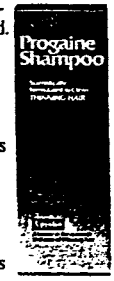


Even when used as directed, most shampoos leave residues behind. These residues can accumulate on your thinning hair or scalp and may affect the performance of other hair care products you use.

Fortunately, new Progaine is not like most shampoos. In fact, there's no other shampoo quite like it.

Progaine is a rich, mild shampoo scientifically formulated to clean thinning hair. Its unique blend of high quality cleansing agents provides a full-bodied lather that gently but effectively cleans thinning hair. What's more, it rinses without leaving residues behind.

Because, unlike other shampoos, Progaine contains none of the commonly used coating ingredients such as polymers, waxes or oils that can build up on hair.



And, hypoallergenic Progaine has been dermatologist tested and proven safe for use with even the most delicate thinning hair.

So, before you apply any other hair care products to your thinning hair, first use Progaine Shampoo to thoroughly clean your hair and scalp.

New Progaine Shampoo. The ideal shampoo for people who really care about the condition of their thinning hair.

Upjohn

A leader in the research and care of thinning hair.

contraceptive counseling before the patient is given Accutane," said Paula Frakes, Roche manager of public policy and communications.

One of the more significant proposals the company made involved the drug's packaging. Roche designed blister packs of ten pills each which contain the pregnancy warning and every time the person would go to take a pill they would see that warning, said Frakes.

Another innovation initiated by the company is an antipregnancy symbol which incorporates the international sign for something forbidden—red circle and slash—superimposed over the silhouette of a pregnant woman.

Prominent dermatologists have spoken out in support of the drug's continued marketing claiming that this is the best treatment for serious forms of acne and it is the closest thing to a cure for the psychologically debilitating and physically deforming disorder.

FDA has made no suggestion that Accutane be withdrawn from the market. Neither is the firm in a hurry to pull from the market this successful drug—it brought in $46 million in sales in 1987. The panel of FDA dermatologists voted unanimously for its continued marketing. Nevertheless, the product has had an "interesting" history, as this chronology shows.

September 1982—Introduction of Accutane for treating severe recalcitrant cystic acne, with birth defects warning in physician materials and patient brochures.

July 1983—Letters to more than 500,000 physicians and pharmacists on new data regarding birth defects associated with Accutane use.

August 1983—Letters to more than 500,000 physicians and pharmacists on revised package insert, reflecting new clinical information and new pregnancy warning stickers for patients.

March 1984—Letters to physicians and pharmacists on additional clinical and safety information, including revised patient brochure.

April 1984—Letters to physicians and pharmacists on a new trade package incorporating patient information literature and pregnancy warning labels.

October 1984—Mailing to physicians and pharmacists on new clinical and safety information added to the package insert and patient information literature.

June 1985—Mailing to physicians and pharmacists on the most recent revisions to the package insert and patient information literature.

October 1985 – Two New England Journal of Medicine articles published on the results of Roche-sponsored studies regarding birth defects and lipid abnormalities.

June 1986 – Mailing to physicians and pharmacists on the most recent revisions to the package insert.

April 1987 – Mailing to physicians alerting them of additional side effects, such as decreased night vision and hepatotoxicity.

June 1987 – Most current package insert.

September – 1988 Most intense warnings program to date was executed, incorporating innovative symbols, packaging, and patient counseling.

Source: *Medical Advertising News*, July 15, 1988; November 1, 1989.

Convenience in an Exclusive Package

Although Squibb Corporation and two Danish companies are still underdogs to the formidable leader, Lilly no longer has a hammerlock on the market for insulin products that millions of diabetics must use every day.

As recently as 10 years ago, Lilly had the U.S. insulin market virtually to itself. But Squibb, its joint venture partner, NOVO Industri AS of Copenhagen, and rival Nordisk Gentofte AS have gained footholds, gradually capturing a combined share of the $400 million market for injectable insulin. The market has grown recently at about 10% a year.

Now the Squibb-Novo joint venture is mounting a big advertising and a direct-marketing campaign to promote a new insulin-delivery product called NovolinPen. The lightweight, portable device looks like a fountain pen. It operates with a dosage-measuring dial, replaceable insulin cartridges and disposable needles, so it can be carried in a pocket, purse or briefcase and used away from home.

By promoting its pen aggressively, Squibb-Novo hopes to alter the makeup of the insulin-device industry, which has relied for decades on conventional syringes and vials. But beyond that, the company is betting that the pens will significantly increase sales of its human insulin product, Novolin, which still lags far behind Lilly's product, Humulin.

Squibb-Novo's basic challenge is to build awareness of the new device among the vast ranks of general practitioners and family doctors who treat the nation's estimated two million insulin-dependent diabetics. Part of the strategy to reach that goal is to get the patients to tell their doctors about the device.

"Most doctors aren't diabetics," says Eric A. Orzeck, a Houston-based physician who evaluated the NovolinPen and rival products for the

American Diabetes Association. "They just don't understand how much of a nuisance it is when you're in a public restroom, trying to balance a syringe and a vial on your knees."

Squibb-Novo began giving away 100,000 of the pens, which retail for about $40 each, and offering attractive rebates to patients who buy the insulin cartridges.

Dr. Orzeck, the Houston physician, says he thinks Squibb-Novo was smart to design the pen so that it accepts only the Squibb-Novo cartridges of insulin and no competitors' products. "That should bring a big boost to their insulin sales," he predicts.

Source: *Wall Street Journal.*

An Azulfidine Footnote

In 1988, Rowasa, a product of Reid-Rowell received FDA approval. Rowasa is mesalamine, a metabolite of sulfasalazine (Azulfidine). It is administered rectally as a suspension enema and is indicated for the treatment of active mild to moderate distal ulcerative colitis, proctosigmoiditis, or proctitis.

Sulfasalazine is an agent in which mesalamine is attached to sulfapyridine. Following oral administration, this molecule, for the most part, remains intact through the stomach and upper intestine and is then split by bacteria in the colon. Most of the sulfapyridine that is released is absorbed through the colonic mucosa, whereas most of the mesalamine that is released is free to move down through the remaining colon with only about 20% being absorbed. Although sulfasalazine has been used effectively in many patients, a number of individuals do not tolerate it well. Studies have shown that the mesalamine component of sulfasalazine provides the beneficial effects in the treatment of ulcerative colitis, whereas the sulfapyridine component, which carries mesalamine to the site at which its action is needed, has little or no therapeutic action itself but is responsible for many of the adverse reactions. As a result of these observations, studies with the use of mesalamine alone were undertaken, and the rectally administered suspension enema represents the first formulation containing this active agent alone to be marketed in the United States.

"Rediscovery" of Azulfidine

Sulphasalazine (salicy-azo-sulphapyridine (salazopyrin)) has been in clinical use for over 40 years. Although the drug was originally introduced for the treatment of "rheumatic polyarthritis" and ulcerative colitis, it is only in the past 10 years that its value in rheumatology has been

appreciated. Controlled studies indicate that the drug is an effective remittive agent in both rheumatoid arthritis and ankylosing spondylitis.

When Nanna Svartz introduced sulphasalazine (SASP) in the late 1930's, it was for the treatment of "rheumatic polyarthritis" as well as ulcerative colitis (UC). At that time, both diseases were thought to be the direct result of bacterial infection but the results of treating them with sulphonamides were regarded as disappointing. The salicylates were known to be effective in acute rheumatic fever; so, Svartz and her colleagues from Pharmacia decided to study the effect of combining a sulphonamide and a salicylate in the same molecule. They looked at a number of different compounds but the most promising was salicylazosulphapyridine, or sulphasalazine, which was synthesized from a combination of 5-aminosalicylic acid (5-ASA) and sulphapyridine (SP).

In 1942, Svartz reported encouraging results with the use of SASP in "rheumatic polyarthritis." Although patients with longstanding disease tended to do badly, those with active arthritis showed a reduction in joint swelling and ESR when treatment was continued for weeks or months. This was in contrast to the simple analgesic effect of salicylate given alone. Despite these early results, other workers were unimpressed with the benefits of SASP in rheumatoid disease.

The value of SASP in UC was not dismissed so easily. Nanna Svartz's enthusiastic reports of the benefits of SASP were followed up by workers in the USA with the result that the drug gradually gained widespread acceptance as a treatment for inflammatory bowel disease. The "rediscovery" of SASP for the treatment of RA did not take place for a further 30 years.

In the early 1970's, physicians in Birmingham (UK) used dapsone in patients with RA because of the similarities between rheumatoid disease and leprosy. Although the drug showed signs of second-line activity, its usefulness was limited by its weak potency as the workers speculated that other drugs which were useful in this immunological disorder might also be effective in RA. One such drug was the sulphonamide, sulphapyridine. At this stage, they were unaware of Svartz's early work with the drug but they did know that it had immunosuppressant properties in inflammatory bowel disease. In 1978, the group published their first report of an open trial of SASP in RA. The results suggested that the drug had "a disease-modifying action not attributable to its salicylate content."

Whatever its mode of action, the rediscovery of SASP has provided a badly needed therapy for the management of RA and seronegative spondarthritis.

Source: Taggart, A. J. in *Clinical Rheumatology*, 1987.

Envisan: Positioning, Packaging and Education

Marion's Envisan and Johnson & Johnson's Debrisan contain the same ingredient (a wound cleaning paste) licensed from Pharmacia. Debrisan, in 1988, sold at a $1 million annual rate, down from a peak rate of $5 million. One of the reasons may have been that it was used on wounds where it does not work.

Marion "created" a wound classification system and educated nurses and pharmacists about it. Red wounds are new and clean. Black wounds are necrotic and require surgical debridement. Yellow wounds, however, generate exudate which needs cleaning and absorption . . . buy Envisan "for yellow wounds only."

In addition to the education Marion supplied Envisan in a unit of use package containing the paste, nylon netting and a semi-occlusive film . . . an important convenience in a labor intensive application.

Source: *Medical Advertising News*, October 15, 1988.

Ibuprofen: From Drug to Drug Products

Ibuprofen is, in many ways, the most interesting drug in the modern history of pharmaceutical marketing. The process by which this new chemical entity became an entire family of drug products offers a smorgasbord of issues: licensing, patent fights, Rx to OTC switch, pricing, promotion and positioning.

Only brief consideration can be given here to ibuprofen. It is loosely based on Porter's Five-Factor Model as described in Chapter 3. (See Figure 10-A.)

Prescription Ibuprofen

FDA approved ibuprofen to be marketed by its originator, Boots, as a prescription drug. (See Figure 10-B.) Because Boots lacked the marketing experience in the U.S. market, it sold Upjohn nonexclusive marketing rights to manufacture and sell ibuprofen in 1974. Marketing the drug as Motrin, Upjohn built it into the fifth-largest selling prescription drug in the U.S. In 1985, sales of the nonsteroidal anti-inflammatory agent Motrin were strongly from 1984; it contributed to the firm's 7.6% sales gain during the second quarter to $543.3 million. In 1986, the sales of Motrin continued to be strong.

In 1981 Boots, which has established a U.S. presence by the acquisition of Rucker Pharmaceuticals in Shreveport, launched its own version of ibuprofen under the brand name Rufen. Competition was keen between Upjohn's Motrin and Boots' Rufen. Both of the companies tried to grasp a

FIGURE 10-A. Selected components of the Ibuprofen environment

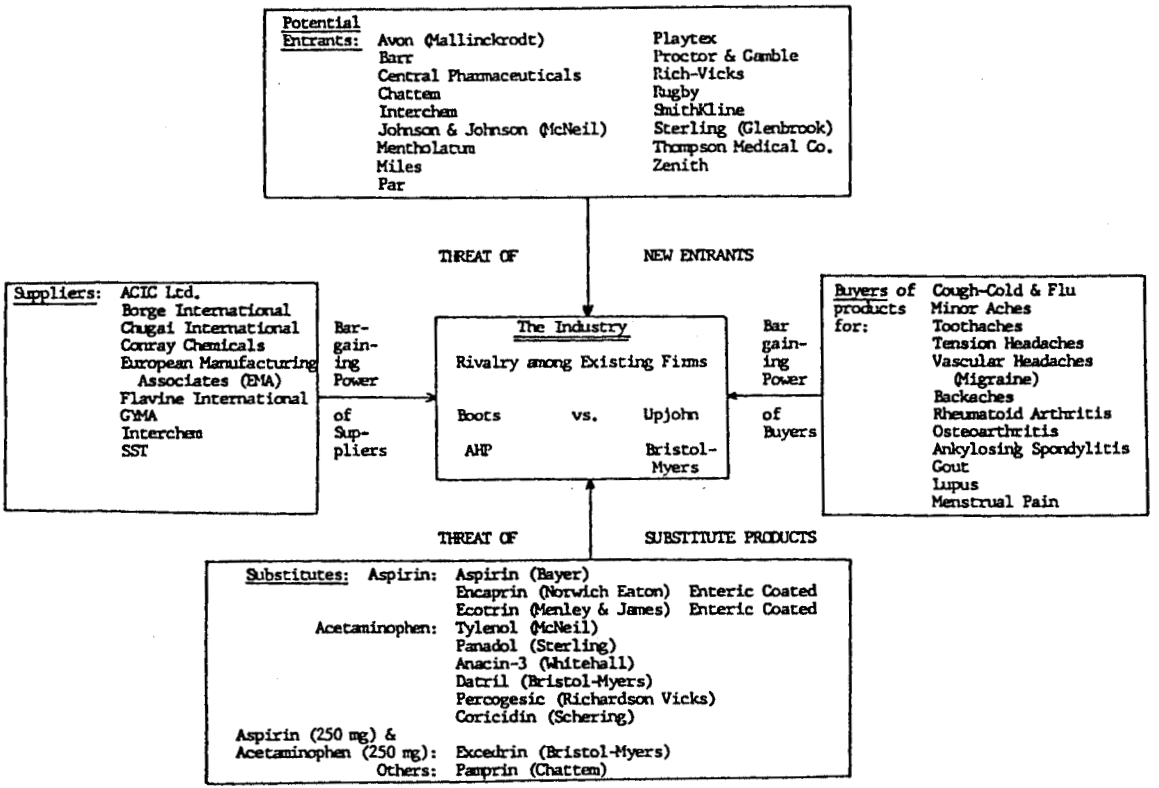
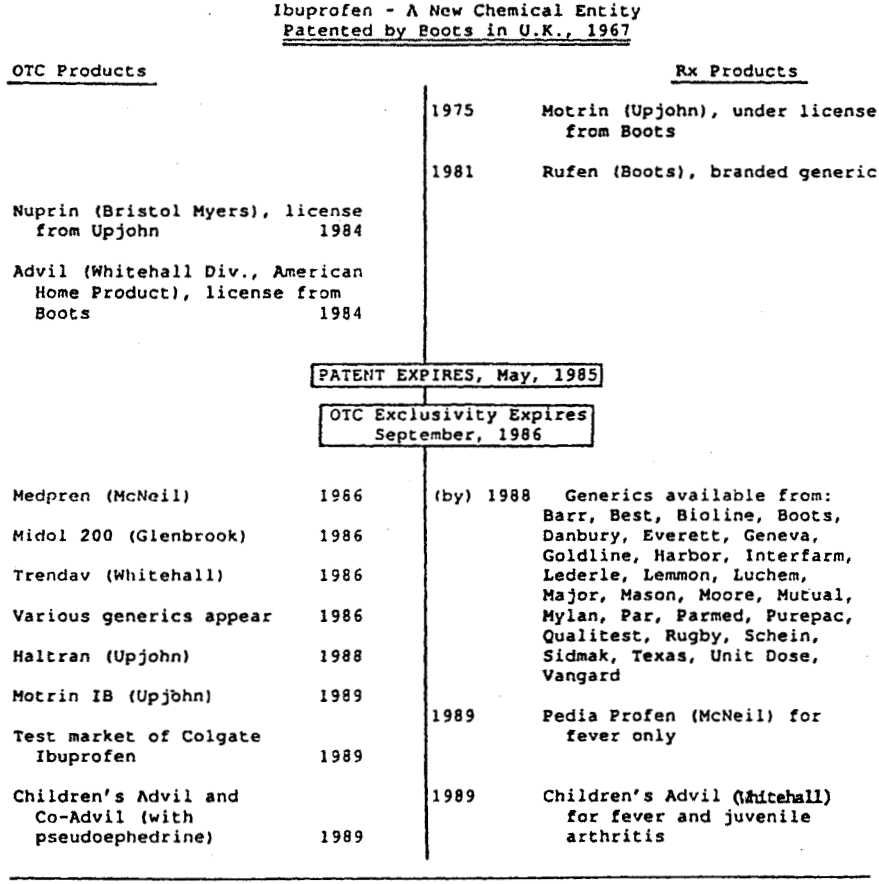


FIGURE 10-B. Ibuprofen from drug to drug products



bigger market share for their single product which was the 400 mg tablets. Boots challenged the leader Upjohn by offering buyers a similar product but at a lower price. In its advertisement, Boots focused on the price differential between the two drugs. Rufen, in 1983, achieved sales of $35 million. They also startled the industry by offering consumer rebates.

On the other hand, Motrin was backed and supported by Upjohn and became well known in the U.S. analgesic market. In its first year of introduction, Motrin was heavily advertised in the medical journals. Motrin targeted the analgesic market where the competition was very tough among available brands. Upjohn followed two consecutive marketing

strategies. The first was the segmentation of the analgesic market to focus on osteoarthritis and rheumatoid arthritis patients (which was the first indication for which they had approval.) The second marketing strategy was to differentiate the drug by showing different and better characteristics of the drug than other drugs available in the analgesic market. The differentiation techniques were shown in 1974 ads as follows:

- *Motrin is chemically unique – unrelated to indomethacin, phenylbutazone, corticosteroids, or salicylates*
- *Motrin has better gastrointestinal tolerance than aspirin*
- *Motrin is suitable for long-term management*

In 1980, and six years after the introduction of Motrin, Upjohn announced tests proving the effectiveness of the drug in analgesia: "Motrin now proved an effective analgesic for mild to moderate pain." Moreover, Upjohn was providing new features to add to Motrin, thus, using new characteristics as a competitive tool for differentiating Motrin from competitors' drugs. "Motrin is not a narcotic, not addictive, and not habit forming."

In 1983, Boots again emphasized in its ads the substantial savings of Rufen over the price of Motrin. For the first time, in TV ads, Boots claimed that Motrin and Rufen were interchangeable and had the same uses, side effects and contraindications, but there is an important difference in that Boots' brand of ibuprofen can cost considerably less.

Upjohn provided new services to consumers. They made a brochure available to MDs for distribution to their patients, which was intended to reinforce information presented by the patients' physicians, enhance patient-physician communication, and improve compliance by clarifying medication instruction.

Subsequently, Upjohn introduced 300 mg and 600 mg. On the other hand, Boots with Rufen 400 mg only extended its line to 600 mg. However, both companies, Upjohn and Boots, were considering the extension of ibuprofen to include the 200 mg category and to be targeted to OTC analgesic market as a pain-reliever. Both were also well aware of looming competition once patent protection was lost.

Going OTC

Both Upjohn and Boots decided to enter the OTC market with a partner experienced in selling to consumers. Upjohn chose Bristol-Myers and Boots picked American Home Products, Whitehall division. The strategic maneuvers which followed continue today. Only a few can be mentioned.

Both Upjohn and Whitehall would present safety and efficacy data from clinical studies before an August, 1983 meeting of FDA's Arthritis Advi-

sory committee. The Whitehall NDA reportedly included worldwide data from three clinical studies of the efficacy and safety of the 200 mg dosage form. However, Upjohn produced its own United States data for approval and formally objected to Boots application on the basis that a full NDA was required and, as such, Boots would have to cross-reference confidential data, which Upjohn was unwilling to provide. In the meantime, while Upjohn and Whitehall were trying to get an FDA approval to market OTC ibuprofen, several companies tried to break the barriers to the patent holder, Boots, and its licensees, Upjohn and Whitehall. Those companies felt the pressure of introducing OTC ibuprofen into the analgesic market and saw the opportunity to improve their position. Chattem and McNeil were the major potential entrant companies among others trying to break the ibuprofen patent.

Chattem sought to head off FDA approval of a recommendation by its Arthritis Advisory Committee to permit the OTC marketing of the Rx analgesic ibuprofen by Upjohn and American Home Products. The grounds of Chattem's argument were that the pharmaceutical industry is a concentrated one, with relatively few companies possessing enormous economic leverage. In addition, only the largest and most heavily resourced companies are able to maintain NDAs as a routine course of business. Thus, whenever FDA restricts the introduction of new OTC products to the best financed companies in the industry, it would be inevitable that further concentration and monopoly would occur.

Thus, Chattem, a small company engaged in the marketing of OTC drugs in the analgesic market, would be irreparably harmed by the creation of a monopoly in the use of a new OTC analgesic. This injury would occur both because of the direct competition with Chattem's current products like Pamprin and because Chattem would be hindered from marketing a competitive ibuprofen product by the NDA system.

Instead of the NDA system, Chattem urged that the FDA include ibuprofen in its OTC monograph for analgesic drugs. This would mean a determination that the drug is "generally recognized as safe and effective" as it has been marketed to a material extent and time for same conditions of general analgesic and menstrual pain and would open up the OTC marketing of ibuprofen to any manufacturer meeting monograph standards.

Moreover, Chattem pointed out that if Upjohn and AHP obtained FDA approval, they will have a great advantage over later competitors, particularly where they have enjoyed a monopoly and have the financial strength to exploit that monopoly. Under these circumstances, Chattem and other small companies would never be able to compete effectively with the large, early marketers of ibuprofen.

Upjohn contended that the apparent but unstated motive for Chattem's petition was to protect its Pamprin menstrual drug product from competition in the OTC marketplace because ibuprofen was being touted as especially effective for menstrual pain. In addition, Upjohn stated that even if ibuprofen were generally recognized as safe and effective for OTC use, it has not been used for a material time under the proposed conditions of use, and a careful evaluation of the published studies will reveal the absence of critical data on the effectiveness of the 200 mg dose which provides an evidence that ibuprofen is a new drug.

American Home Products contended that "the true purpose of Chattem's request is simply to prevent AHP and Upjohn from marketing (OTC ibuprofen) before the patent expires."

McNeil sought to limit ibuprofen's impact on the OTC analgesic market by saddling the 200 mg dosage with the Rx label warnings. In a petition submitted to FDA in March, 1984, McNeil asked for a series of restrictions, including a contraindication for the product OTC in persons allergic to aspirin. McNeil noted that many patients with known hypersensitivity to aspirin may well select ibuprofen as an alternative "non-aspirin" analgesic which would create the potential for severe and even fatal reactions due to cross reactivity of ibuprofen with aspirin.

Neither of these efforts was successful.

On May 18, 1984, FDA approved OTC 200 mg ibuprofen to be marketed by Bristol-Myers and Whitehall under the brand names Nuprin and Advil, respectively. One of the most important aspects of the original ibuprofen switch was that the patent was to have run out on May 28, 1985, thereby opening up the marketplace for a host of other products. However, under the Price Competition and Patent Restoration Act of 1984, exclusivity was granted for an extended period on the OTC version.

Advil and Nuprin were promoted as general pain relievers for headaches, dental pain, muscular aches and pains, reduction of fever, and dysmenorrhea. However, neither drug was labeled for arthritis as Motrin and Rufen were. Such indications would place Upjohn and Whitehall head-to-head against competitive products or substitutes from aspirin and acetaminophen manufacturers.

Aspirin products were still the cheapest of the over-the-counter painkillers, with generic or house-brand aspirin cheaper than brand names. Thirty Bayer could cost $1.25, 100 Bayer $1.99, and 100 of a generic brand, $0.79. Acetaminophen products were about twice the price of aspirin, with 50 Tylenol about $3.99 or 60 Datril $2.79, but 100 generic, $1.99. As the newest product, ibuprofen was the most expensive. Fifty tablets of Advil were about $4.19 and 50 Nuprin, $3.79.

American Home Products and Bristol-Myers were blitzing consumers

with coupons and spending at least $35 million each on introductory advertising that made essentially the same pitch "ibuprofen, once available only by prescription, can now be bought in nonprescription strength," that might make some consumers think that ibuprofen is better for aches and pains than substitutes aspirin or Tylenol.

In response to the appearance of Advil and Nuprin, Johnson & Johnson (Tylenol) announced a program of heavy investment spending to increase Tylenol's massive $50 million advertising budget. Moreover, Johnson & Johnson planned to introduce its own ibuprofen – a one-a-day dose – after the patent expired.

By the end of 1986, Advil and Nuprin had combined for about 15% of the market, taking share this time primarily from aspirin. Aspirin had 40% of the analgesic market, acetaminophen 45%.

American Home beat Bristol-Myers to market in 1984 and spent more on advertising. In 1986 Advil outsold Nuprin by about 3 to 1. In 1985 about $35 million in Advil advertising produced retail sales of more than $85 million; Bristol-Myers estimated $25 million brought sales of only about $35 million for Nuprin. Just two months before the expiration date of OTC ibuprofen on September 26, 1986, Upjohn decided to introduce its own brand of OTC ibuprofen under the brand name Haltran. Upjohn positioned Haltran in the menstrual pain market in which the company's supplemental approval was exclusively for the dysmenorrhea indication. Thus, Haltran had a two-month advantage over the next wave of OTC ibuprofen introductions.

Next and upon the expiring of the exclusive marketing period of OTC ibuprofen, several drug companies were ready to jump on the bandwagon. They provided new substitutes and a major challenge to Advil and Nuprin. However, they avoided going head-to-head with them. Instead they advertised their products as menstrual-pain relievers, a $65 million market.

McNeil introduced Medipren, Par and Barr launched a generic ibuprofen, Chattem, Glenbrook Laboratories, Danbury, Chelsea and many others joined the battle to have a slice of the menstrual-pain market.

While most of the later entrants positioned their OTC ibuprofen in the menstrual pain market, the initial OTC ibuprofen products were positioned as painkillers with a reference to menstrual pain. On the other hand, prescription ibuprofen drugs of 400 and 600 mg were positioned in the arthritis market. Thus, ibuprofen has been positioned through its life in different markets.

One consideration in the positioning strategies of OTC ibuprofen is whether consumers would perceive OTC ibuprofen as a new brand or a

new product? One manufacturer attempted to position its OTC ibuprofen as a new product as evidenced by its television advertisement stating "First there was aspirin, then there was Tylenol, and today there is ibuprofen." Another used the following:

"In the 50's menstrual pain meant Midol.

In the 70's it also meant Pamprin.

Now there's Trendar. Today's choice for menstrual pain."

Motrin and Rufen chose arthritis as their core segment and hoped to reap the fringe benefits from the menstrual pain and body aches/strains segments. Advil and Nuprin's core positioning strategy was for headaches, fever, aches and pains, while Haltran, Midol-200 and Trendar favored a position for relief of menstrual cramps. Medipren positioned itself as a better choice than aspirin for body aches and pains.

In the case of prescription ibuprofen, the introduction of Motrin offered many the features not then available in the existing products and which were important to the prospective users of the drug. These features were a drug which was effective for pain relief and inflammation, less irritating to the stomach, non-addictive, non-sedating, had relatively few other side effects and drug interactions and was safe. Many of these features were not currently being fulfilled by such products as butazolidin, high dose aspirin corticosteroids, narcotic and non-narcotic analgesics, and acetaminophen. Thus, both Motrin and Rufen utilized these features in their positioning strategy.

The OTC market represented a somewhat different arena. The unfulfilled needs are a safe product which is effective for pain relief and inflammation, non-irritating to the stomach, has few other side effects and drug interactions, and doesn't cause Reyes Syndrome. Aspirin, acetaminophen and ibuprofen are approximately equally effective (ibuprofen MAY be slightly more effective in headaches); ibuprofen is less irritating to the stomach than aspirin but more so than acetaminophen. Both aspirin and ibuprofen provide anti-inflammatory effects yet cause Reyes Syndrome. Thus, the newly introduced ibuprofen did not really fulfill the unfulfilled needs.

In the introduction, obviously promotion was the core strategic effort for Advil and Nuprin. Both companies blitzed consumers with coupons and spent at least $35 million each on introductory advertising. Later, product was a strong supporting strategy for Advil as the focus of a $100 million promotion was its distinctive looking tablet. AHP believed that consumers identify Advil so closely with the terra cotta coating that it is part of the brand image. This promotional advantage actually was serendipitous – the coating was developed to protect against adulteration! In

January 1986, Advil became the second largest pain reliever in the U.S. and AHP changed their strategy mix to emphasize distribution efforts in concert with its promotional effort. They were looking to give Advil a further boost through physician detailing by a newly created OTC product sales force. They hoped to strategically increase endorsements by the medical profession through extensive sampling and promotion.

Johnson & Johnson, makers of Medipren and Tylenol, began a heavy ad campaign for Medipren to convince Americans to give up what they are using and give Medipren a try. It was promoted for use against body aches and pains lest it pull headache customers away from Tylenol. Promotional effort was and is essential–McNeil offered coupons to customers and spent $50 million on a TV ad campaign. McNeil also flooded physicians with free samples for their patients, a tactic used successfully when it introduced Tylenol 25 years before.

The two original ibuprofen licensers introduced ibuprofen-based pain relievers for menstrual cramps–Trendar by AHP's Whitehall Corporation and Haltran by Upjohn. Previously the OTC ibuprofen had not been promoted heavily for menstrual pain, a major market for Extra Strength Tylenol.

Upjohn spent an estimated $25 million in a magazine and TV campaign for "the tough cramps women get" and attempted to establish Haltran as a new product (not a line extension) in its pitch "a new generation pain reliever for menstrual cramps." The promotional messages are concentrated in journals read predominantly by women and during high television viewership by the female sector. Upjohn said Nuprin and Haltran don't compete against each other since Haltran is a menstrual cramp reliever and Nuprin is a regular pain reliever.

AHP's Trendar was positioned as "Today's choice for menstrual pain"–again, an attempt to establish ibuprofen as a new product by making the other options obsolete (but not necessarily less effective). Sterling Drugs' Midol-200 hoped to leapfrog the other two by name recognition. The company's aspirin-based Midol has been a leader in the cramp relief market. Recognizing that the pain-relief market is a fairly mature market, these companies hoped that segmentation for menstrual pain relief would be one way to compete with Advil and Nuprin.

Packaging for OTC products is another form of promotion and should consider consumer likes, dislikes, preferences, convenience of use, ability of package to command attention, deliver a promotional message, convey the proper company image and stimulate purchase.

Three OTC ibuprofen packages are notable. Haltran, the menstrual pain reliever, is packaged in "ladylike" soft pink with neon/high-tech red and blue print. This package conveys the image to the purchaser that is

for females but is a new generation menstrual pain reliever. Advil, packaged in a blue and yellow grid pattern, also portrays a high tech/new generation image. Medipren's package shows several images of bodies in different positions which demonstrates its attempt for the package to deliver the promotional message that it is for body aches and pains and those who don't have time for the pain. "Let's get moving with Medipren!"

Glitches in Switches

The Rx-to-OTC switch was not as smooth as hoped. For example, when Actifed and Robitussin went OTC, they maintained the same brand name utilized when available only from the pharmacist. The Advil/Nuprin strategy unfolded under fundamentally different conditions. First, the dosage changed when moving from prescription to non-prescription status and secondly, the prices fluctuated throughout its first year on the market, possibly confusing customers. On introduction, heavy couponing made the effective price per tablet approximately equal to aspirin and acetaminophen. In 1985, Advil (50 tablets) cost $3.99 while Nuprin (50 tablets) cost $4.39. Anacin and Tylenol sold for $2.99/50 tablets. Even though the dosage was different, i.e., one tablet to ibuprofen vs. two tablets for aspirin and acetaminophen, the two ibuprofen brands seemed more expensive to the unfamiliar customers.

Another problem emerged from the licensing agreements with Boots/AHP and Upjohn/B-M (Bristol-Myers). Neither AHP nor B-M could use the established names, Rufen and Motrin, since Boots and Upjohn were still marketing their products under those names to physicians. Moving from prescription to OTC status often has a "made to order" market strategy – marketers are often ensured success by stressing the "ethical" history of the product. This strategy was foiled in the initial introduction of OTC ibuprofen. Anxious to present the drug as a new entity rather than a line extension, the two marketers devised new brand names. But consumers could not graft their awareness of the prescription pain reliever on the OTC form.

In addition, because of the Upjohn suit filed against AHP for using the name Motrin and Motrin's orange color in its initial advertisements, positioning messages moved from one claim to another with a net result of consumer confusion.

As if the companies weren't having enough trouble, there was resistance in the field. As the products were reaching the shelf, certain local pharmacy associations took great pains to point out the dangers of ibuprofen. This adverse publicity was not completely altruistic. Many pharmacists saw $250 million in prescriptions threatening to evaporate. And,

they were angry the drug had moved from Rx-to-OTC without being classed as an ethical pharmaceutical for a few years. This situation represented a dilemma for the two companies in attempting to satisfy all of their corporate publics with a company strategy. As shown, conflict may arise between two or more of these publics—in this case, the consumers, stockholders and the public unique to the pharmaceutical industry, the decision maker/influencer/pharmacist.

Notes on Upjohn Strategic Decisions

OTC ibuprofen could and did affect Rx Motrin. Motrin sales dropped by 20 percent during the first year of marketing OTC ibuprofen products.

Also, the 5% Upjohn would earn from sales of Nuprin as agreed with Bristol-Myers would not bring Upjohn enough to make up for what was happening to Motrin, which accounted for 40% of Upjohn's profits in 1983. A price war with Rufen was squeezing those profits, and Upjohn's stock dropped from $61 a share in early July 1983, to $45 in August 1984.

Upjohn's own OTC venture with Haltran was unsuccessful (down to $2 million in 1988) and it was not until 1989 that the name Motrin appeared on OTC shelves (as Motrin IB). Ads appeared in July. Consumer promotions included TV and print ads, sampling and couponing. Professional journal ads to physicians and pharmacists were also planned. The TV ad from Motrin IB played on the strength of prescription Motrin's brandname recognitions, which studies showed were well over 85%. The ad, which intoned the Motrin IB name four times, stated in part: "You are about to see the most important words on pain relief in 100 years: Motrin IB. No prescription needed. Now the doctor-recommended pain reliever in Motrin is available in nonprescription strength . . . It's going to be the new generation of pain relievers."

Would this work? Why had Upjohn waited so long?

Upjohn made a major push into the over-the-counter ibuprofen market partly because Motrin's prescription sales were off sharply while its nonprescription competitors are selling briskly. "We will take the mark Motrin over-the-counter ourselves because we think the market is receptive to further analgesics of this type," Theodore Cooper, Upjohn's chairman and chief executive officer, said.

Partly because of generic substitutes, Motrin's 1988 prescription sales were off by about 20% from 1987. Meanwhile, the best-selling nonprescription brands of ibuprofen, Advil and Nuprin, were growing at a faster rate than any other segment of the $2 billion over-the-counter analgesic market. Advil, sold by American Home Products, was the more popular of the two, with about 13% of the market. Nuprin, sold by Bristol-Myers under a licensing agreement with Upjohn, had a 4.5% market share. An-

other ibuprofen brand, Medipren, sold by Johnson & Johnson, is a distant third.

In an article in Medical Advertising News (August 15, 1989) marketing consultant Hemant Shah called Upjohn's licensing of Nuprin the "goof of the century." He blamed it on a lack of commitment to the OTC market.

Observers have said that 1984 would have been the perfect time for Upjohn to launch a nonprescription ibuprofen and associate its name with Motrin. Instead, the company launched a nonprescription product back then, named it Nuprin, and licensed Bristol-Myers to market it. Upjohn marketers abandoned the nonprescription ibuprofen market, thinking that they did not have the know-how to sell to consumers.

Upjohn CEO, Theodore Cooper, would see things differently.

> *Motrin is a good example of how Upjohn plans to develop the "full potential" of its more mature products—yet it also typifies the sometimes difficult task of getting such improvements through the regulatory process. A slow-release form, Motrin SR, is now under development at Upjohn, but its NDA filing—despite "early advice" meetings with FDA—seems bogged down in unresolved issues of pharmacokinetics that Cooper says have left both FDA staff and the company in a state of confusion.*

Usually not mentioned in those discussions is the 1988 approval of Upjohn's Ansaid (flurbiprofen) a non-steroidal anti-inflammatory of the same chemical family as Motrin.

At FDA, Ansaid had to compete for attention with many other NSAIDs waiting approval and had only a 1C priority rating. In Europe, however, it has already been on the market for years, with an "excellent record," says Cooper. Competing with older medications in the United States, he says, is thus a marketing advantage rather than a problem.

Unlike Motrin, Cooper says, Ansaid will suffer no early competition from an OTC form of the product. Although Upjohn also licensed flurbiprofen from Boots, the originator of ibuprofen, the current product is protected against any OTC licensing to another company.

The contributions of Mohammed Rawwas and Patti Tucker to the development of this case are gratefully acknowledged.

Chapter 11

Promotion

The promotion of pharmaceutical products is the linchpin of the marketing mix. Promotion is the vehicle by which the product, its price and methods of distribution should be described to the firm's audiences in a way that is both coherent and persuasive.

Definition: "What and how markets are informed of the firm's product, place and price."

Promotion, especially advertising, tends to have more glamour than do the other mix components. It is certainly more visible and often appears to be more creative. The other elements are of little value unless their advantages are communicated to those who need to know. On the other hand, promotion cannot long succeed if the other elements of the marketing mix are unsatisfactory.

Promotion can sell a good product or service, but it cannot take the place of it or sustain poor products or services for long. (Some of the finest television advertising is for franchised goods and services. Do you see much resemblance between the television McDonalds or Century 21 or Midas Muffler and your local version? It is a long way from Madison Avenue to Main Street USA).

In this chapter we will examine several issues relating to promotion. The first is what to say. In essence this means how best to explain to the customers and physicians what the company wants them to know about its goods and services. The next question addressed is who should receive these messages. This is followed by descriptions of the various media available to accomplish this communication. Finally, we discuss some technical aspects of promotion, especially evaluation.

WHAT TO SAY

The prescription drug industry is subject to the same "truth in advertising" regulations as is any other industry. False and misleading advertising is prohibited and regulated by the Federal Trade Commission. In addition, however, the promotion of the therapeutic qualities of prescription drugs

is closely monitored by the Food and Drug Administration, which has overlaid additional restrictions on top of those of the FTC.

Promotion of legend drugs cannot even suggest efficacy or safety attributes that are not backed up by the package insert. In turn, it is based on the New Drug Application approved on the merits of the clinical investigation. (This highlights again, the need to have marketing involved in even early stages of clinical testing.) In other countries, as well, there is extra governmental regulation when medicines are involved. As in the United States, such regulations tend to involve both labelling and advertising.

While requirements relating to information on pharmaceuticals and to labelling and advertising are generally included in the substantive statutes or regulations, many countries have enacted special statutes for drugs.

Different countries have devised different kinds of control strategies. Some countries have specific requirements regarding labelling and advertising, such as prior approval or mandatory inclusion of certain details. Other countries have negative stipulations, such as that an advertisement should not contain any false statements.

The regulation of labelling is easier than that of advertising because the latter is a multidimensional method of communication. There can be a legal requirement regarding the minimum information that should appear on the label of a product, together with appropriate instructions and warnings. Labels, package inserts, and advertisements can be scrutinized with a view to approving them, with or without modifications. In the case of advertisements, different requirements would be needed for different kinds of advertisements. Drug advertisements cater to different target groups – doctors, patients, retailers, etc. – and deal with different categories of drugs – prescription drugs, non-prescription drugs, etc. Different regulatory provisions can be formulated to regulate the different situations in which a manufacturer or distributor might advertise. In fact, national laws represent a wide spectrum of regulatory patterns.

At the 1981 World Health Organization Consultation on Basic Elements of Drug Legislation and Regulatory Control for Developing Countries it was recommended that countries desirous of screening information and advertising materials should have a multidisciplinary committee consisting of representatives from:

- The drug control agency;
- the pharmaceutical manufacturing industry;
- the pharmaceutical profession;
- the medical profession;
- the news media, and
- the advertising agency.

It is difficult to make any quantitative assessments of the information required by the categories of people who need to use or have access to such information. It has been suggested that, in terms of typewritten pages, the information required by the various categories would probably be of the following orders of magnitude:

a. The pharmaceutical industry – 4000 pages
b. The regulatory agency – 2000 pages
c. Academic investigators – 500 pages
d. Prescribers – 20 pages
e. Patients – 2 pages

(Herxheimer, 1978, in *The Scientific Basis of Official Regulation of Drug Research and Development*, Ghent, Heymans, Found.)

Faced with so many restrictions one might expect those in charge of pharmaceutical promotion to be reduced to staid, colorless, industrial messages. On the contrary, the challenge of regulation seems to have engendered an extraordinary level of creativity in writing, illustration, and media.

For prescription drugs the most frequent target for promotion is still the physician and we will use the physician as our main example in this section.

Copy refers to the content of an advertisement. In the advertising industry the term is sometimes used in a broad sense to include the words, pictures, symbols, colors, layout, and other ingredients of an ad. Copywriting is a creative job, and its quality depends to a large extent on the creative ability of the writers in the advertising agency or the company. However, creativity alone may not produce good ad copy. A marketing strategist needs to have his or her own perspectives incorporated in the copy and needs to furnish information on ad objectives, product, target customers, competitive activity, and ethical and legal considerations. The creative person will carry on from there. In brief, although copywriting may be the outcome of a flash of inspiration on the part of an advertising genius, it must rest on a systematic, logical, step-by-step presentation of ideas, especially for pharmaceuticals.

Physicians tend to be more rational in their decision making than ultimate consumers. They prescribe to fit the needs of their patients and these needs normally are of a practical nature. But it should not be forgotten that these physicians are individuals having personal needs which sometimes become enmeshed with their roles as decision makers for their patients.

Thus, even choice of a prescription drug may be made on bases which are nonrational or emotional.

The advertisers have recognized the various factors which influence prescribing decisions and have structured their advertising appeals toward these factors. Table 11-1 contains a list of types of appeals used to influence prescription drug decisions.

The Advertising objectives could be any one or all of the following:

1. To generate product awareness--------→RECALL
2. To communicate new information------→COMMUNICATION
3. Increase interest or product usage
4. To generate positive convictions about the product ----→PERSUASION

Effective advertising of any product depends on a chain of events similar to this: attention----→interest----→consumption (of the message)---→ motivation---→action. Appeals, as presented are most active (or inactive if unsuccessful) in the first two or three steps, but they are a part of the entire process. The last step, however, is the key to the sequence. If there is no action, the advertisement is a failure.

The function of the advertising, as all marketing people know but sometimes ignore, is to communicate effectively information preplanned to encourage directly or indirectly the purchase of goods or services. For pharmaceutical advertising the same function includes three parts:

1. To secure a greater part of an existing market;
2. To broaden the range of indications;
3. To expand the total market.

Any advertiser attempts to relate the specific benefits of his product to the specific needs of the consumer of the advertising message. Varying advertising appeals are merely reflections of varying needs of the advertising target as determined by the advertiser. This is true for any advertising. Prescription drug advertising is a special case, however. Some of the distinctive characteristics of this market are listed below:

1. The consumer of the advertising is often not the consumer of the product.
2. Institutional advertising (designed to enhance the firm's image rather than promote a specific product) is of greater importance here than in many other markets.
3. Because of the nature of the products, advertising and scientific com-

TABLE 11-1. A typology of pharmaceutical advertising

Rational Appeals	Non-Rational Appeals
Product Related Appeals	Empathy
Economy	Humor
Degree of Innovation	Sex
Differentiation/Position	Curiosity
Packaging	Fear
Dosage Form/Taste	Unusual non-clinical illustration
Physician Related Appeals	Ego gratifying
Peer/Specialist Approval	Anger/Defensiveness
P&T Committee Approval	Patriotism
Therapeutic Aid in Practice	
Clinical Use Appeals	
Dependability	
Safety	
Clinical Illustration	
Effectiveness	
Reminder	
Patient Related Appeals	
Compliance	
Quality of Life	
Patient Acceptance/Preference	
Manufacturer Related Appeals	
Experience	
Service	
Special Expertise	

munications tend to be confused. On one hand, advertisements may disseminate research results. On the other, favorable scientific reports in reputable journals may stimulate the sale of products. Some claim that pharmaceutical advertising at times becomes educational in character since the information it contains may constitute a valuable aid to therapy. It is certainly true that physicians and pharmacists read advertising.

4. The plethora of information on prescribing physicians and purchasing pharmacists in the United States practically fixes the population of the market and allows for more exhaustive analysis. Theoretically, this should mean that it is easier to tailor the advertising message to suit their needs.

5. In theory, the physician is a rational decision maker, somewhat similar to the industrial goods purchaser so that the emotional appeals of consumer advertising might (again in theory) be inappropriate to the audience. In actual practice, however, it is not at all unusual to see an emotional appeal in prescription drug advertising. Our working hypothesis is that the rational appeal is more useful for primary-demand stimulation, and the emotional appeal for selective-demand stimulation.

6. Actual readership seems to depend largely on the physical character-

istics of the advertisements. This, of course, is somewhat the case in any kind of graphic advertising. The copy may represent the profession in ego-gratifying terms and, because of the peculiar nature of the market, medical advertising often contains offers of samples while it ordinarily avoids any mention of terms and specific prices.

7. Readership of an ethical drug advertisement may depend in large part on the general readability and reputation of the journal in which the advertisement is published. A favorable attitude toward advertising may be expressed simply because of the confidence in the journal itself. Many journals have screening personnel who disallow the publication of dubious claims or presentation of doubtful products.

8. There may be predisposed confidence in the advertiser, particularly large ethical drug houses. Product and institutional advertising (or combinations) are important to the pharmaceutical manufacturer trying to establish its brand names. Although straight-forward advertisements by unknown manufacturers may be effective under special conditions, they may be viewed with some suspicion by some readers.

9. Ethical pharmaceutical products seem to be adopted in response to the combined stimulus of an unusual number of different forms of promotion (detailing, journal advertising, direct mail, and communication with other physicians and/or pharmacists). The relative influence of each advertising medium in stimulating the *continued use* of a drug product may be entirely different from its relative influence in *introducing* the same product.

10. Drug advertising is unique in presenting both the good and the bad about the product. Although federal regulation plays a large role in this, few, if any, other industries routinely point out the shortcomings of their products in their advertising.

Appeal Objectives

The appeals that might be used to advertise a given product are as numerous and varied as the motives of those to whom they are directed. The possibilities for verbalizing or symbolizing a given appeal are infinite; however, the appeal objectives of typical pharmaceutical promotion usually fall into one or more of the following categories:

1. Create awareness of the existence of a product or brand;
2. Create a brand image;
3. Supply information regarding benefits and superior features of the brand, e.g., reduction of side effects, ease in administration;
4. Combat or offset competitive claims;

5. Build familiarity and easy recognition of package or trademark;
6. Build corporate image and favorable attitude toward the company;
7. Establish a reputable platform for launching new brands or products;
8. Register a unique selling proposition in the minds of the prescriber while stimulating sales.

As Table 11-1 shows, we have identified several fairly distinct types of appeals beyond this classification. In general, the major distinction is between appeals to what might be termed rational and nonrational prescribing motives. These might be defined respectively as those which involve the process of matching means with ends and those more involved with the emotions and senses. This classification is made with the qualifications that the concept of rational versus nonrational behavior is not fully accepted by marketing theorists and that behavior may be rational but stupid.

RATIONAL APPEALS

Product-Related Appeals

Economy: In years past, medical advertising entirely and pharmaceutical advertising largely have avoided any mention of cost; however, that is no longer the case.

Innovation: Innovation is a traditional part of the development of the pharmaceutical industry. New products are the staff of life to the industry. As a consequence the word "new" appears with sufficient frequency in drug advertising to lose some of its effect. Nevertheless, the effect of a message that a significant medical advance has appeared may be powerful.

Differentiation: It is sound marketing policy to attempt in some way to differentiate your product from the otherwise similar products of the competition. Flavors, dosage forms, and unique packaging are methods of accomplishing this.

Mode of action or use: This is one of the most rational of appeals. In this case the doctor is told what the product is good for or how it works. Particularly when the physician has or recently has had a patient requiring this activity, his interest is aroused.

Physician-Related Appeals

Approval of peers: A product gains something in reputation by use among large numbers of physicians.

Therapeutic aid to physicians: In advertisements of this type it is made very clear that the product is a tool for the use of the physician. In the context the product appears valuable without subtracting from the importance of the physician.

Clinical Use-Related Appeals

Product dependability: The advertisement is designed to capture attention and arouse interest by presenting a claim that is impressive but believable. Copy and layout strategy is designed to inspire confidence by presenting unmistakable evidence of the product's successful use.

Safety: This is reflection of the medical dictum, *Primum non nocere* (first do no harm). Safety is a primary consideration at present with the current interest in adverse drug reactions.

Clinical illustration: In some cases the quality of the art in the advertisement offers an aid in explanation of the workings of the compound in vitro. The producer of the advertisement is in the position of creating a more believable instrument by illustrating a clinical situation rather than giving a sterile presentation of facts.

Reminder: The manufacturer orients the pictorial message to the physicians' experience. The advertising message tends to be perishable for two reasons: (1) The physician may forget about products used infrequently; (2) the products themselves change. For these reasons the reminder advertisement is important.

Patient response: The principal objective of this type of appeal is to show the actual effect of the drug. The before-and-after illustration is frequently employed in this type of advertisement.

Manufacturer-Related Appeals

In this type of appeal an effort is made to give a favorable impression of the manufacturer to the physician. Since confidence in the manufacturer is one element in prescribing motivation, such an effort is justified.

NONRATIONAL APPEALS

Empathy: Empathy is the participation in the feelings or ideas of another. As used in the present context it describes the appeal used in pharmaceutical advertising to project the feelings of the patients into those of their physician.

Humor: Humorous approaches to the advertising message are common in both medical and consumer advertising. Marketing people recognize, however, that merely succeeding at being funny is not tantamount to success in conveying the advertising message. The ability to construct an advertisement in which the humor is a natural lead-in to the effective advertising message is a rare talent.

Sex: There is a temptation to introduce sex into advertising of products which would not logically lend themselves to this appeal when nothing better can be developed. When this occurs, the result is the irrelevant use of both copy and illustrations.

Curiosity: Curiosity seems to be a quality inherent in physicians in even greater quantities than the rest of the population. As a consequence, it is frequently used as an attention-getting device in the drug advertisement.

Illustration-layout: The incongruous, the shocking, the unusual all can be used to advantage in adding attention value to the advertisement. If they are carefully selected so that they are relevant to the rest of the message, they literally may be "worth a thousand words."

Ego-gratifying: This appeal is basic, going to that which is most interesting to anyone—oneself. In advertisements of this type the physician is primary; the product, secondary.

Since analysis of the advertising content of medical journals shows both rational and nonrational types of appeal, it would seem to follow that the physician may be subject to nonrational motivations in the choice of prescription drugs. How can this be justified in a decision area which seems to demand only rational considerations?

An internal debate is constantly being waged by the physician. He must justify each prescription to himself, relating his decision to his own value system. Nonrational appeals play a part in his process of justification. The degree of rationality is, in the final analysis, a function of the physician's ability to match ends and means. The theory of cognitive dissonance may help us to understand this.

Cognitive dissonance is a multifaceted research tool which has been used to give further meaning to many types of motivational behavior. Ever since Festinger's theory of dissonance first appeared in 1957, it has at the same time tantalized researchers with its fascinating possibilities while being widely criticized as an oversimplification of a set of factors not readily amenable to such analysis. . . .

Inherent in every decision process is a certain degree of uncertainty. It has been hypothesized that this will lead to a psychological discomfort which Festinger refers to as dissonance. In an effort to reduce dissonance the decision maker will seek positive or favorable elements (i.e., information) which will hopefully reinforce his choice. These elements may take the form of advertising, irrational or biased thinking, or favorable opinions from supposed authorities. . . .

Physicians constantly receive various kinds of information about pharmaceuticals from colleagues, direct-mail advertisements, journal ads, medical journals and texts, detail men, and a variety of other sources. According to the theory of cognitive dissonance, physicians would much prefer to have all of these bits of information consistent with one another. If these cognitions are not consistent, the theory holds that physicians will try to reduce the inconsistency (dissonance), and that physicians try to reduce dissonance after making prescribing decisions.

Thus a doctor who selects Brand A tranquilizer over another brand might experience dissonance because he is aware of the beneficial features of the rejected brand and of the unattractive features of Brand A. One way for him to reduce dissonance would be to read advertisements of Brand A tranquilizer (the one prescribed) that would reinforce his decision.

In January, 1967 the *Journal of Marketing* featured an article by Robert Holloway describing an experiment aimed at determining the effects of several dissonance-producing factors (inducement to buy, anticipated dissonance, information, cognitive overlap) on dissonance experienced by consumers. Some of the theory presented in conjunction with this experiment has potential application to the physician/marketing interface. This statement is made even though we recognize that analysis of physician behavior involves many interacting forces, and the post-decision emphasis of dissonance theory represents only one part of a complex problem.

As Table 11-2 shows, one prescribing situation may produce dissonance while another does not. In this table we have taken some of the dissonance and buying situations from the Holloway experiment and applied them to the prescription situation. As this tabulation shows, several factors may be operative at the same time; one may produce dissonance, two others may be dissonance-reducing. It is equally true that the dissonance aroused by these differing conditions may be reduced in a variety of ways. The doctor may change his evaluations of the drug, select supporting information about the drug, or ignore (consciously or unconsciously) conflicting information.

Experimental studies are needed to determine the extent to which cognitive dissonance is a factor in the marketing of prescription drugs. Inventive design of such studies might well point out means of bringing more

TABLE 11-2. Dissonance and prescribing

Factors Affecting	Prescribing	High Dissonance	Low Dissonance
1. Attractiveness of rejected alternative	Doctor must choose between four Tranquilizers.	Three proven to be effective	One is clearly superior.
2. Negative factors in chosen alternative.	Doctor chooses between two similar drugs.	Chosen drug has desired action--is habit forming	Chosen one has desired action--not habit forming
3. Number of Alternatives	Doctor wants to to prescribe a diuretic	There are eight brands to choose from	Only two choose from
4. Cognitive Overlap	Doctor prescribes cough medicine	Both have codeine, other ingredients vary slightly	Both have codeine, other ingredients differ
5. Positive Inducement	Doctor prescribes antiobesity preparation	Patient three pounds overweight	Patient 30 pounds overweight
6. Information Available	Doctor prescribes for angina pectoris	Prescribes new pharmaceutical entity--little data available	Prescribes Nitroglycerine
7. Anticipated Dissonance	Doctor insists on very expensive brand name drug for hospital patient	Drug not on formulary--similar drugs are	Drug on hospital formulary

efficiency to the promotion of these products. Both pharmaceutical marketing and postgraduate medical education stand to benefit from increased knowledge of the psychological factors which influence the choice of drugs and information about drugs.

TO WHOM SHOULD YOU PROMOTE YOUR PRODUCTS?

Choosing targets for promotion of prescription drug products seems comparatively straightforward. Promotional messages should be sent to those who need information about the firm's price, place, and product and who make or influence decisions concerning product purchase.

Deciding to whom to promote precedes such additional strategic decisions as:

- What appeal is best?
- What part of your budget should be spent on this promotional target?
- Which promotional method(s) is/are the best choice? (See below.)

Clearly, prescribing physicians are a logical target for promotion of prescription drug products. Beyond that, basic decisions are decisions about pharmacists, nurses, administrators, and even the consumer. Table 11-3 provides a very general idea of the diversity of concentration in just a few markets by pharmaceutical advertisers.

The data in Table 11-3 certainly show differing levels of journal advertising by differing health professionals. That diversity reflects *inter alia* the company product lines, the degree to which a given health professional is believed to warrant attention *and* the other promotional media used. As an example of the final point, a 1988 survey by *American Druggist* showed the following rankings of most frequent detail calls by company:

Wyeth/Ayerst	1
Upjohn	2
Parke Davis	3
Merck	4
Lilly	5

The importance of product type/line is underscored by the presence of five generic producers among the top 50 advertisers to pharmacists and only one among the top 50 journal advertisers to physicians.

Recently, there has been considerable shifting of promotional targets. Tucker and Smith (*Medical Marketing and Media*, May, 1989) note that

TABLE 11-3. Leading pharmaceutical advertisers by expenditure, 1988, 1989

	Rank in Advertising Expenditures					
	Medical Journals		Pharmacy Journals		Nursing Journals**	
Company	1988	1989	1988	1989	1988	1989
Merck	1	1	2	5	*	42
Pfizer	2	5	30	28	*	*
Upjohn	3	2	4	1	1	2
Glaxo	4	8	1	2	*	*
Wyeth-Ayerst	5	6	*	6	3	12
Roerig	6	11	25	12	*	*
Squibb	7	21	32	46	*	*
Searle	8	4	20	17	*	*
Roche	9	10	19	14	*	*
Parke Davis	10	9	5	3	*	*

* = Not in top 50
** = Rank among pharmaceutical manufacturers

Source: *Medical Marketing and Media*, March, 1989; September, 1989

the growing phenomena of managed care and the previous five years of cost constraints and reimbursement changes due to the Medicare Prospective Payment System have caused a hospital marketplace metamorphosis. One of the most notable changes is the decision maker involved in the drug purchasing and selection process. The pharmaceutical company is facing a new breed of gatekeeper: one whose motivations, role, background, education, and title are all markedly different than that of the physician and even the pharmacist—considered the more traditional decision makers. In many settings, such as managed care organizations and hospital consortia, this new gatekeeper controls access to major portions of the marketplace with a single formulary or purchasing decision.

In order to maximize the effectiveness of their product promotions, pharmaceutical marketers must make certain that the content of their message coincides with the information needs of the new decision maker. As a result of the hospital administrators' background and position responsibilities, these Chief Executive Officers (CEOs) may evaluate hospital products for purchase—or inclusion on a formulary—differently than the more traditional decision-making physician or pharmacist. As a result, promotional efforts must be designed to meet the product and information needs of this new decision maker.

Several pharmaceutical companies have already recognized the emerging importance of hospital administrators in drug purchasing and selection decisions. Stuart Pharmaceuticals, a division of ICI Americas Inc., promoted the cost advantages of Cefotan over cefoxitin and other antibiotics in several 1988 issues of *Hospitals*, a widely-read journal targeted toward hospital management. Cipro, Miles' oral quinolone product, was also advertised in *Hospitals*. Cost comparisons with parenteral antimicrobials were annotated. *Modern Healthcare*, a weekly hospital business news journal, has been the forum for Abbott's ADD-Vantage System advertisements, while Travenol has widely promoted the waste-, cost-, and time-saving advantages of premixed medications in the VIAFLEX Plus Plastic Containers.

Wyeth (now of Wyeth-Ayerst Laboratories) promoted the Tubex system as the cost-effective choice in injection therapy in *Healthcare Executive* a couple of years ago. Cefobid, a Roerig product, was promoted in *Modern Healthcare*, with copy which read "In today's environment, ways for providing cost-conscious quality care are of interest to all healthcare professionals." In *Hospitals*, the "Cefobid Guarantee, an innovative program in cost-effective antibiotic therapy" was directed toward hospital administrators and other top management. *Healthcare Executive* has also been the forum for SmithKline's ads for Tagamet as well as for Squibb's

advertisements for Capoten showing the results of a study documenting the ace-inhibitor's ability to decrease hospital length of stay.

In a study of hospital administrator preferences, the promotional appeals (see preceding section) were examined. Table 11-4 provides data to support the view that hospital CEO's have very definite drug concerns which they wish to see addressed in ads targeted to them.

A SPECIAL CASE: PRESCRIPTION DRUG ADVERTISING TO CONSUMERS

The 1980's saw a revolution of sorts in prescription drug promotion. For virtually the first time advertisements to the general public alluded to conditions for which the treatment was to be a prescription drug. (See Table 11-5.)

The strategies, concerns, and expectations which led to some of the earliest experiments in direct-to-consumer (DTC) prescription drug advertising are illuminating. In a 1986 symposium jointly sponsored by the American Medical Writers Association and the Pharmaceutical Advertising Council, the views of some of the early practitioners were expressed and included those of Elizabeth Moench who described some of the strategic considerations as DTC of Boots:

> In 1969 the Boots company, a British based $3 billion company, licensed to the Upjohn Company for the U.S. market a product called "Ibuprofen." Upjohn has been marketing Ibuprofen under the brand name of Motrin since 1974. Boots at the time of the licensing arrangement, made it clear that, at some time in the foreseeable future, as and when Boots established a presence in the states, Boots would market its own version of Ibuprofen. With the acquisition of Rucker Pharmacal in Shreveport, Louisiana in 1977, Boots established its base and introduced Rufen Ibuprofen in September, 1981.
>
> Boots faced many difficulties in marketing Rufen, unique to Boots, and also to the industry. Boots was to compete against its licensee Motrin which was the brand leader.
>
> Boots had only 110 sales representatives, against 5,164 representatives at that time in the nonsteroidal anti-inflammatory market. In the U.S. Boots was virtually unknown and the company had to convince both pharmacists and physicians that Rufen was not a generic but that Boots was both the patent holder and developer of Ibuprofen.

TABLE 11-4. Ranking of pharmaceutical product written appeals according to mean scores for hospital administrators

Appeal	Ranking*	Mean**
Cost-effective	1	1.15
Reduced hospital operating costs	2	1.23
Reduced chance of medication error	3	1.24
Reduced total cost of patient care	4	1.34
Clinical efficacy	5	1.37
Assurance of quality from manufacturer***	6	1.42
Reduced inventory costs***	7	1.42
Decreased patient length of stay	8	1.51
Increased productivity	9	1.51
Reduced preparation labor costs	10	1.61
Reduced drug administration labor costs	11	1.61
Decreased drug waste	12	1.62
Reduced risk of bacterial contamination	13	1.66
Preferred by medical staff	14	1.89
Decreased drug pilferage	15	1.90
Ready-to-use unit-dose	16	1.97
Product standardization	17	2.19
Increased time to devote to clinical activities	18	2.25
Extended expiration dating	19	2.42
Preferred by pharmacy staff	20	2.54
Easier recycling	21	2.90
Preferred by nursing staff	22	3.01

* Ranking with mean scores carried to four decimal places.

** Mean based on average scores from a seven point Likert-type scale with the following values and anchors: (1) very important, (2) important, (3) slightly important, (4) neutral, (5) slightly unimportant, (6) unimportant, (7) very unimportant.

*** Indicates a tie when mean scores carried to four decimal places; appeal assigned a rank equal to the average rank of the tied group.

Due to patent expiration in 1985, Boots had a limited time in which to establish Rufen in the market place. The only selling message that Boots had was the "Rufen was the same as Motrin but cost less." The cost/benefit advantage was to be the marketing approach in detailing Rufen to physicians. This posed a final dilemma. How could Boots assure the doctor that his patients would indeed receive Rufen at a lower price? The answer was the introduction of the $1.50 rebate coupon, and a 25-cent contribution to arthritis research

TABLE 11-5. "Genealogy" of direct to consumer advertising

YEAR	PRODUCT/INDICATION	COMPANY
1981	Pneumonia vaccine	Merck
1982	Hepatitis B vaccine	Merck
	Consumer program	Pfizer
1983	Rufen versus Motrin	Boots
1983-85	FDA moratorium on DTC advertising by product name	
1984	Menstrual cramps	Syntex
	Quit smoking	Merrell Dow
1985	Painful leg cramps	Hoechst-Roussel
	Quality of life	Squibb
1986	Genital herpes	Burroughs Wellcome
	Allergy sufferers	Merrell Dow
1987	Diabetes/recipes	Roerig Pfizer
	Arthritis/angina	Pfizer
	Tavist-1	Sandoz
1988	Ulcers	Smith, French /Glaxo
	High cholesterol	Merck

Source: Kathleen McRoberts in *Pharmaceutical Executive*, November, 1988.

for every coupon redeemed. This marked also the first time price rather than a product's clinical and therapeutic advantages had been detailed to physicians, and the first test of consumers' response to price.

The $1.50 rebate program became the catalyst for Boots' direct-to-consumer advertising program for Rufen.

In preparing for the direct-to-consumer approach, it was necessary to first conduct market research, with consumers, then with physicians and pharmacists. The consumer research was done in three waves:

First, consumer knowledge and understanding about arthritis and prescription drugs was determined. Second, price advertising concepts were tested in order to measure reaction and comprehension. The third wave of testing was the television commercial itself. From the market research the target audience was identified and a strategy was designed to test the advertising concept.

Boots would advertise in two markets. Tampa, with Miami as the control, and Oklahoma City, with a control of Tulsa. In the selection of the test market many factors were considered, including population demographics, third-party pay/Medicaid reimbursement, and advertising costs. The test would be for 6 months, during which time, independent market research, and research by Boots' own market research team would be conducted.

Prior to the launch of the consumer program, it was essential to test physician response to the television commercial in the Tampa area, and to inform them of the program.

If you are asked to give your opinion on direct-to-consumer advertising for a prescription drug, what comes to mind? Would you be in favor or adamantly opposed to the concept? When physicians were asked to picture a prescription drug being advertised to consumers they were principally opposed, having nothing to compare the commercial to other than those already on television for OTC products. It is human nature to assume the worst, and when physicians were surveyed by asking to give their views as to "Should prescription drugs be advertised directly to the public?" the answer is almost always "No!" Such research was conducted by Boots. In the January 1986 issue of *Pharmacy Times* this question was asked. They found that 4 out of 5 (79%) responding physicians were opposed to the concept.

This brings me to the point of emphasizing that Boots felt during this time, there was a need for more in-depth market research, for specific commercials out of the laboratory setting, and that they be implemented by both industry and FDA in order to evaluate the merits of direct-to-consumer advertising and in formulation of policy. In comparing the Boots' Rufen commercial to other OTC medications which make veiled promises to rheumatic patients, I would ask you to make your own decision as to its merits. The physicians sampled in Florida were highly in favor of the Rufen commercial. Information kits about the consumer program were sent to all health care professionals in the Tampa area.

With the additional data regarding physician acceptance, the first commercial was launched on May 19th. Boots received on May 20th a regulatory letter from FDA alleging that the commercial violated agency regulations, and demanding withdrawal of the commercial by noon May 23rd. On the morning of the 23rd, Boots' President John Bryer appeared on the *Today* show with Commissioner Hayes

and on the afternoon of May 23rd, the FDA held their first consumer exchange meeting in Washington, where the consumer ad was discussed. The commercial was withdrawn and a letter sent to the FDA rebutting all the comments made in their letter, especially since Boots felt the advertisement, composed mostly by attorneys, complied with all existing regulations.

FDA was then provided with this alternate commercial which was then approved May 24th. The newspaper advertisement was delayed for several weeks since it was revised to adhere to all the points raised in the regulatory letter.

I should point out that the consumer advertising program was not just a television commercial and newspaper advertisement, but included patient information, physician information, and a new magazine called "Go!" specifically designed for arthritis patients, with $1 from each subscription to be given to the Arthritis Foundations.

The public relations campaign was highly successful; press kits containing full information were sent to all major media. The launch of the consumer program was planned for May 19th to coincide with the article in the *Wall Street Journal*. In one day Boots talked to over 30 reporters and held a press conference in New York, the same week Cable Health Network announced FDA approval for the advertising of prescription drugs.

Boots viewed FDA's action to approve Cable Health Network (Lifetime) as somewhat hypocritical, where on the one hand they had requested a moratorium on direct-to-consumer advertising other than price. Yet permitted advertisements to air on a consumer network whereby FDA publicly stated they could expect "eavesdroppers" with demographics of "8.5 million consumers, and 40,000 physicians" (at that time).

Following the launch of the first direct-to-consumer advertising program for Rufen, I spoke at the FDLI (Food and Drug Law Institute) meeting and stated:

> This is the first time a marketing plan has been devised where the consumer is the central core: in other words, we have responded to the needs of consumers without impairing Boots' relationship with doctors, and what we have done must surely be a sign for what is yet to come.

On February 26, 1986 Zenith announced a consumer program for tolazamide modelled after the Rufen $1.50 rebate coupon. The company has also announced that more innovative programs are yet to be

launched. Many other companies have come close to a direct-to-consumer approach, but none have taken the quantum jump.

Direct-to-consumer advertising can and will only succeed when the profile of the respective patient can be clearly defined, understood, and a marketing program narrowly tailored to that particular audience. I also believe that products for long-term chronic use will be the products most conducive to direct-to-consumer advertising. But as Milton Friedman recently wrote in *Newsweek*—"Be wary of the self-proclaimed 'experts' and an expert on predicting the future I am not, only a speculator!"

Kirk Schueler, an award-winning marketer at Merrell Dow, describes their approach differently.

OTC drugs are advertised directly to consumers, and appropriately so, since in order to qualify for over-the-counter status a product is supposed to be (1) for a condition which is easily self-diagnosed, (2) can be reasonably self-treated, (3) with a modest or reasonable level of information necessary regarding proper use. The product itself is one for which (4) there is a substantial amount of experience and (5) general recognition of safety and effectiveness.

Rx drugs differ from OTC drugs on one or more and sometimes all of the above criteria. They can be for (1) difficult to diagnose conditions, (2) which require professional treatment decisions and monitoring, (3) with a more in-depth level of information required regarding proper use. Rx products may have (4) a limited amount of usage experience, and (5) a still developing safety and/or efficacy profile.

These distinctions mandate a different method of distribution, the requirement of the involvement of a physician, and a different mode of promotion. It is in our opinion, unacceptable to advertise prescription drugs in a manner similar to OTC drugs.

What factors, then, lead us to favor direct-to-consumer promotion? By definition, we are excluding product-specific ads. The promotion we are including is disease-oriented advertising and there are many factors which favor such promotion:

1. Consumers desire more in-depth information on health issues. A better informed consumer is generally a healthier consumer. Pharmaceutical manufacturers can help consumers become better informed about important health issues.
2. Consumers are generally more oriented to self-treatment than

ever before. While this is beneficial to them in some circumstances, it can be detrimental in others. Direct-to-consumer promotion can help consumers identify appropriate times and circumstances where a physician's guidance can be beneficial.

3. Our medical knowledge and the availability of treatment alternatives is expanding. Direct-to-consumer promotion can help consumers be more aware of this information and thereby use it to their advantage.
4. Drugs are often used incorrectly. Compliance might be improved through direct-to-consumer promotion. Greater communication between patients and health care professionals can also be fostered regarding proper use and potential side effects of medications.

These direct-to-consumer promotional efforts can have a favorable impact on the sales of specific products, but without a brand name orientation within the promotion. So, what's wrong with brand name focus? Why do we oppose prescription drug advertising to the consumer? There are several important reasons.

1. Product-specific ads will result in product-specific requests from consumers to physicians. As we've discussed, if a product is on prescription status, it requires a physician's expertise. That expertise may be essential for proper diagnosis, proper treatment selection, and proper usage instructions. Drug manufacturers should be preserving and indeed building the doctor-patient relationship, not eroding or circumventing it.
2. Product-specific ads that result in physicians prescribing products based on patient request would increase the drug manufacturer's liability since the learned intermediary role of the physician is compromised. Primary responsibility of communicating precautionary information to the patient would now fall on the manufacturer rather than the physician. We certainly can't want to increase liability issues.
3. Adequate precautionary information would be extremely difficult to provide in prescription drug advertising to the consumer. Attempts to provide that information would also add considerably to the cost of such advertising due to the air time and publication space needed for that information.
4. Multiple product-specific ads within individual therapeutic categories would be likely to result in considerable consumer confusion and a general increase in health care promotion

costs. To speak to the confusion issue, let's take the anti-hypertensive market as a hypothetical example. Imagine one manufacturer of an alpha blocker promoting the "alpha advantage," another manufacturer the beta difference, a third emphasizes the importance of once-a-day dosing, a fourth says a major factor in hypertension is fluid retention and our product is the "most potent diuretic or fluid reducer on the market." How is a consumer supposed to sort out these messages? Imagine further that a consumer found the "alpha advantage" message very convincing and went to his or her doctor asking the physician to "give me the alpha advantage." The patient/product match may not be appropriate. The physician is then placed in the position of either talking the patient out of the "alpha advantage" or possibly risking losing the patient to another physician who would honor the patient's request. If the doctor succumbs to the pressure and prescribes the product for fear of losing the patient from the practice, then we run into the problems we talked about with increased manufacturer liability and a deterioration of the doctor-patient relationship. I don't think that's the kind of health care system any of us want.

In summary, prescription drug advertising to the consumer could result in improper matches of product and patient, insufficient precautionary information for patients, a deterioration in the doctor-patient relationship, increased liability for the manufacturer, and escalated health care promotion costs.

Now, I would like to put these thoughts together and state Merrell Dow's position on the issue of direct-to-consumer promotion.

Merrell Dow believes that limited applications of direct-to-consumer advertising by pharmaceutical manufacturers are beneficial and can result in a more informed public consulting with physicians on health care matters and therapeutic advances and hopefully complying better with treatment regimens. Key guidelines for such promotion include:

1. Prescription products should not be mentioned by name.
2. The role of the health care professional in diagnosis and treatment selection should be reinforced.
3. Any indirect references to products should conform to that product's approved labeling.

These guidelines become clearer by reviewing programs which Merrell Dow has run in the past several years.

A Merrell Dow campaign I'll describe was tested in the fall of 1985 and has just begun national implementation. As with our smoking cessation campaign, this campaign is based on results of survey work with consumers and is in support of a recent Merrell Dow product introduction.

Extensive research with allergy sufferers revealed a high level of dissatisfaction with allergy treatments then available. The primary area of dissatisfaction was with the drowsiness or sedation associated with the conventional antihistamines. Millions of allergy sufferers had either stopped taking these products or took them on a less-than-scheduled basis when the side effects of the medication were more bothersome to them than the symptoms of their allergy. The term we use to describe these people is "silent sufferers."

In May of 1985, Merrell Dow introduced Seldane (terfenadine) to physicians. This product provides efficacy equal to conventional antihistamines but a level of drowsiness equivalent to placebo and therefore it represents a major advance for allergy sufferers. In the fall allergy season of 1985, Merrell Dow began an allergy educational awareness campaign directed at silent sufferers in three test markets. As with the smoking cessation campaign, one area received only print exposure to a one-page advertisement. The lead-in to the ad is "if you hesitate to take seasonal allergy medications because they make you drowsy . . . " and the ad obviously appeals to the silent sufferers. The ad goes on to describe silent sufferers, inform consumers that advances in prescription medications have been made and encourage people to ask their doctor about treatment alternatives.

Another geographical area had a higher print level plus radio and a third added TV. This spring's national campaign will include print and radio and other mixes will be tested.

Returning to our guidelines, the Allergy Campaign:

1. Makes no specific reference to Seldane by name.
2. Reinforces the role of physicians. Within the ad it is stated that "only your doctor can determine which form of treatment is best for you" and also that your doctor "will assess your condition, recommend a program of therapy, and follow your progress."
3. Indirect reference is made to Seldane by referring to treatment

that "provides effective relief of symptoms without the degree of sedation associated with commonly used antiallergy products." Other treatments also fit that reference but the ad is also in compliance with Seldane labeling.

Our surveys revealed a consumer concern. Our advertising helps inform patients of advances which address that concern and encourage them to seek physician guidance which will help many sufferers receive a more useful treatment for them.

I think it's important to note that we've presented the smoking cessation and allergy campaigns to physicians and received favorable reactions. They recognize that these campaigns will increase office visits for these areas while allowing the physician to make the appropriate diagnosis and treatment decision free of undue pressure for a specific product.

So, Merrell Dow's experience with direct-to-consumer promotion has been very favorable. The campaigns have increased consumer information, reinforced and indeed built the role of the physician and the physician-patient interaction while also making good business sense.

Similar campaigns may not make sense for many products or fields of therapy. Smoking cessation and allergy each have a target audience of around 40 million people. Our products are new and distinctive. Physician awareness of the products is extremely high. Non-physician alternatives proliferate. Consumer information needs are high.

We see that somewhat limited application of direct-to-consumer as a benefit. It will help keep the number of campaigns at a level where consumers can be better informed rather than more confused and it should contribute to a much more favorable image for our industry.

What about directions for the future? Some industry observers have seen efforts such as the Merrell Dow campaigns as preludes, a testing of the waters, prior to an aggressive foray into product-specific advertising. We don't view it that way and hope it doesn't become that.

We think product-specific ads are inappropriate for prescription products. It could be a Pandora's box which once opened would unleash demons that would have a lasting effect on our industry. If a manufacturer feels a product is appropriate for OTC-style advertis-

ing, they should file for OTC status. If and when that status is received, product-specific ads should be pursued, but not before.

Direct-to-Consumer Advertising would seem to make sense only when certain conditions exist.

- The consumer can be taught to identify the condition your product treats.
- The consumer can be convinced to visit a physician for help.
- The physician will have only *your* product available.
- The physician will prescribe it.

As the 1980's drew to a close-three DTC situations were being watched very carefully. The biggest economically was the Tagamet-Zantac television war.

Tagamet took prescription ulcer therapy to the airwaves in March, 1988 as a clay form of a stomach told viewers that persistent stomach problems could be signs of an ulcer and urged them to see their doctors for treatment. Weeks later, Glaxo responded to the competitive pressure by running its own television spots and print ads with the same message. So far so good, but what was the physician to do?

The increased attention to ulcers might help to expand the market by getting new patients on medication. The big question is, once consumers go to their doctors and an ulcer is diagnosed, which medicine will be prescribed? By the time the ads ran, the physician had a choice of four. One, Axid, may have even had an advantage over the two DTC advertised products—its packaging. The product comes in 30-day convenience pack that will be labelled with the days of the week. The package is designed to encourage people to take the medication even after the pain of the ulcer has disappeared.

This particular situation is complicated by the hope that both Tagamet and Zantac would ultimately be granted OTC status. Perhaps toward that end Glaxo attempted to enlist pharmacist support for their campaign as well. A second DTC case was that of Rogaine, which received prime-time television advertising as well as print support in such expensive publications as *Time*. Rogaine, of course, fits the criteria cited above *and* there is the potential for indirect name recognition during promotion of its companion non-prescription shampoo product, Progaine. (See Chapter 10.)

The final DTC case, one with important implications for the future, is one placed by Lexis Pharmaceuticals for its generic birth control pills, N.E.E. 1/35. The ads represent the first FDA-approved use of a prescription product name in consumer advertising.

An FDA spokesperson said the agency allowed the ads since they were being run in the print medium, which allows for full disclosure. Had the ads been designed for television, she said, "it would have been another matter."

Lexis' ads mention the product N.E.E. 1/35m, the bioequivalent of the most widely prescribed birth control pills and the fact that the product sells for 50 percent below the price of branded oral contraceptives, according to a company spokesperson.

Lexis ads ran in *Ms. Magazine*, *Cosmopolitan*, *Mademoiselle*, *Glamour*, *Shape*, *Rolling Stone*, and *Self*.

Moreover, women who buy a six month's supply of the Lexis product were eligible for a $10 rebate check. Twelve months of purchases were rewarded with $20.

Clearly, the marketing equation for the pharmaceutical industry has changed. Pharmaceutical marketers must identify and investigate the new target audiences and add them to the marketing equation. Regardless of the marketing issue a pharmaceutical company is facing, it must first determine the participants in the decision-making process and the roles they play.

WHERE TO PROMOTE: STRATEGIC CHOICES AMONG MEDIA

Strategic decisions in the area of promotion concern the allocation of effort among the different methods of promotion (media). For prescription drugs the broad classes of media available are:

1. Advertising: journals, direct mail, and other.
2. Personal selling (detailing): in person by telephone, at conventions, etc.
3. Sampling
4. Sales promotions, giveaways, calendars, pens, other product reminders.
5. New media: television, radio, computers.

There is a critical need for developing a conceptual framework to make promotion-mix decisions. A variety of factors may be considered to determine the appropriate promotion mix in a particular product/market situation. These factors may be categorized as product factors, market factors, customer factors, budget factors, and marketing-mix factors, as outlined

in Table 11-6. Discussed below is the significance of each of these categories in determining the promotion mix.

Product Factors

Factors in this category relate principally to the way in which the product is prescribed, used, bought, consumed, and perceived. The perceived risk of a decision is another variable here. Generally speaking, the more risk a prescriber perceives to be associated with prescribing a particular product, the higher will be the importance of personal selling over advertising. He generally desires specific information on the product when the

TABLE 11-6. Sample criteria for determining promotion mix

PRODUCT FACTORS
1. Nature of Product
2. Risk/benefit relationship
3. Degree of exploration required for successful use
4. Potential for demonstration
MARKET FACTORS
1. Position in its life cycle
2. Market share
3. Industry concentration
4. Intensity of competition
5. Demand perspectives
6. Generic Competition
CUSTOMER FACTORS
1. Hospital or Drug Store
2. Customer power
3. Physical distribution considerations
ENVIRONMENTAL FACTORS
1. Regulatory Controls
2. Social Climate
BUDGET FACTORS
1. Financial resources of the organization
2. Traditional promotional perspectives
MARKETING-MIX FACTORS
1. Relative price/relative quality
2. Distribution strategy

perceived risk is high, and this necessitates an emphasis on personal selling. Personal selling is also important in delivery of messages of unusual or complicated product benefits.

Market Factors

The first market factor is the position of a product in its life cycle. The creation of primary demand, hitherto nonexistent, is the primary task during the introductory stage: therefore, a high level of promotion effort is needed to explain a new product to potential customers or prescribers. This is often the logical time to use samples.

In the maturity phase competition becomes intense, and advertising, along with sales promotion, is required to differentiate the product from competitive brands. During the decline phase, the promotional effort does not vary much initially from that during the maturity phase except that the intensity of promotion declines. Later on, as price competition becomes keen and demand continues to decline, overall promotional perspectives are reduced.

For a given product class, if market share is high, both advertising and personal selling are used. If the market share is low, the emphasis is placed on either personal selling or advertising.

If a market is concentrated among a few firms, advertising will achieve additional significance for two reasons. One, heavy advertising may help discourage other firms from entering the field. Two, it sustains a desired position for the product in the market. Heavy advertising constitutes an implied warranty of product performance and perhaps decreases the uncertainty associated with new products. In this way new competition is discouraged and existing positions are reinforced.

Intensity of competition tends to affect promotional blending in the same way that market share does. When competition is keen, all types of promotion are needed to sustain the product's position in the market. This is because promotion is needed to inform, remind, and persuade. On the other hand, if competitive activity is limited, the major function of promotion is to inform and perhaps remind about the product.

Hypothetically, advertising is more suited for products which have relatively latent demand. This is because advertising investment should open new opportunities in the long run, and if the carryover effect is counted, expenditure per sales dollar would be more beneficial. If demand is limited and new demand is not expected to be created, advertising outlay would be uneconomical. Thus, future potential becomes a significant factor in determining the role of advertising.

Customer Factors

Certainly the choice of promotion mix will be determined by the customers. Selling in a multi-million dollar bid situation certainly requires personal presence and the facility for give and take. On the other hand, promotion of a seasonal cold-remedy deal may be accomplished as well through a journal ad.

Environmental Factors

We have already noted the stringent controls on prescription drug promotion imposed by F.D.A. There are social considerations, as well. Television networks, for example, have been reluctant to accept ads for contraceptive products. The drug diversion problems which reached a peak in the 1980's resulted in both regulatory controls on samples and some professional distaste for the procedure itself.

Budget Factors

Ideally the budget should be based on the promotional tasks to be performed. However, intuitively and traditionally, companies place an upper limit on the amount that they will spend on promotion. Such a limit may influence the type of promotion which may be undertaken. Budget factors affect the promotional blend in two ways. First, a financially weak company will be constrained in undertaking certain types of promotion. Second, in many companies the advertising budget has been traditionally linked to revenues as a percentage. This method of allocation continues to be used so that expected revenues will indicate how much might be spent on advertising in the future. The allocated funds, then, automatically determine the role of advertising.

Marketing-Mix Factors

The promotion decision should be made in the context of other aspects of the marketing mix. The price and quality of a product relative to competition impact the nature of its promotional perspectives. Higher prices must be justified by actual or presumed product superiority. Thus, in the case of a product which is priced substantially higher, advertising achieves significance in communicating and establishing the product's superior quality.

The promotion mix is also influenced by the distribution structure employed for the product. If the product is distributed directly, the sales force will largely be counted on to promote the product. Indirect distribu-

tion, on the other hand, requires greater emphasis on advertising since the sales force push is limited.

*MEDIA**

In this section we will touch briefly on the major promotional media available for use by the prescription drug industry. Specifically, we will touch on:

- Space media (journals, magazines, newspapers)
- Direct mail
- Personal selling (detailing, conventions and meetings, telemarketing)
- Samples
- Sales promotions, electronic and "other" media

Space Media

Space expenditures represent the amount of money spent for advertising in journals, magazines, and newspapers. The annual cost of such advertising in physician-oriented media alone amounted to nearly $400 million in 1989.

Distinction is made between journals, magazines, and newspapers, with the difference between them being in the editorial content. Journals, for the most part, offer technical information relating to an individual's professional practice. *The Journal of the American Medical Association*, *Archives of Internal Medicine*, *GP*, and the *Journal of the American Pharmaceutical Association* are examples of professional journals. *Medical Economics*, *American Druggist*, and *Dental Management* are in the magazine category because their editorial content is not specifically devoted to the scientific aspects of the reader's training, but is nonetheless important to the business side of professional practice. Newspapers require no definition and include publications such as *Medical Tribune* and *Family Practice News*.

Another distinction involves the matter of payment. Physicians may subscribe to individual publications (e.g., *New England Journal of Medicine*), they may pay for it as part of a professional membership (e.g., *Journal of the American Medical Association*), or they may receive it without charge, so-called "controlled circulation."

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*Dr. Max A. Ferm contributed materials for this section in previous editions.

Among other methods by which space media may be distinguished are:

- Circulation, general/specialty/mixed
- Advertising/editorial ratio
- Readership studies
- Physical placement of ads (e.g., throughout or only at beginning and end sections
- Cost structure
- Whether press releases are accepted
- Presence of advertisers' index
- Frequency of publication

There are, literally, hundreds of different publications from which the advertiser may choose. Some deal only with matters of clinical interest. Some cover aspects of practice such as politics and economics (*Medical Economics* is a perennial leader in advertising revenues). Others, while they contain drug ads, feature editorial content on travel (*Physician's Travel and Meeting Guide*), financial planning (*Physician's Assets*), and leisure activities (*Diversion*).

There are many other options including single-sponsor publication and "house organs." A single-sponsor publication is independently published and has just a single advertiser-supporter rather than many advertisers. In most other ways—purpose, audience, editorial content—it is about the same as an open-advertising publication. It is not a house organ, which traditionally reflects the views and activities of the company that sponsors it. The content of the single-sponsor publication is divorced from the sponsoring company. *Diversion* began as a mixture, owned by Johnson & Johnson and carrying only J. & J. drug ads, but also ads for non-drug products of other companies.

Direct Mail

The use of direct mail has a distinct advantage over space advertising in that it can be directed to specific individuals rather than groups of individuals. A premium is paid for this advantage because on a per contact basis direct mail is more costly. It is, however, a separate medium and requires understanding of the facilities available to be employed properly.

The American Medical Association (AMA), for the most part, provides basic lists used in medical promotion to franchised mailing houses, from whom they are available. An AMA royalty fee is included in the mailing charge each time the list is used. Lists are supplied on computer tape and

are frequently revised because inaccurate lists give rise to undelivered mail, which adds a heavy burden to the cost of this medium.

Lists are available in almost any manner desired. One can purchase the use of physicians' names by specialty, age, type of practice, state or county of practice, and other statistics.

Direct mail, in addition to its selectivity, permits the use of promotional techniques not readily available in space media. For example, past experience has shown that physicians are not easily motivated by coupon insertions in journals, while product requests from the physicians can be obtained in the form of self-addressed business reply cards included with direct mail promotional material. This is an important consideration because it establishes a relationship between manufacturer and physician that can be measured and utilized.

When a campaign is developed, various types of mailing pieces are employed by manufacturers. Some of these are in the form of self-mailers, envelope mailers, letters, or box mailings. The least expensive is the self-mailer, which requires no envelope and is usually prepared as a jumbo card (two sides) or a four-page mailer. A mixture might include all or several of these types, each one printed in sufficient quantity to be used more than once. For example, one might select three individual pieces, each mailed three times for a total of nine mailings.

Studies with business reply cards as the measurement have focused upon the difference in response that can be obtained by altering such factors as the introduction of a letter, the use of postage stamps instead of printed indicia, personalization, and other variations.

Although direct mail is a desirable medium, it has a major disadvantage. Unlike journals, which offer an editorial environment designed to appeal to the physician's need to improve clinically, economically, or culturally, the average mailing piece is obviously promotional in design. The challenge is to create interest while delivering a selling message.

One device employed to overcome this drawback is the preparation of a manufacturer-sponsored journal, or "house organ." This provides the advantage of both types of media by offering an interesting editorial format with direct mail specificity. It is an expensive means of promotion that has found favor among advertisers. The preparation of editorial matter incurs the majority of cost because it requires additional staff not required for advertising needs. For this reason companies have been formed to gather the editorial material. By specializing in one area—such as news or clinical abstracts—a single staff of writers can be employed for the preparation of several house organ magazines appealing to different physician specialties.

Personal Selling/Detailing

Done well, detailing is generally accepted to be the most effective form of pharmaceutical promotion. Comparisons and contrasts between this form of promotion and print advertising are shown in Table 11-7.

Although practices vary, companies tend to limit their advertising departments to space media and direct mail media, while the balance of promotional expenditures is usually administered by the sales promotion department. The distinction between the responsibilities of the advertising department and those of the sales promotion department can best be described by their different methods of communicating the selling message—the advertising department primarily employs written or visual messages, while the sales promotion department primarily relies upon the use of sales personnel in personal, primarily oral, presentations.

Pharmaceutical sales department field staff can be quite large in number. In 1988, the combined sales forces of the ten top staffs in size totaled nearly 13,000. (See Table 11-8.) The attractiveness of such positions with the leading firms is attested to by a report from Merck that it received 28,000 applications and interviewed 4,900 candidates before hiring 480 sales trainees in a five-week period in 1988 (*F-D-C Reports*, October 31, 1988).

Inasmuch as the detailperson becomes a firm's personal representative while in the field it should not be surprising that considerable attention is given to his/her training. In one of the few published studies of field staff training (*Medical Marketing and Media*, March, 1988), Kodiyalam, Segal, and Pathak reported on responses from half of the P.M.A. members concerning emphasis placed on various training topics. The results are shown in Table 11-9.

The environment of personal selling of pharmaceuticals is becoming increasingly restrictive and specialized. In two sequential surveys, for example, Thomas (*American Journal of Hospital Pharmacy*, March, 1989) found increased controls by hospital pharmacy directors on the activities of professional service representatives (PSRs) in their hospitals.

Half of the respondents reported that their hospitals planned to increase restrictions on products that PSRs would be permitted to detail or sample. The most common reason given for anticipated policy changes was a desire to improve control of the formulary. The directors viewed information about new products as the most useful PSR service, most directors wanted PSRs to discontinue sampling or excessive sampling, and most desired greater educational support from PSRs.

From late 1983 to 1986, approximately 20 percent of hospitals had

TABLE 11-7. Advertising and detailing: Similarities and contrasts

	Advertising Differences	Similarities	Detailing Differences
Functional Characteristics	One-way communication. Abundant "noise" in the communication channel. Relatively inflexible. Good control over the message. Almost impossible for phsician to avoid some exposure to the message.	Both must be: understandable, interesting, believeable, persuasive.	Two-way communication. Some control over "noise." Can be tailored to the situation. Difficult to maintain company control of the message. Physician may refuse refuse to see.
Perceptual Characteristics	Difficult to reinforce the message during the course of presentation.	Both must penetrate sensory mechanisms of the physician, with careful selection of stimuli necessary.	May stimulate all five senses as well as vary them selectively. May reinforce and repeat in a single call.
Cognitive Characteristics	Works primarily by suggestion. Primarily an interest-arousing technique.	Both attempt to present firm and product as different and better than competition.	May carry physician through reasoning process. May be a problem-solving technique.
Feeling State Characteristics	Single message may elicit varying feelings. No possibility to adapt.	Both attempt to induce favorable feelings.	May evaluate and take advantage of either favorable or unfavorable feelings.
Transactional Characteristics	Primarily pretransactional, with post-transactional activity primarily limited to dissonance reduction.	Both important as reminders to continue use.	May also effect a prescription as a direct result of sales call. Possible to supply sample for patient in the office at the time.

TABLE 11-8. Size of largest sales staffs

RANK	COMPANY	NUMBER OF SALES PEOPLE
1	Wyeth-Ayerst Laboratories	1,900
2	Merck Sharp & Dohme	1,500
3	Schering Laboratories	1,334
4	Glaxo	1,300
5	The Upjohn Company	1,300
6	Eli Lilly & Co Pharmaceutical	1,250
7	Roche Laboratories	1,200
8	Smith Kline & French Laboratories	1,100
9	Sandoz Pharmaceuticals	1,000
10	Parke-Davis	952

Source: *Medical Advertising News*, September 1, 1988.

increased restrictions on the activities of PSRs, and many of the respondents anticipated further increases in restrictions. Most increased restrictions appeared to be related to a perceived need to contain costs. A few pharmacy directors view all PSR activities as undesirable, but most appear to believe that PSRs provide useful assistance.

Managed care, in the form of HMOs and other configurations, will also affect personal selling as a medium of promotion. A study by Arthur D. Little Inc. offered scenarios including staffs reduced in numbers and changed in character. (See Table 11-10.)

As noted above, personal selling is expensive. Two methods of retaining some of the benefits of personal selling are convention exhibits (manned by sales staff) and telemarketing.

Convention exhibits combine some of the qualities of advertising (the physical display) and personal selling and because of their hybrid nature bring their own strategic decisions. Douden (*Medical Marketing and Media*, March, 1980) suggests seven steps in a marketing approach to exhibit planning. These steps are elaborated on below.

1. Careful evaluation of upcoming shows, on a 12-month basis.
   From other marketing plans you already know target markets. But for each medical specialty, there is a long list of state, regional, national, and international meetings, workshops, conventions, and symposia that allow exhibitor participation.
2. Development of specific objectives for each show considered on the upcoming year's schedule.

TABLE 11-9. Emphasis placed on training topics

Subject	Average score (on scale where 1= no emphasis, 5 = maximum emphasis*) Initial training	New product training	Retraining/ CE programs
Company mission and goals	3.86	3.78	3.22
Verbal communication skills	4.47	4.18	4.14
Writing skills	1.86	1.70	1.97
Product knowledge			
Anatomy	4.07	3.78	3.11
Physiology	4.26	3.89	3.30
Pharmacology	4.02	4.02	3.44
Biochemistry	2.86	2.94	2.52
Microbiology	2.81	2.77	2.34
Medical terms	4.43	4.16	3.45
Clinical drug interactions	3.81	4.00	3.57
Government regulations	3.23	2.97	3.02
Ethics	4.39	3.55	3.75
Comparative analysis of competitors'			
Products	4.55	4.71	4.30
Pricing	3.45	3.97	3.28
Distribution	3.23	3.34	2.77
Promotion	4.05	4.34	3.74
Sales force	3.18	3.39	2.82
Communication skills with			
Physicians	4.89	4.83	4.80
Pharmacists	4.34	4.36	4.11
Nurses	4.08	3.94	3.88
Drug wholesalers	3.37	3.43	3.26

Source: *Medical Marketing and Media*, March 1, 1988.

One strategy would be to use the year's exhibit schedule to introduce and demonstrate a new product to various segments of the market. Firms with no new products can take advantage of trade-show opportunities by gathering marketing and product R&D data from booth visitors or by providing additional product information.

3. Determination of budget funds available, and allocation of them among the desired shows. Trade-show participation is expensive, but studies have indicated that the cost-per-visitor-presentation can be far lower than a trip to the person's individual office. So exhibit expenses should be viewed as a necessary marketing "background"

expense that often sets up such other activities as direct mail and office visits.

Studies also show that firms that don't cut back on their trade-show exposure during difficult economic times make speedier sales recoveries when more prosperous times return, because they have maintained their market visibility. So exhibiting also has some long-term marketing investment factors to consider.

4. Decision on how best to carry out the above objectives, in terms of exhibit design, production, scheduling, shipping, and return.

   If detailed one-on-one marketing messages are planned one may want to design screened-off quiet areas; if it is to be an educational audiovisual display, make it the focal point. Whatever the purpose, be sure the final physical design uses modular pieces that can be adapted to fit various booth sizes and can be modified to meet other objectives as they change during the three-to-five-year life of a booth.

   Some booths have only a logo and no marketing copy; others will have so many signs that the passerby doesn't know where to start. To avoid the pitfalls of supplying too much or too little information, think of the booth as a billboard, and cut the message down to a simple statement of an exclusive feature or the overriding product benefit. As a guideline for determining the content, go back and review your exhibiting objectives. The aim is to give visitors a quick message about who you are and what they will find in the booth.

5. Careful planning of backup materials and facilities, including invitations, special registration, hospitality rooms, and special events during the show.

6. Firm plans for participation by the right personnel, given thorough orientation on conduct and objectives.

   The actors on the stage of the booth can make or break the performance, so representatives need to be taught about the difference between making an everyday office call and conducting a trade-show exhibit "encounter."

   Thus, the purpose of talking to a booth visitor is to qualify the person quickly and to determine the proper follow-up activity. That is really about all the time one can spend with each visitor and probably all the time that each one will linger in the booth.

   The staff person who becomes involved in an extended conversation with one person is wasting valuable time that could be spent meeting other equally qualified people.

   Also consider including in the booth people who are not detail

staff. Perhaps someone from the lab or research and development department could be on hand to help the reps answer questions. In addition, invite important clients to stop by the booth, and then introduce them to other visitors and encourage them to tell in their own words the benefits they have enjoyed with your product. Moreover, other members of the marketing team, such as the advertising director and customer service people, could use the exposure to update their knowledge of the "climate" of the marketplace.

7. Development of a built-in system for measuring results from each show participated in.

   All the lead cards collected at the booth should go to the home office after each show. There, photocopies can be made, the names can be added to your centralized prospect mailing list, and the appropriate follow-up literature, as noted on each card, can be sent out, along with thank-you letters. Then the original cards can be mailed in batches to the proper sales representative for further follow-up.

Telemarketing is sales promotion via telephone. Certainly many of the advantages of in-person communication are lost (eye contact, body language, demonstration) as is what is often a personal relationship of some standing. Nevertheless, this technique retains the advantage of give-and-take and is certainly less expensive than in-person calls.

Most telemarketing is conducted by specialists in the field on assignment from the drug manufacturer. Telemarketing sales people need special training and skills which are usually easier to give on an as-needed basis rather than to develop the in-house capabilities to perform this function. Examples of some of the uses of telemarketing are:

- Generate sales leads
- Supplement/follow-up field staff
- Detail products not normally supported in the field
- Reach physicians who refuse to see detail staff
- Reach physicians in specialties not usually detailed.

CASES IN POINT

Sales Training

Merck uses physician "mentors" in sales training. Each representative is assigned a physician mentor. These physicians specialize in rheumatology, cardiology, orthopedics, surgery, gastroenterology and other spe-

TABLE 11-10. Future changes in the personal selling environment

Group Practices and HMOs Will Be Increasingly Active in Controlling Interaction with Member Physicians
- -Access limited pre-arranged seminars or specified times
- -Appointments granted only with selected representative physicians, typically not the major prescriber

Characteristics of the Target Market Will Shift
From
- -Individuals with significant leeway to manage their own time and practice

To
- -Members of organizational entities faced with pressures for group performance

Practice
- -Dramatic growth in "managed care" systems: 50% of the population will be members of HMOs or PPOs by 1995
- -Increasing availability of ambulatory alternatives: By 1995, 60% of all surgical procedures will be performed on an outpatient basis driven by technological advances, as well as system pressures
- -More standardized medical practice and less individual physician leeway

Pharmaceutical Firms Must Market to Three Levels

	Issues
The Buying Group	Price Delivery Other Service Factors
The Individual Group, Hospital, or HMO	Product Acceptance Service Factors
The Individual Physician	Product Usage

Implications
- -Heightened requirement for skills in business, finance, contract negotiations, and group interaction/selling
- -Need for increased back-up information on product cost-effectiveness
- -Search for differentiating services

In the Future, Companies May Elect to Limit Personal Selling to Buying Groups and HMO/Group Practice Headquarters
- -Communication with individual physicians could occur primarily through alternate modes: Product line dependent

Source: Arthur D. Little, Inc.

cialties. Sales reps spend a half day per quarter at the doctor's practice site, where they receive hands-on training, including use of patient instructors who are afflicted with a given disease.

The first phase of training starts immediately after hiring with a nine-week course designed as a primer in medicine, with lectures on anatomy, physiology and disease states. Trainees undergo 20 exams in which they are required to score consistently at the 90%-level or better to remain in the program. Intensive pre-employment screening has maintained only a 1%-2% failure rate during phase one.

The second phase of training involves a three-week stint at Merck headquarters in which trainees develop communications skills and learn the legal aspects of medical detailing. Trainees are also briefed by the company's medical and marketing departments about disease entities and product information. At the conclusion of this phase, trainees are assigned a sales territory under the supervision of a district manager. . . . They also begin a home study course in which they are tested on two products each quarter. Trainees are required to maintain a 90% scoring record on those exams as well.

After three to six months in the field, trainees spend a week at a medical school where they attend lectures by physicians who are the foremost authorities in their fields.

Trainees return to corporate headquarters at the end of the first year for an additional two weeks of training. They receive an update on medical knowledge and use computer-simulations for territory sales planning and analysis. Sales reps also attend a half-day seminar on business ethics.

Sales training continues throughout representatives' careers. One-week refresher courses are required every two years . . . and hospital-based training is required before a sales representative is allowed to operate in that market.

Source: *F-D-C Reports*, October 31, 1988.

Telephone Detailing/No See Physicians

Problem

This company had a group of orthopedic and cardiovascular surgeons who would not see representatives. Therefore, there was no way that these physicians could be detailed on an antibiotic administered during surgery.

Solution

Telemarketing was utilized to contact these "no see" physicians to detail this ethical product, obtain permission to see the local representative and receive future telephone detail calls.

Results

- *52% of these "no see" physicians received a completed telephone detail call.*
- *74% of these detailed physicians agreed to see the local representative.*
- *56% consented to receive future telephone detail calls on a regular basis.*

Source: Promotional brochure, Professional Telemarketing, Inc.

Sampling

The use of samples is, in some ways, the most rational of promotional medicine. If a medicine is effective, what better way to demonstrate this than by actual use in a patient. Each physician, after all, must ultimately conduct a personal "clinical trial" with each new product prescribed. Nevertheless, sampling practices have long been controversial and, as a result of the Prescription Drug Marketing Act of 1988, it is much more difficult to do.

In a study conducted for the Pharmaceutical Manufacturers Association by National Analysts in 1986, sampling was found to be generally well-received by physicians. Among the conclusions of the study were those below.

1. Physician use of drug samples appears fairly restrained; four out of five patients seen in a typical week of practice receive no sample of prescription medication.
2. Samples do not appear to divert substantial revenue from retail pharmacies. When used to provide immediate therapy in the doctor's office, they serve a function for which a retail pharmacy's inventory cannot substitute. Moreover, the vast majority of samples are accompanied by a prescription which must be filled at a pharmacy.
3. Physician familiarity with many of the medications which they provide as samples should not be misinterpreted to show that samples serve no trial function. Prescription samples are frequently used in a "test mode," especially by internists; familiarity with the product in general does not imply familiarity with its activity in any given patient. The data make it clear that physicians attach greater impor-

tance to assessing efficacy and side-effects when the drug is new to the patient, rather than new to the doctor.

4. Samples play an important direct therapeutic role, particularly for pediatricians, and when pharmacies are closed or not easily accessible, they may be the only resource at hand. Any modification of existing sampling procedures would need to address this time-critical function in some way.
5. Among the various alternatives to sampling, rejection of a proposed substitution of coupons is overwhelming. Even though economic reasons are frequently cited as a basis for using samples, they are not sufficient to allow approval for a procedure which would address economic concerns but not medical (e.g., immediate medication, assessing patient tolerance) concerns.
6. It is likely that a coupon system will impede physician use of new pharmaceutical products. Those who have used coupons can be regarded as "expert witnesses" on how the system works; their general agreement with nonuser physicians that the coupon system is inferior to the current system of distributing pharmaceutical samples, and that it will delay adoption of new medications, is significant because of the experience base which underlies it.
7. A policy of requiring a written request for pharmaceutical samples, while not eliciting as strong a reaction as coupons, also appears to have potential for retarding trial of new products, since these physicians indicate less likelihood of requesting unfamiliar drugs, compared to products which they have used frequently.
8. Requiring physicians to sign receipts for packages of medication samples arouses the least opposition among the possible modifications to the current system of sample distribution. Although over a third of physicians view it as inferior to the current system, three-quarters would have obtained the most recently sampled medication had such a requirement been in effect.

In spite of the results just reported it was the view of Congress, translated into law, that "the existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired and adulterated pharmaceuticals." The resulting Amendment to the Food, Drug and Cosmetic Act includes the following provisions:

- It requires state licensing of wholesale distributors under federal guidelines that include minimum standards for storage, handling, and record keeping.

- It bans the reimportation of drugs produced in the U.S., except when reimported by the manufacturer or for emergency use.
- It bans the sale, trade, or purchase of drug samples.
- It bans trafficking in or counterfeiting of drug coupons.
- It requires practitioners to ask for drug samples in writing.
- It prohibits, with certain exceptions, the resale of drugs purchased by hospitals or health-care facilities.
- It sets forth criminal penalties for the violation of these provisions.

The essence of the requirements on sampling was spelled out in FDA's letter.

> The manufacturer or distributor of a prescription drug may distribute samples to a licensed practitioner—or to a pharmacy of a hospital or other healthcare entity at the request of a licensed practitioner—by mail or common carrier, provided the licensed practitioner submits a written request setting forth certain specified information and the recipient of the drug sample executes a written receipt upon its delivery and returns the receipt to the manufacturer or distributor.

In other words, sales staff will not be able to drop off unsolicited samples anymore. A detailer could deliver a sample in response to a written request but must get a signed receipt.

FDA will permit firms to distribute preprinted request forms for practitioners to send to the company to obtain a sample. These forms must contain all required information identifying the requester, the name of the drug, the amount wanted, the name of the manufacturer or distributor, and the date of the request.

"FDA requests that separate written requests be made for each sample or group of samples and that open-ended or 'standing' requests not be used to order drug samples," the agency's letter stated.

The requirement for written requests may be the least burdensome of the new rules. There appears to be no bar to an almost instantaneous exchange of requests and samples between practitioner and detailer.

Where the burden will be felt is in the storage, distribution, and record keeping requirements that the new law imposes. FDA's interim policy statement requires, among others:

- Proper storage of drug samples: All drug samples have to be stored under conditions that will maintain their stability, integrity, and effectiveness.
- Inventories of company representatives: Drug manufacturers have to

conduct complete inventories of all drug samples in the possession of the representatives.
- List of representatives: Drug manufacturers will have to maintain lists of the name and address of each of their representatives who distribute drug samples and the sites where the samples are stored.

Although practices will, of necessity, change, it is unlikely that sampling will disappear. An example of attempts to adapt to the new restrictions is the Sample-Plus program developed by Medical Marketing Group, Inc. The stages in that program, taken from a promotional brochure, are:

- Your representative delivers a set of Sample-Plus patient enrollment booklets to the physician.
- The physician simply provides appropriate patients with an enrollment booklet and a prescription for your product.
- The patient completes the enrollment form, presents it along with the prescription at a retail pharmacy and obtains a free trial supply.
- The patient receives a Sample-Plus card in the mail.
- This plastic card is used each time the prescription is refilled, in order to accrue credit toward additional free supplies, discounts, and other program benefits.
- Periodically, the patient receives a refill credit statement and compliance enhancement messages.
- Pharmacy claims are administered by an established nationwide network of more than 52,000 retail pharmacies.
- Medical Marketing Group, Inc. develops your proprietary database of usage and reports tracking information to you.

Alternate Media

The combination of new technology, competitive pressure, "clutter" in the traditional media, and changing characteristics of promotional targets have resulted in the development of a collection of promotional techniques which, because the phrase seems to have found common usage, we will call "alternate media." Such media range from computer software designed by Upjohn to assist formulary committees in their review process to full-blown scientific symposia. The media are too diverse to be covered here in detail, and certainly it is impossible to weigh their relative merits here. Rather, we will simply describe some of those available.

One class of promotional tools has been described as desktop media. These and other media are listed in Table 11-11. The listing should be considered as exemplary, not exhaustive.

TABLE 11-11. Examples of desktop and other media

Product	Brief Description
Compendium of Drug Therapy	An alphabetized drug reference manual arranged by therapeutic category. Drug information is arranged in tabular form and includes indications, contraindications, warnings, dosages, and other information. Each category is sponsored by from two to four advertisers, depending on the size of the category. Ad units are two or three pages, four-color. The Compendium has an editorial: advertising ratio of 85:15.
Doctors Diary	A spiral-bound calendar in a day-at-a-glance format (5 in. x 7 in.) for physician's personal use. The diary has 312 pages with product ad messages at the bottom of each page. Advertising can be purchased exclusively or shared, usually among six advertisers.
Formedic Charting Systems Record Forms	A variety of advertiser-and Patient supported physician record forms for various needs and specialties. Advertising is provided at the bottom of each form. There are from 12 to 30 ads per service, depending upon the service category.
Masson Prescription Pads	Prescription pads consisting of 50 sheets provided by specialty. Advertising is single-sponsor and product, with four-color ad messages, including full disclosure, placed every ten sheets; five exposures per pad.
Medi-Scripts	A personalized prescription pad Prescription Pads service with 30 advertising pages interleaved among 150 prescription blanks, one ad every sixth sheet. Physicians receive an estimated six-month's supply.

Modern Medicine Pocket Guides	A rapid reference work supplying basic information about major diseases entities by category, including diagnosis, treatment, drugs, side effects, etc. Single-sponsor advertising at a flat rate.
1983 Physician's Appointment Book	Two week-at-a-glance format, single-sponsor calenders. One is a spiral-bound desk reference with 106 two-color ads at the bottom of each page. The other is a pocket-sized planner with note pad and 106 copy lines.
Physician's Desk Reference	A comprehensive listing of paid drug labeling information, including product ingredients, instructions, dosage, usage, etc. Three separate editions are available. The Physician's Desk Reference (PDR), PDR for Nonprescription Drugs, and PDR for Ophthalmology.
Triple I Prescription Pads	A personalized, 50-blank prescription pad. Three four-color ads and one black-and-white ad for the same product are bound in, along with a re-order card. Pads are packaged in groups of 24.
Audio News Network	15-22 Fair Lawn Avenue Fair Lawn, NJ 07410 (201)796-6500
Description of Services	Audio News Network is an independent news gathering service utilizing correspondents worldwide to interview and gather medical news and information for healthcare professionals. These highlights are produced on audio cassette tape and distributed by Audio News Network under grant from sponsoring companies.
CliniForms	30 West 63rd Street New York, NY 10023 (212)957-1053
Description of Services	CliniForms Patient Record Charts with an area for a product message are provided by direct request to

TABLE 11-11 (continued)

	physicians. CliniForms for GP/FPs and Internists targets only Scriptrac high prescribers. For 11 other specialties all office based primary specialty physicians within that specialty are targeted.
Daily Business Satellite	Potomac Television/Communications 444 North Capitol Street NW Washington, DC 20001 (202)783-8350
Description of Services	Daily Business Satellite produces and distributes video news releases and satellite media tours. The service is available free to more than 650 local and national tv news operations. News stories of FDA approvals and product introductions are transmitted via satellite to stations and networks. Medical reporters/producers are notified by telex and telephone of availability. Client receives usage reports detailing where material was aired and size of audience.
Fact Pak for the Pharmacist	Fact Pak Inc. 1550 Northwest Highway Park Ridge, IL 60068 (312)699-7110
Description of Services	Co-op direct mail with editorial included that allows advertisers to distribute promotional mateiral to all retail pharmacies plus hospital and nursing home pharmacists.
Hospital Satellite Network	2020 Avenue of the Stars Los Angeles, CA 90067 (212)277-6710
Description of Services	HSN offers publication services and network distribution. Production includes continuing education taped programs and interactive videoconferences. HSN accepts outside produced programs and will include commercials on programs. HSN provides support servics of accreditation, syllabi, marketing, and videocassettes.

Lifetime Medical Television	1211 Avenue of the Americas New York, NY 10036 (212)719-7230
Description of Services	Lifetime Medical Television is a cable television network for physicians and other health care professionals. Advertising opportunities include: primary-care and specialty programming, single-sponsored special event programming, monthly program guide, and videocassette distribution.
Mediscan	Infoscan Corp. PO Box 3000 Colmar, PA 18915 1-800-MED-DATE
Description of Services	MEDISCAN is a physicians' calendar that delivers published, fully referenced articles in abstract form. A new article, along with client's brand promotional message, is delivered every day.
Medi-Scripts	Medi-Promotions, Inc. 200 Broadacres Drive Bloomfield, NJ 07003 (201)750-3170
Description of Services	Medi-Scripts supplies prescription pads to requesting physicians and podiatrists. Four-color ads appear on the inside front cover and interleaved every fifth Rx blank. On the average, each physician will receive Rx pads totalling 2700 prescription blanks every six months. Minimum schedule is 6 months.
Physicians Radio Network	One Dock Street Stamford, CT 06902 (203)324-1700
Description of Services	PRN's basic programming policy is to provide the primary care physicians with the latest medical news and information relevant to their practice. News programming inlcudes announcements of FDA

TABLE 11-11 (continued)

	approval of important new drugs, coverage of product introduction press confernences, reports and interviews from major medical conventions. Stories based on unpublished studies conducted at research centers, daily dispatches from PRN's Washington bureau.
Scriptech	Medical Publishing Enterprises 15-22 Fair Lawn Avenue Fair Lawn, NJ 07410 (201)796-6500
Description of Services	Scriptech is a prescribing system. The prescription pads are bound into a vinyl binder -- each vinyl binder contains three ads, heat-sealed into the inside of the front cover and writing backer of the binder. Other ads can be interspersed within the pad.

Source: *Medical Marketing and Media*, July, 1982.

Deciding on the Media Mix

By now it should be obvious that the promotional media decision is a complex one. Indeed, it is even more complex than one might infer from the rather general information provided. There is room for strategic decisions at every level. As the data in Table 11-12 show, for example, physician specialty has an influence on media preference.

TABLE 11-12. Preferred communication mode to the individual physician by specialty

	FP/GP	Pulmonary	Cardiology	Neurology	Psychiatry	OB-GYN
Scientific Meetings	H	VH	VH	VH	H	M
Seminars	H	VH	VH	VH	H	L
Sales Representatives	VH	H	M	L	M	H
Direct Mail	L	M	L	L	L	M
Journal Ads	L	L	L	L	L	L

Samples	VH	VH	M	M	VH	VH
Journal Articles	M	H	H	VH	VH	L

VH = very high M = medium
H = high L = low

Source: Arthur D. Little, Inc.

Certainly, drug manufacturers reach differing conclusions regarding media selection. Using IMS Promotional Audit data we have compared the media mix of two pairs of competing products for detailing direct mail and journal advertising as an illustration.

The data presented are for the year 1983 and should be used for their value in comparing company strategies, not for their absolute numbers. The first pair of products, Visken and Wytensin, were introduced in 1982, so these figures represent their first full year of promotion. Both are cardiovascular products but, as the data show, Sandoz and Wyeth chose noticeably different approaches in the mix of the three promotional media and within the journal lists.

PRODUCT AND COMPANY TOTALS, $000 AND (%)

	Visken	Wytensin	Sandoz	Wyeth
Journals	4,699 (36)	1,646 (17)	11,006 (22)	8,922 (20)
Mail	400 (3)	399 (4)	1,698 (3)	2,167 (5)
Detail	8,129 (61)	7,535 (79)	37,131 (75)	34,503 (75)

DETAILING

	Visken	Wytensin
Details, Minutes (000)	316	340
Details, Dollars (000)	8,129	7,535

DIRECT MAIL

	Visken	Wytensin
Dollars (000)	400	399
Number of Ads	14	13
Circulation (000)	728	718

JOURNAL ADVERTISING

Month	Visken # pages, cost ($000)	Wytensin
January	276, (1079)	94, (268)
February	288, (1113)	80, (225)

Month	Visken # pages, cost ($000)	Wytensin # pages, cost ($000)
March	156, (537)	51, (150)
April	118, (419)	50, (151)
May	114, (394)	56, (184)
June	66, (241)	48, (160)
July	82, (255)	51, (145)
August	8, (13)	11, (19)
September	70, (227)	28, (79)
October	70, (217)	33, (100)
November	72, (199)	32, (109)
December	8, (6)	17, (56)
TOTAL	1328, (4699)	549, (1646)

The second product pair, Lasix and Dyazide, are both diuretics and both were "mature" products at the time of these data. Both had been on the market for the same length of time. Despite these similarities, there are significant differences in the promotion allocations of the respective manufacturers, Hoechst and SmithKline.

Journals Selected	Number of Ads Visken	Wytensin
-Hypertension	-	5
-Geriatric Medicine Today	3	-
-Geriatrics	4	-
-Physician and Sports Medicine	2	-
-Drug Therapy	-	3
-Family Practice Recertification	3	7
-Diagnosis	1	-
-Family Practice News	3	-
-Journal of Family Practice	2	-
-Medical Times	6	-
-American Medical News	11	16
-Drug Therapy	8	2
-Emergency Medicine	9	7
-Journal of Cardiovascular Medicine	-	4
-MD Magazine	4	7
-Medical Economics	10	5
-Medical Tribune	-	3
-Medical World News	7	2
-New England Journal of Medicine	-	12
-Physician's Management	7	3
-Post Graduate Medicine	7	1
-Private Practice	-	8
-American Family Physician	3	-
-Consultant	4	-
-Diversion	6	-

Journals Selected	Number of Ads Visken	Wytensin
-Hospital Medicine	6	-
-Hospital Practice	9	-
-Medical Aspects of Human Sexuality	7	-
-Modern Medicine	8	-
-Patient Care	3	-
-American Journal of Cardiology	10	4
-Cardiovascular News	4	9
-Cardiovascular Reviews and Reports	10	11
-Practical Cardiology	7	10
-American Heart Journal	10	-
-Cardiovascular Times	8	-
-Circulation	8	-
-Clinical Cardiology	9	-
-J. Cardiac Rehabilitation	6	-
-Progress in Cardiovascular Disease	6	-
-American Journal of Medicine	-	11
-Archives of Internal Medicine	-	8
-Annals of Internal Medicine	8	-
-Internal Medicine News and Cardiology News	10	-
-Journal of the American Osteopathy Association	5	-
-Hospital Formulary	4	2
-Hospital Physician	8	-
-Physician and Patient	3	-
-Drug Topics	-	2
-Kidney International	-	6
-Internal Medicine for the Specialist	4	6
-Primary Cardiology	10	3
-Therapaeia	-	2

PRODUCT AND COMPANY TOTALS, $000 AND (%)

	Lasix	Dyazide	Hoechst	SmithKline
Journals	762 (33.0)	1,981 (29.0)	2,384 (15.5)	12,249 (8.9)
Mail	73 (3.4)	298 (4.4)	445 (2.9)	1,408 (1.0)
Detail	1,441 (63.2)	4,455 (66.2)	12,579 (81.6)	124,589 (90.1)

Physician Specialty	Dollars and (%) Spent Detailing	
	Lasix	Dyazide
General Practice	533 (37)	1828 (41)
Internal Medicine	568 (39)	1464 (33)
Obstetrics	73 (5)	186 (4)
Surgery	114 (8)	348 (8)
Pediatrics	----------	43 (1)
Dermatology	----------	21 (0.3)
Psychiatry & Neurology	23 (2)	94 (2)
Urology	----------	31 (1)
Osteopath	130 (9)	440 (10)

Selected Journals	Number of Ads and (Pages)	
	Lasix	Dyazide
National		
Consultant	8(18.64)	12(12.00)
Drug Therapy	8(18.64)	17(17.00)
Emergency Medicine	9(20.97)	12(12.00)
Hospital Medicine	9(20.97)	8(18.00)
Hospital Practice (office)	9(21.14)	11(16.00)
Medical Tribune	5 (7.50)	
Medical World News	1 (1.17)	6(16.00)
Post Graduate Medicine	9(21.14)	12(24.00)
Patient Care	8(18.81)	10(23.00)
Journal of American Med. Assoc.		6 (6.00)
American Family Physician		16(16.00)
Journal of Cardiovascular Medicine		6 (6.00)
Medical Aspects of Human Sexuality		10(10.00)
MD		9 (9.00)
Medical Economics		16(25.00)
Modern Medicine		9(16.00)
New England Journal of Medicine		20(31.00)
Physician's Management		7(14.00)
Sexual Medicine		3 (3.00)
Pharmacy		
Drug Topics	10(12.16)	1 (1.00)

Drug Update		6 (9.00)
Pharmaco Therapy		6 (6.00)
Pharmacy Times	8 (8.00)	1 (1.00)
American Druggist	3 (3.99)	
Chain Drug Review	4 (4.00)	
NARD Journal	1 (1.00)	
All Journal Advertising	116(246.45)	499(664.24)

Media Selection Procedure

Media selection calls for two decisions: (1) which particular medium to use and (2) within a given medium, which specific vehicles to choose. For example, if magazines are to be used, which particular ones should ads be placed in? The following two approaches can be used in media selection: (1) cost-per-thousand-contacts comparison and (2) matching of audience and medium characteristics.

Cost-per-Thousand-Contacts Comparison

Traditionally, the cost-per-thousand-contacts comparison has been the most popular method of media selection. Although simple to apply, the cost-per-thousand method leaves much to be desired. Basing media selection entirely on the number of contacts to be reached ignores the quality of contacts made.

Further, the cost-per-thousand method can be highly misleading if one considers the way in which advertisers define the term exposure. According to the media definition, exposure occurs as soon as an ad is inserted in the magazine. Whether the exposure actually occurs is never considered. This method also fails to consider editorial images and the impact power of different channels of a medium.

Matching of Audience and Media Characteristics

An alternative approach to media selection is to specify the target audience and match their characteristics with those of the medium.

Medium selection, even just among print media in journals, is a complex, multi-variate exercise. There are more than 300 publications just for physicians. Each must be evaluated on such criteria as:

- editorial climate of the journal;
- the frequency of publication;
- amount of paid circulation;
- stacking of ads;
- availability of special issues;

- closing dates; and
- market and audience profiles.

Pharmaceutical media specialist, Georgiana Papazian, provided excellent guidance for this process in *Pharmaceutical Executive* (March, 1985).

> Media selection is a direct extension of the marketing plan; the journal is one marketing tool that a product or service may use to help accomplish its marketing goals. Good marketing/media input derived from the marketing plan, therefore, is the key to developing the journal program.
>
> The journal budget, target audiences, and advertising strategy are no longer enough to formulate a journal schedule. In today's climate, other questions must be asked—and answered—and other issues addressed to provide data that will help in the journal selection process. Some of those questions and issues are:
>
> - What is the therapeutic class and what are the major competitive products within the class?
> - What is the advertising period? This should be explicit to give the planner good insight into how to place the ads.
> - Into which market sector should advertising be concentrated: office-based, hospital-based, or both? Should equal target weighting be assigned the physician specialties in each of the marketing areas?
> - Should special consideration be given to reinforcing the coverage and awareness in markets with upward sales trends or, conversely, to markets on a downward trend?
> - Are any nonphysician audiences being targeted? What is the time frame for this advertising? The advertising strategy? Is this part of the promotion included within the overall budget?
>
> Although some planners are more comfortable compiling journal schedules manually, the proliferation of journals, with its attendant confusion, has fostered increased use of computers to compile publication schedules. Computer capabilities permit merging the target audience with valid and tested audience research and other variables to develop a quantitative analysis. Journal rankings and target specialty breakdowns for specific journal groupings primary to the product's promotion are recalled, examined, and reexamined. Dif-

ferent programs are tested on the computer until the right journal combination evolves—one that closely matches the target goals.

Industry, as a rule, views journal media as conveyors of advertising messages. The number of exposure opportunities offered by a single publication or the journal schedule customarily is not analyzed per se; but these opportunities now can be subdivided into reach and frequency, and their cost efficiency analyzed.

Reach is best defined as the number of different readers exposed to one publication or schedule within a given time period. Frequency is the average number of times each person is exposed to one publication or schedule during the same time frame.

Considering reach and frequency when compiling a program ensures that the advertised message gets wide exposures and is not restricted to a limited target audience.

DECIDING HOW MUCH TO SPEND

The amount that a company may spend on its total promotional effort, which consists of advertising, personal selling, and sales promotion, is not easy to determine. There are no unvarying standards to indicate how much should be spent on promotion in a given product/market situation. This is so because the decision on promotion expenditure is influenced by a complex set of circumstances. Evidence of the variability of the conclusions reached in promotion decisions is provided in Table 11-13.

Promotion expenditure makes up part of the total marketing budget. Thus, the allocation of funds to one department, such as advertising, will affect the level of expenditure elsewhere within the marketing function. For example, it may be debated whether additional expenditures on advertising are more desirable than a new package design. In addition, the perspectives of promotion expenditure must be examined in the context of pricing strategy. A higher price obviously provides more funds for promotion than does a lower price. The amount set aside for promotion expenditure is also affected by the sales response of the product, which is very difficult to estimate accurately. A related matter here is the question of the cumulative effect of promotion. The major emphasis of research in this area, even where the issue is far from being resolved, has been on the duration of advertising effects. While it is generally accepted that advertising effects, and maybe that of other forms of promotion as well, may last over a long period, there is no certainty about the duration of these benefits.

TABLE 11-13. Promotional expenditures for selected products, 1988

Product	$ Millions Spent on Promotion	% Increase from Prior Year	Promotion as a % of Drug Store Purchase $	Estimated Promotion Cost Per New Rx ($)
1. Tagamet	32.3	67	7	5.38
2. Zantac	31.8	35	4	4.18
3. Capoten	30.3	70	9	8.42
4. Zestril	29.2	9,633*	138	73.00
5. Cipro	27.9	1,368*	29	11.63
6. Ceftin	23.4	2,825*	43	18.00
7. Calan S.R.	21.9	(-)26	11	7.82
8. Feldene	20.0	37	7	5.56
9. Prinivil	18.8	4,600*	78	62.67
10. Ceclor	18.3	3	6	1.56

Source: IMS Promotional Audits
*Products introduced during 1987

Promotion induces competitors to react, and there is no way to accurately anticipate competitive response and thus decide on a budget.

Despite the difficulties involved, practitioners have developed rules of thumb for determining promotion expenditures which are strategically sound. These rules of thumb may be distinguished as being of two types: breakdown methods and the buildup method. Before discussing these methods, however, it will be worthwhile to briefly review the application of marginal analysis to the promotion expenditure decision.

The marginal approach was the earliest organized framework for developing a promotion budget. With this approach, the expenditure on each ingredient of promotion should be made so that marginal revenue is equal to marginal cost. For example, the outlay on advertising should be incurred to the point where it just equals the incremental profit earned on the additional business generated by advertising. Similarly, the expenditure on personal selling should be equal to the profit on sales generated by the sales force. For the communication mix as a whole, the optimum budget should be set so that the marginal revenues per dollar of cost from advertising, personal selling, and sales promotion are equal. In other words, the appropriation for each of the ingredients of promotion should be increased or decreased until marginal revenues are equal.

Theoretically the approach appears sound. However, measurement of marginal costs and revenues poses a difficult problem. Even if margins can be estimated, the marginal approach may not be feasible. For example, no firm may want to hire and fire salespeople in an attempt to reach the optimum point where marginal cost is equal to marginal revenue. Besides, what if the margin is reached at three-fourths of a salesperson? Likewise, in advertising, either one places an ad in a magazine or one does not advertise in a magazine at all.

The question of the carryover effect of advertising is a complex one, and there is no agreement on how long advertising affects sales. Traditionally, it has been held that advertising's effect on sales lasts several years. Some work in the area, however, suggests that the effect of advertising on sales is a short-term phenomenon, lasting between 3 and 15 months. In brief, then, while the marginal approach for allocating promotional expenditures provides a good theoretical framework, its practical use is limited.

Breakdown Methods

There are a number of breakdown methods that can be helpful in determining promotion expenditures. Under the percentage-of-sales approach, promotion expenditure is a specified percentage of the previous year's or predicted future sales. Initially this percentage is arrived at by estimate.

Later on, historical information is used to decide what percentage of sales should be allocated for promotion expenditure. The rationale behind the use of this approach is that expenditure on promotion must be justified by sales. This approach is followed by many companies since it is simple, it is easy to understand, and it gives managers the flexibility to cut corners during periods of economic slowdown. Among its flaws is the fact that basing promotion appropriation on sales puts the chicken before the egg. Further, the logic of this approach fails to consider the cumulative effect promotion. This approach then considers promotion a necessary expenditure that must be apportioned from sales revenue without considering the relationship of promotion to competitors' activities or its influence on sales revenues.

Another approach for allocating promotion expenditure is to spend as much as can be afforded. In this approach the availability of funds or liquid resources is the main consideration in making the decision on promotion expenditure. In other words, even if a company's sales expectations are high, the level of promotion will be kept low if its cash position is tight. This approach can be questioned on several grounds. It makes promotion expenditures dependent on the company's liquid resources, when in fact the best move for a cash-short company may be to spend more on promotion with the hope of improving sales. Further, this approach involves an element of risk. At a time when the market is tight and sales are slow, a company may spend more on promotion if it happens to have the resources available. This approach does, however, consider the fact that promotion outlays have long-term value, i.e., the cumulative effect of advertising. Also, under conditions of complete uncertainty, this approach is a cautious one.

The competitive-parity approach assumes that promotion expenditure is directly related to market share. The promotion expenditure of a firm should, therefore, be in proportion to those of competitors in order to maintain its position in the market. Thus, if the leader in the industry allocates 2 percent of its sales revenue on advertising, other members of the industry should spend about the same percentage of their sales on advertising. Considering the competitive nature of the industry, this seems a reasonable approach. There are, however, a number of limitations. First, the approach requires a knowledge of competitors' perspectives on promotion, and this information may not always be available. For example, the market leader may have decided to put its emphasis not on promotion per se but on reducing prices. Following the firm's lead in advertising expenditures without reference to its prices would be an unreliable guide.

Second, one firm may get more for its promotion dollar through judicious selection of media, timing of advertising, skillful preparation of ads, a good sales-supervision program, etc. Thus it can realize the same result as another firm which has twice as much to spend. Since promotion is just one of the variables affecting market performance, simply maintaining a promotional parity with competitors may not be enough for a firm to preserve its market share.

Buildup Method

Many companies have advertising, sales, and sales promotion (merchandising) managers who report to the marketing manager. The marketing manager specifies the objectives of promotion separately for the advertising, personal selling, and sales promotion of each product line.

In practice it may not always be easy to pinpoint the separate roles of advertising, personal selling, and sales promotion, since the three methods of promotion usually overlap to some degree. Each company must work out its own rules for a promotion mix. Once the tasks to be performed by each method of promotion have been designated, they may be defined formally as objectives and communicated to the respective managers. On the basis of these objectives, each promotion manager will probably redefine his or her own goals in more operational terms. These redefined objectives then become the *modus operandi* of each department.

Once departmental objectives have been defined, each area works out a detailed budget, costing each item required to accomplish the objectives of the program. As each department prepares its own budget, the marketing manager may also prepare a summary budget for each of them, simply listing the major expenditures in the light of overall marketing strategy.

The buildup method forces the managers to analyze the role they expect promotion to play and the contribution it can make toward achieving marketing objectives. It also helps maintain control over promotion expenditure and avoid the frustrations often faced by promotion managers as a result of cuts in promotion appropriations due to economic slowdown.

Conclusion

The promotion mix consists of advertising, personal selling, sales promotion, and publicity. Objectives should be established in each of these areas, and the objectives established for each element of the promotion mix should collectively reflect the objective established for the promotion function. Likewise, the objectives established for the promotion function should, in conjunction with those established for the other elements of the

marketing mix (product, price and place) reflect the objectives established for the marketing function, and so on.

When sales objectives are established for advertising, they are usually marketing objectives. Despite the likely assumption that sales increases occur because of the marketing manager responsible for developing the strategy, to produce an increase in sales uses every tool in the marketing mix. Such sales increases that take place may be due to a reduction in price, a change in channels of distribution, a change in the product (or package), or a faster method of delivering the product (logistics)—all in addition to, or instead of, advertising. Thus it would be difficult, if not impossible, to identify any one tool as the only factor producing the sales increase.

If one of the reasons for establishing objectives is to facilitate measurement of performance, how can the effectiveness of advertising be determined if its contribution to the sales increase cannot be isolated? If, after an advertising campaign sales did in fact increase by 10 percent, how much of that increase was due to advertising alone? Continuing research can help.

John Palshaw (*Medical Marketing and Media*, September, 1982) has described the sequence of events in a marketing communications cycle as follows (* = research procedure needed):

- Review of a marketing problem or opportunity
- Market satisfaction study*
- Decisions on positioning, market segment of opportunity
- Benchmark research versus key competition*
- Application of findings to campaign planning, goal setting
- Quantitative concept testing of claims or features*
- Input to the creative team, initiate ad development
- Qualitative pre-screening of ad roughs*
- Decisions on ad production following sifting
- Quantitative, diagnostic, and predictive pre-testing*
- Final creative decisions, finetuning, and production
- Campaign appearance in the media
- Post-test evaluations of per-unit ad performance*
- Tracking of overall campaign impact*
- Recycle

Ultimately, promotion and its effects move along a hierarchy as follows:

- Awareness
- Knowledge

- Liking
- Preference
- Conviction
- Prescription Purchase

CASE IN POINT

Agency Services

Thomas G. Ferguson Associates is a New Jersey-based health care agency with billings in excess of more than $100 million. The following material is taken from the company's descriptive brochure, with permission. It is presented as an example of the range of services which such an agency might offer. Certainly there are a variety of services mixes and philosophies throughout the many health care agencies.

Client Service Organization

Thomas G. Ferguson Associates, Inc. is structured to effectively complement each of our Clients' internal organizations. Because each of our Clients' requirements is different, we provide the flexibility necessary to operate on an "as-needed" basis in the development of business plans and communications programs.

Too often, healthcare agencies cannot provide the organizational flexibility required to assist their Clients effectively. This is frequently due to top-heavy administrative staffing and managerial "dead wood" that does not contribute directly to the Clients' business development.

Thomas G. Ferguson Associates, Inc. is staffed to effectively manage the varied requirements of its Clients, with a Client Service Organization structured into two basic groups: Client Service "Contact" Team and Client Service "Support" Team.

A. Client Service "Contact" Team

Those Agency staff members involved in daily Client contact and responsible for orchestrating the efforts of other Agency staff are the Account Supervisor, Account Executive and Account Coordinator.

1. Account Supervisor/Account Executive

The Account Supervisor is responsible for the overall effectiveness of the Agency's contribution to its Client, relative to all aspects of the Client/Agency relationship. It is his/her job to ensure that the Agency staff complements the Client's requirements for maximum productiv-

ity and efficiency. The Account Supervisor is an experienced Agency professional, fully versed in all aspects of Agency operation.

The Account Supervisor functions as the primary Client contact and is thoroughly familiar with the Client's markets, business planning and overall program development. He/she is responsible for working with Client management to ensure that all programs developed by the Agency effectively and creatively meet the Client's communications objectives.

Properly handling a Client's business sometimes requires the assistance of an Account Executive. In this case, it is the responsibility of the Account Executive to work with the Account Supervisor on a day-to-day basis as a primary Client contact.

An Account Executive is assigned to a Client Service "Contact" Team depending upon workload requirements as well as individual expertise.

2. *Account Coordinator*

The "right arm" of both the Account Supervisor and the Account Executive is the Account Coordinator.

Once a job is initiated at the Agency, it is the responsibility of the Account Coordinator to ensure that the assignment progresses smoothly and efficiently through each phase of its development until the job is completed and delivered to its ultimate destination. Preparation of Time and Event Schedules, Production Estimates, Status Reports, Budgets, etc., are the responsibility of the Account Coordinator. These responsibilities create a need for almost daily contact between the Account Coordinator and Client and relieve the Account Supervisor and Account Executive of detail follow-up that is so critical in the development of any assignment. This provides senior account management personnel the time required to plan more effectively and to monitor the program results more completely.

B. *Client Service "Support" Team*

The Client Service "Contact" Team is supported by several other Agency departments, known collectively as the Client Service "Support" Team. They are:

1. *Marketing Research*

This vital capability permits development of marketing research information essential to the marketing planning process for new and existing products. A full range of primary and secondary marketing

research tools is utilized to assist in the development of creative marketing strategies. Specifically, Clients are assisted in areas such as:

- *revitalization of existing products*
- *evaluating new product opportunities*
- *acquisition studies*

2. *Information Services*

   This department is primarily concerned with the maintenance of an important data bank on companies, products, markets and diseases. This valuable fact-gathering resource assists Client and Agency personnel in conducting a wide range of planning activities. Combined, the Marketing Research and Information Services departments represent a significant amount of experience and expertise to aid Clients in keeping abreast of developments in the healthcare marketplace as well as contributing to the marketing planning process.

3. *Creative Services*

   The creative team is comprised of copywriters, editors, art directors, studio personnel, photographers, retouchers, proofreaders, etc., who are responsible for all creative development work on Client assignments. The work of these individuals is supervised by the respective department head who is responsible for the quality control of all creative output.

   The creative staff works closely with the Account Service "Contact" Team in the development of all Client programs and participate directly on an as-needed basis in discussions between Client and Agency.

4. *Production Services*

   The Production Manager is responsible for ensuring that all layouts can indeed be executed within budget and for ensuring the highest possible quality in all print and audiovisual production on behalf of the Client. As needed, the Production Manager will operate in direct contact with the Client in the print production phase of especially complex jobs or simply on those assignments where the client prefers to be involved firsthand in the production of a job.

5. *Media Selection*

   The Agency staff—consisting of the Account Supervisor, Account Executive and Account Coordinator—working with the Director of Marketing Research and Media Services, develops sound cost-effective media schedules. The appropriate media services are utilized to

maximize journal schedules based on product, objectives and space budgets.

This unique combination of efforts results in Clients receiving media schedules based on sound rationale for each journal recommended.

Following Client approval of the proposed media schedule, the Agency assumes responsibility for issuing insertion orders and space cancellations as well as for verifying placement and product quality.

6. *Financial Services*

Because we work under several different fee systems with our Clients, it is critical that all of our internal financial and cost-accounting procedures be exact, retrievable and current. Estimating must be prompt and accurate. The Financial Services Department is responsible for:

- *ensuring that each Agency staff member maintains an accurate daily record of time spent for a Client*
- *constantly monitoring incoming supplier invoices to ensure that actual costs on every Client job do not exceed the approved estimate by +10%*
- *processing client fee, production and media billing on an accurate and timely basis*
- *preparing financial review information for each Client on an as-needed basis.*

In assuming these responsibilities, the financial staff works closely with the Account Service "Contact" Team in maintaining the overall effectiveness of the Client/Agency relationship.

Computerized Cost Accounting

Clients look to an agency for many different things, but, in a word, Clients look to an agency for "creativity." The business planning, marketing and promotional creativity of Thomas G. Ferguson Associates, Inc. is second to none in the healthcare industry today. Our excellent record of growth speaks well of our creativity. But the same yardstick that measures creativity in communications must also be applied to the business aspects of a Client/Agency relationship. We call it "creative accountability."

Our staff is disciplined in business matters of time allocations, reporting and budgetary controls. Our internal cost-accounting procedures ensure accurate accountability of the time spent on our Clients' behalf. Each

member of our staff completes daily time sheets, which record all time allocations (by Client and by individual job) to the one-quarter hour. These time sheets are the basis of our computerized accounting system.

A computerized summary of the Agency's hours (by department and individual) is prepared for our Clients' review monthly, quarterly, biannually, or as needed, to ensure effective and efficient management of our contributions to our Clients.

At our regularly scheduled financial reviews with our Clients, a complete discussion is held regarding overall effectiveness of Agency work, communications between Client and Agency, suggestions for improvement in any area of our business relationship, and any other matter that will assist in the overall management and development of a better business relationship.

Services

Listed below are the services Thomas G. Ferguson Associates, Inc. offers to its Clients:

A. *Business Planning*
Increased diversity within the healthcare industry has created a need among most manufacturers for an improved long-range planning process. If this diversity is not managed properly, substandard performance at various levels could result. A modern tool that fulfills the need for managing diversity is the Strategic Business Planning System, built upon familiar, traditional elements and fully responsive to the needs of a diverse business.

The elements of a Strategic Business Plan are:

- *defining a natural business*
- *classifying a business in terms of industry and maturity*
- *characterizing a business' competitive position*
- *selecting appropriate unit strategies*
- *conducting financial and managerial congruency tests*
- *analyzing risk.*

The dissecting and interplay of these elements by management result in a profiling tool for that business which identifies what strategic emphasis should be employed and where the business is positioned within the priority matrix of the company.

Thomas G. Ferguson Associates, Inc. has the experience with this process that permits us to develop Client programs that are finan-

cially judicious and strategically effective. This process represents an organized approach by establishing strategies that are congruent with the condition of the Client's strategic business. Additional dimensions of this planning process include:

- *segmentation resulting in opportunity*
- *concentration and focus for optimizing efforts*
- *prioritizing opportunities*
- *managing relative to financial constraints*
- *identifying problems and opportunities*
- *understanding of business at all levels of management.*

B. Marketing/Market Research

1. *Strategy and counseling in marketing and communications.*
2. *Preparation of complete marketing plans and product forecasting.*
3. *Availability of the following market research services:*

- *Market reviews*
- *Situation analyses*
- *Monthly competitive advertising/promotion analyses*
- *Attitude studies*
- *Field surveys*
- *Focus group interviews*
- *Concept testing*
- *Advertisement/collateral material testing*
- *Establishment of parameters for measuring success of marketing goals.*

4. *Development of test marketing including complete campaigns for testing new products in specified markets. We assist in the selection of these markets and establish controls for analyzing and evaluating results.*
5. *Review of all product lines with suggestions for improvements or product additions to a company line which can result in major product developments.*
6. *Attendance at major marketing meetings, new product/product development/product improvement meetings.*

C. Advertising and Sales Promotion

1. *Preparation of complete advertising and sales promotion proposals and detailed budgets. (These are based upon a marketing plan.)*

2. *Creative planning and copy preparation of advertising and promotion pieces:*

   - *Journal advertisements*
   - *Direct mail pieces*
   - *Sales promotion aids (sales literature, visual aids and portfolios, comprehensive technical brochures, product folders, file cards, product briefs, instruction sheets, wall charts)*
   - *Complete catalogs, price sheets, catalog sheets, selling display sheets, signs and posters, package or product inserts*
   - *Packaging concept and design.*

3. *Completed production of all of the above.*
4. *Media evaluation, including a complete analysis of the market in line with the product objectives, together with a review of all available media. We recommend medical, hospital, trade and other journal programs, based upon this evaluation, in addition to broadcast media.*
5. *Placement and checking of all media advertising space.*
6. *Preparation of complete direct mail programs, including follow-up to salesmen's calls, pre- and post-convention and hospital exhibit mailings, in addition to product promotion campaigns.*
7. *Preparation of films, slides, tapes, film strips, records, audiovisual cartridges, audiovisual cassettes, self-testing materials, monographs, programmed learning materials, audiovisual materials for sales meetings and in-service training materials. Publication of sole-sponsorship publications and other medical journals, such as Ostomy Management, Hospital Pharmacy STAT and The Teaching Hospital.*
8. *Complete arrangements for conferences and symposia.*
9. *Translations of English to all major languages for worldwide product promotion.*

D. *Sales Meetings/Sales Development/Conventions*

1. *Attendance at major sales meetings.*
2. *Attendance at major conventions.*
3. *Creative services for the preparation of hospital and medical exhibit design.*
4. *Preparation of service programs for primary audiences to "assist the customer in his job."*
5. *Preparation and execution of all trade publicity.*
6. *Development of Professional Relations Programs including complete*

arrangements for professional conferences, seminars and symposia. We can provide services to bring together any type of group for product discussion and prepare other research proposals and/or promotional material from the results of these meetings.

7. *Development of sales incentive programs in collaboration with the Client's sales department.*
8. *Suggestions for and preparation of programs for customer participation at conventions and other trade gatherings.*
9. *Availability of professional consultants in virtually every healthcare-related field.*

Chapter 12

Strategic Marketing in the 21st Century: Futuribles

In the preceding chapters we have attempted to elucidate the principles underlying the marketing of pharmaceuticals as it occurs late in the 20th century. In this final chapter we shall attempt to peer ahead into the next century.

Anyone can predict the future. The trick, of course, is to do it accurately. The ideas which follow might be called "futuribles." The term is derived from the Futuribles Project commissioned in France in the early 1960s. Combining the words "future" and "possible," it seems sufficiently removed from actual prediction yet based on sufficient present experience and direction to be more than mere idle speculation.

The futuribles, which are presented in only bare outline form, are not designed to be exhaustive, but only suggestive, of the nature and diversity of change that may affect pharmaceutical marketing by the year 2000 and beyond.

ENVIRONMENT

Several words can be expected to typify environmental developments affecting pharmaceutical marketing in the years ahead:

- Internationalization
- Economic Pressure
- Social Change
- Regulatory Change
- Sophistication of consumers
- Changing demographics

Some examples follow.

The most significant immediate prospect on the international front is the program to develop a one-Europe market by 1992. Ross and Eyckmans of Kallir, Phillips, and Ross (*Medical Marketing and Media*, November, 1988.) have identified advantages for U.S. marketers.

- U.S. pharmaceutical companies that already are active in some European countries but not in others can expect an almost automatic expansion of their market.
- The cost of doing business in Europe, particularly for companies that for largely political reasons have manufacturing facilities in various countries, will be substantially reduced through consolidation.
- For companies that have not to date started European subsidiaries, the entry fee will go down and the potential will go up, recasting the equation that persuaded them to stay away.
- For health-care advertising agencies it will mean that there is truly, at last, a way of doing business in Europe, rather than in the United Kingdom plus France plus Germany plus Italy, and so forth.
- Americans competing in Europe will have the advantage of feeling at home in a huge, multicultural marketplace, unlike Europeans who are used to more orderly, often highly restricted environments.

On the minus side, a Single Europe will strengthen multinational European companies. One of the great advantages U.S. companies have enjoyed is that their tremendous domestic base provides the momentum for entering foreign markets. In fact, foreign revenue has often been looked upon as an add-on: nice, but not essential for staying in business. Companies in smaller European countries have not enjoyed that luxury. But soon European companies will have a domestic base larger than North America, a great boost not only in competing in the Third World, but also in penetrating the U.S. market even more effectively than some have done already.

On the economic front several trends are relevant. If the U.S. Catastrophic Drug Program is implemented in some form, it will add yet another major third-party drug program. This and others will continue to mean pressure to slow drug price increases. In addition pharmacists and others seem likely to continue to fight "discriminatory" pricing and certain members of Congress, perhaps remembering as far back as Estes Kefauver, seem ready to make drug prices a political issue. All of these will result in continued emphasis on generic substitution.

Pharmaceuticals have made the transition from a "social good" to an "economic good." Traditional insurers have recognized this and now re-

quire sharing of financial risk by consumers and providers. Employers are now taking an active role in cost containment for health benefit plans.

Examples of additional predicted social trends are included in Table 12-1.

On the regulatory scene, change can be expected as well. In the U.S. and abroad, it is clear that proof of safety and effectiveness may not be enough to assure timely marketing. For the past decade FDA has given top priority to real breakthroughs—category 1A drugs—at the expense of less-innovative products, which have received lower categorization. Now this differentiation is becoming keener, with such drugs receiving increasing priority over other types of applications.

Before the 1960s most countries assessed pharmaceuticals on quality or purity only. Since then, worldwide regulatory hurdles have become higher and increased in number. First came safety, then efficacy, and finally "need." The World Health Organization's list of "essential

TABLE 12-1. Some long-term trends affecting U.S. Business

General

- Economic prosperity with only minor adjustments
- Rise of knowledge industries
- Rise of middle class society
- Cultural homogenization
- Increased physical and occupational mobility

Technology

- Technology is central and dominant in society
- Integration into an international economy
- Increased role of R&D in the economy
- Telecommunication/Information transfer breakthroughs

Medicine

- Major advances in genetic engineering
- Organ transplant advances
- Computer-based diagnosis expands
- "Bloodless" surgery expands dramatically
- More and better artificial organs
- Continued increase in use of generic medicines
- Greater expectations of and participation in medical decisions
- Improved nutrition

Excerpted from: "Into the 21st Century," World Future Society, 1988.

drugs," first published in 1977, now designates 277 drugs as recommended. Me-too products stand a poor chance of being listed in Third World countries, where the essential drug list is most influential. Only on the basis of cost or unavailability of a listed drug would a me-too be substituted.

Developed nations impose their own constraints. Norway, for instance, exercises a regulatory need clause quite stringently. A pharmaceutical product's efficacy and safety must be superior to existing products, and a demonstrated need for the product must exist.

At present, such examples may have little global effect on total world pharmaceutical sales, but a trend is certainly emerging worldwide to include need as a criterion for registration.

The FDA is interpreting need in a more sophisticated way, taking risk as well as benefit into account. The path is being smoothed for breakthrough products for AIDS, where benefits of a need for Retrovir (zidovudine or AZT) were considered to far outweigh risks of the product. More recent developments indicate this procedure will become formalized for expedited approval of other breakthrough products.

Some advocate an increase in post-marketing surveillance in return for a reduction in pre-marketing testing requirements. By adding a fourth phase to the testing process, the drug candidate could complete the first three pre-marketing phases faster and thus be available for marketing earlier. Some critics of this proposal fear that Phase IV will simply be an add-on requirement and will not lessen pre-marketing requirements. Others worry that the implementation of Phase IV may make consumers wary of utilizing the drug; however, some proponents view this as a good result. It is likely that some increase in post-marketing surveillance will occur in the U.S. The effect on drug development and utilization will depend on the form this program takes.

Consumer involvement in choice of prescription drug therapy seems likely to grow in any case. This will result, in part, from the industry's own efforts such as direct-to-consumer advertising. Chronically ill patients will continue to grow in number and they have already demonstrated that they know their medicines much better than was the case in the past.

Consumer sophistication is best exemplified by the best-seller status of the *Physicians' Desk Reference*. There is increasing reliance on self-help books and the influence of television on consumer knowledge is enormous. They are demanding to know about their medication and beginning to take an active part in its selection.

CUSTOMERS

The number of customers (not consumers) who buy from drug companies will be smaller, but the customers themselves will grow in size. Some of this development will be the result of buying alliances. In other cases mergers, acquisitions, and government programs will simply breed "giant" customers. The net result will be much greater customer power. Example: American Healthcare Systems has long-term supply contracts for pharmaceuticals with nearly a dozen firms. One of these firms, Baxter, realized an assured market of 77,000 beds through such an arrangement (*Pharmaceutical Executive*, July, 1989).

New relationships will yield new kinds of customers within the manufacturing segment. An example may be found in the copy of an advertisement in *SCRIP* by Syntex.

> Syntex will produce naproxen and naproxen sodium for use in its branded prescription products and also for customers in the generic and OTC markets, including the United States after the key naproxen patent expires in December 1993. Dealing with Syntex will ensure quality and on-time delivery of naproxen and naproxen sodium at competitive prices. We have in place a dedicated support group ready to assist potential purchasers.

Syntex President, Paul Freiman, is quoted in the ad: "Syntex views generic companies as potential customers, not enemies."

A second page of the ad sounds a note of caution, however:

> The last key United States patent held by Syntex covering naproxen and naproxen sodium will expire on December 21, 1993. This and other key naproxen patents have been respected by the industry and Syntex continues to have complete confidence in them.
>
> Syntex also has many naproxen process patents issued and pending, both in the United States and internationally, which afford protection for naproxen with sodium beyond 1993.
>
> You should be aware that Syntex will protect its patent position.

Freiman again: "Syntex has every intention of protecting its patent position."

COMPETITION

Certainly the future will continue to be characterized by intense competition between pharmaceutical firms but, as we have noted, the intra-industry competition is likely to be tempered by various joint ventures and charged by the increasing size of the players. International activity, already substantial, will grow.

It seems likely that other forms of competition will emerge. Therapeutic or medical foods are an example of non-drugs that can be expected to compete with drug therapy. (The *Journal of the American Medical Association* regularly carries advertising extolling the iron content of beef and the cholesterol-lowering properties of beans.)

In 1972, the Food and Drug Administration (FDA) published a notice in the *Federal Register* that Lofenalac—a formula for infants with phenylketonuria, an inborn error of metabolism—would no longer be "regarded as a drug by the Food and Drug Administration, but as a food for special dietary use, coming under the purview of the Administration's Bureau of Foods." This was the first formal recognition by the agency of the concept of medical foods. Based on the history of the notice its publication has been interpreted as an announcement of the agency's intent to regulate all such products, not only those for infants, but for all ages, as foods instead of as drugs.

The FDA does not include single nutrient products marketed for therapeutic use in the category of medical foods. Certain nutrients may be useful in treating specific medical conditions, such as zinc to treat acrodermatitis enteropathica. The FDA believes that these nutrients are best considered as drugs and regulated as such, despite the fact that one might be able to walk into any supermarket or pharmacy in the country and purchase a supplement that would be suitable for the purpose.

Traditional foods for special dietary use, such as weight-loss products, do not fit the medical foods definition. Although it might be argued that obesity is a medical condition and that those persons seeking to lose weight should be under medical care, these products generally are available for use without the degree of medical oversight that is seen as necessary for true medical foods. Such products should continue to be regulated as foods for special dietary use.

Finally, health messages on food labels do not transform those food products into medical foods. For example, medical or drug claims for dietary supplements in tablet form would never fit in this regulatory category. When one speaks about health messages, the reference is to using the labels of conventional foods to convey to the consumer information

about the role of total diet and proper food choice of the risk of chronic degenerative disease. Health messages concern, for instance, the role of dietary fat in affecting the risk of coronary heart disease, or the role of sodium in hypertension. They are directed toward the general, healthy population. They emphasize the importance of the total diet and highlight some problems of definition.

Had the development of medical foods been restricted solely to enteral nutrition products, the need for a more precise definitional framework would not exist. Enteral foods have a defined client population; they are utilized always with direct professional attention; and, until recently, they almost always were administered in a hospital or clinical setting.

Where do medical foods fall between the food and drug definitions? Clearly, medical foods are products that make a claim. They have an intended use that goes beyond the mere provision of a food substance on the supermarket shelf. They specify a use. Beyond that, most medical foods contain a legend stating that the product is to be utilized under the supervision of a physician. While this is not the same as a prescription it does bring such products forcibly to medical attention as adjuvants to or even substitutes for drug therapy.

MARKET RESEARCH

The computer is the key to developments in market research. This is true less because of its use within the research organization than because computers will be a part of the operation of every health care provider.

Third-party payers are already selling data from their operations to interested customers. As payment for drug purchases becomes increasingly centralized it will be even easier to supply masses of detailed data and, perhaps, consumer mailing lists for targeted promotion.

The expanded possibilities for quantitative data will not obviate the need for qualitative research. Focus groups, psychographics, and other techniques will continue to be refined. In addition, it is highly likely that market research will interact with such disciplines as pharmacoepidemiology and pharmacoeconomics in preparing cost-benefit, cost-effectiveness and quality of life studies. Computer predictive modeling seems likely to grow in importance as well.

It has been suggested that market research in the pharmaceutical industry still has far to go to reach parity with clinical research in that industry. Progress toward such an end is likely to depend on dynamic tension between manufacturers and vendors of market research services *and* on training of career professionals in pharmaceutical market research.

CORPORATIONS AND COMPETITION

The year 1989 saw several pharmaceutical romances blossom. They seem likely prototypes of what lies ahead.

In the first instance two companies did not go so far as marriage, but did agree to "live together." The 50-50 joint venture between Merck & Company and Johnson & Johnson to develop and market non-prescription products from Merck's prescription research is the biggest of a series of joint ventures. More will certainly follow.

One of the biggest weddings so far was that between SmithKline and Beecham, creating the second largest drug company in the world. The broad reaction to the merger has been that it is the first major step in what many believe will be a worldwide consolidation of the pharmaceutical industry. As research and development and marketing costs escalate, as governments exert more and more control over prices, and as competition, particularly from generics, intensifies, the belief is that only the very large will survive in the international pharmaceutical industry. This view is not shared by all, however. Dr. Harry Schwartz (*Pharmaceutical Executive*, July, 1989) has noted:

> One need think only of what Tagamet did for SmithKline and what Capoten did for Squibb to see that even for a company much smaller than the industry's giants, a single blockbuster drug can radically increase a company's size and open new opportunities for its leaders. And I thought of the uncanny way in which some relatively small Scandinavian companies, Astra among them, keep coming up with innovative and profitable new products that they choose to capitalize on by licensing rather than by trying to become international giants.
>
> A huge company may be muscle-bound and rendered impotent by its own bureaucratic clumsiness. A small- or medium-sized company can combine nimbleness of decision making with particular skills in R&D or marketing to prosper.

Schwartz's views notwithstanding, the 1980s saw such mergers as: Monsanto/Searle, Kodak/Sterling, Robins/American Home Products, Marion/Merrell Dow, Squibb/Bristol-Myers, and Fujisawa/Lyphomed. A number of other companies were regularly mentioned as merger/takeover possibilities. It is not likely that the ultimate result will be one great organization, THE DRUG COMPANY, but it is clear that a new era has begun.

A shrinking number of pharmaceutical firms will have a significant impact on the firms that service them, including advertising and public relations agencies, law firms, medical journals, market researchers, and creative services. Depending on how these united companies are organized, decision-making power—the power to decide which drug research projects to pursue, which agencies to hire, and which marketing campaigns to adopt—could be concentrated in a few hands.

A potential risk is the loss of brand name identity and loyalty. Many doctors and pharmacists attach definite personalities and images to brand name companies. Can that loyalty be transferred? Or can the knack for finding new drugs and marketing them successfully be transferred?

In addition to consolidation, internationalization seems certain to continue. The Japanese, especially, seem destined to become a major pharmaceutical force in the U.S. and elsewhere. The Iron Curtain countries will certainly become more attractive markets . . . Searle announced in 1989 its plans to do clinical trials for Cytotec in the Soviet Union.

Joint marketing and co-marketing represent a middle-ground for expansion which has already seen substantial activity. Examples:

Co-marketing

Brand	**Partners**
Anspors, Velosef	SK&F, Squibb
Ancef, Kefzol	SK&F, Lilly
Calan, Isoptin	Knoll, Searle
Motrin, Rufen	Upjohn, Boots
Intal, Aarane	Fisons, Syntex
Bactrim, Septra	Roche, Burroughs-Wellcome
Ventolin, Proventil	Glaxo, Schering
Bricanyl, Brethine	Astra, Geigy
Zestril, Prinivil	Stuart, Merck
Beconase, Vancenase	Glaxo, Schering
Procardia, Adalat	Pfizer, Miles
Amoxil, Larotid	Beecham, Roche

Joint Marketing

Brand	**Partners**
Zantac	Glaxo, Roche
Versed	Dupont, Roche
Capoten	Squibb, McNeil
Tagamet	SK&F, Dupont
Ceftin	Glaxo, Roche
Zantac (OTC)	Glaxo, Sandoz

PRICE

Pressure on drug prices will increase for a number of reasons.

- In the U.S. the Congress will respond to growing pressure to do something about the price of prescription drugs. The pressure will come from a growing elderly citizens lobby and from government itself as the national drug bill grows. Congressional hearings in the early 1990s showed interest in negotiated discounts offered to the Department of Defense and in prices outside the United States.
- Smaller customers will continue to press for protection against "discriminatory" pricing.
- There will be fewer but larger customers in the private sector with greater bargaining power.
- There will continue to be pressure on prices internationally, but the effect of the EEC is still in doubt. Elsewhere, the drug industry has shown a willingness to fight. When the Australian Pharmaceutical Benefits Scheme limited the price differential between alternate brands of the same product to 20 cents, Hoechst placed ads in the medical press to protest.
- It is expected that a new round of price investigations will result in a consumer-directed appeal by groups of pharmaceutical firms but also by individual companies in defense of the prices of specific products.
- Long-term earnings and profitability are determined by generic vulnerability, price increases and new product introductions. The price increases, especially those that have typically preceded loss of patent protection, seem to be a less attractive possibility in the years ahead. This suggests an increase in research and development activity.

Marketing to managed care systems will have a dual focus: on the one hand, marketers will emphasize pricing-related programs that can be broadly characterized as "creative margin maintenance." Such programs may include rebates, performance discounts, product "bundling," and price-protected agreements, such as those that are commonly negotiated with hospital group purchasing organizations.

On the other hand, even more creative—and perhaps even more valuable to manufacturers in the area of long-term competitive positioning—are research-based efforts designed to demonstrate product cost-effectiveness over a period of time. Outcome management programs may show, for example, that the use of a specific drug can save an HMO significant

patient-care dollars over the longer term. Such data speak directly to the "quality/cost management" mandate of managed care systems and provide an opportunity for manufacturers to proactively influence pharmaceutical purchasing decisions (*Pharmaceutical Executive*, May, 1989).

DISTRIBUTION

The traditional functions of distribution must continue to be fulfilled. Among the future variables which are likely to have an impact on the components of distribution channels are the following:

- New products, less shelf space
- Fewer, more powerful suppliers
- Fewer, more powerful customers
- New customer targets

For the wholesaler some future expectations include:

- Attempts to shift risk to institutions/buying groups
- Limited number may assume risk on Managed Health Care/Retail Rx contracts
- Information and technology will be driving forces of change
- Continued pressure on margins
- Continued efforts to purchase products competitively
- Explore ways to sell services to bolster profits
- Continued consolidation
- New market exploration

PRODUCT

The driving force for future products will continue to be effective research and development. Richard Faust, of the American Foundation for Pharmaceutical Education, has identified ten "Megatrends" which suggest direction to the year 2000. They are:

- Biomedical research and drug development will continue to become more complex, time-consuming, and costly.
- The pharmaceutical industry will evolve gradually to encompass three types of firms, and research will be carried out in two of those three types.
- The leading pharmaceutical firms will give increased attention to

improving research efficiency at the two critical steps in the creation of a new product.

- As new technologies and scientific achievements evolve in diverse areas, many developments will have a positive effect on the drug discovery and development process.
- Recombinant DNA technology and related research in immunopharmacology will foster the development of major new therapeutic agents.
- Novel drug delivery systems and techniques carrying agents to specific receptor sites will improve the utility of many therapeutic modalities.
- As new diagnostic tests are able more efficiently to detect minor biochemical changes indicative of early disease states, the pharmaceutical scientist will create drugs to alter the progression of the disease process or to prevent its development.
- Increasing attention will be directed to Phase IV research activities, postmarketing surveillance, and epidemiological studies.
- The drug discovery and development process will be characterized by more collaboration and interactions of various kinds between industry, academia, and government.
- Environmental forces and the voices of various stakeholders in the drug discovery and development process will become even more important in influencing R&D strategies, operations, and success.

During the summer of 1986, Bristol-Myers Company asked Louis Harris & Associates to examine priorities and promising areas of medical research in the next century. Interviewed were 227 prominent research scientists including leaders in the fields of cancer, cardiovascular diseases, central nervous system disorders, infectious disease, biotechnology, nutrition, and medical implants. Some of the findings were:

- Physicians in the early 21st century will find themselves increasingly empowered to attack disease at its roots rather than just minister to its symptoms. This will come from an increase in our fundamental understanding of how life and disease function at the cellular level.
- People will live longer. As a consequence, the main health threat in the developed world will be diseases of aging.
- In the third world, malnutrition, infectious and parasitic diseases will overshadow all other problems. An ever-deepening understanding of the molecular basis of cancer will translate into cancer cure

rates rising, with two out of every three patients cured – up from the 50 percent cure rate today.

- Prevention coupled with advances in non- or minimally-invasive therapy, should produce major progress in preventing heart attacks, strokes, and hypertension.
- In the developed world, the main priority for infectious disease research will probably be AIDS. In the developing world, the chief target, they say, should be malaria, still the major killer among parasitic diseases.
- Implants of every conceivable type are likely to be in wider use, including a wide range of artificial devices such as implantable drug infusion systems and pumps, interocular lenses, bones for bone banks, artificial blood and implantable hearing aids.

There is ample opportunity for companies with successful research and development programs. In but a single market, neuropharmaceuticals, one consultant (Sheri Lesser, *Pharmaceutical Executive*, October, 1989) projects a $15 billion potential by the year 2007. Details are provided in Table 12-2.

PROMOTION

Future possibilities in promotion include:

- Continued, but selective, growth in promotion of prescription drugs directly to consumers.
- Expansion of interest in new targets for promotion such as hospital and HMO CEOs.
- Continued growth in use of "rational" appeals such as economics and quality of life improvement.
- Expansion of the use of electronic media to incorporate tailor-made or on-request drug information in the prescriber's office or at other drug use sites.
- Greater attention to promoting corporate image in conjunction with individual product promotion.

TABLE 12-2. Market opportunities based on unmet needs

Market Potential
A = Annual market potential of more than $500 million.
B = Annual market potential of $250-$500 million.
C = Annual market potential of $100-$250 million.
D = Annual market potential of less than $100 million.

Conditions	
Alzheimer's Disease	
Drug that halts underlying disease progression	A
Symptomatic treatment for cognitive decline	A
Symptomatic treatment for anxiety	C
Symptomatic treatment for depression	C
Anxiety Disorders	
Therapy for generalized anxiety disorder	B
Therapy for obsessive-compulsive disorder	A
Eating Disorders	
Improved treatment for:	
Obesity	B
Overweight	C
Mixed overweight/obese	A
Bulimia	D
Anorexia	C
Epilepsy	
Once-a-day formulation of current product	A
Improved drug for patients refractory to available therapies	D
Mood Disorders	
Therapy for depression with faster onset or reduced side effects	A
Therapy for bipolar disorder/mania	C
Multiple Sclerosis	
Drug that halts underlying disease progression	A
Symptomatic therapy for chronic fatigue	B
Parkinson's Disease	
Drug that halts underlying disease progression	A
"Next generation" of L-Dopa	C
Symptomatic treatment for "freezing"	C
Symptomatic treatment for dementia	B
Schizophrenia	
Incremental improvement on current therapies (reduced side effects and compliance problems)	A
Agents for treating negative symptoms	A
Improved therapy for tardive dyskinesia	C
Sleep Disorders	
Nonaddicting therapy for chronic insomnia	A
Stroke	
Agents for acute management of stroke	A
Neuroprotectants for management/prevention of neuronal death	B
Stroke-preventive agents	D

Source: The Wilkerson Group, Inc., "The Challenge of Neuroscience: Clinical Perspectives and Commercial Prospects."

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