H. Harald Sedlacek
Alice M. Sapienza
Volker Eid

Ways to Successful Strategies in Drug Research and Development

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Basel · Cambridge · Tokyo

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You shall know them
by their fruits

(Matth. 7.16)

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Preface and Words of Thanks

Strategic planning is a critical subject, central to the success of any scientific and economic undertaking. The planning of realizable strategies in drug research and development needs not only the considerable scientific background of many persons, but also an intuitive feeling of what may occur in the future - which approach may be competitive, and which option can be achieved. Finally, a prerequisite for planning realistic strategies is the knowledge of how to accomplish this planning.

Several years ago, I became fully aware of this necessity when the task of strategic planning of the R&D activities of our company was delegated to me. At this time I had a scientific understanding of the strategies for research work necessary to prove a hypothesis. But, how to develop an overall core strategy for our research activities was completely unknown to me.

Reading several books, which in the view of business economists cover the topic "Strategic Planning in the Pharmaceutical Business," did not give me the specific help I needed.

As good luck would have it, I had the advantage of help and advice from Helmut Weber. He was versed in all aspects of strategic planning in the pharmaceutical business. A chemist by training, his industrial career had led him from research via the medical department, marketing and product management to the development of strategies. Thus, in the pharmaceutical business, he was skilled in how to collect, analyze, and evaluate facts, data, conflicts and dilemmas; how to select appropriate components and assemble them into different options; and how to propose the best possible strategy.

After a few years of learning by doing, we discussed the idea of summarizing our experiences as scientists in strategic planning. The objective was to give other scientifically trained people employed in the health care system the opportunity to understand the methods of strategic planning in drug research and development. In addition, we aimed to point out the internal and external parameters and forces which have to be taken into consideration to give a formulated strategy a chance of success.

I proposed this idea to Alice Sapienza, a well-known and exceptionally outstanding expert in the field of organizational behavior. She has unique experience in having repeatedly analyzed all major pharmaceutical companies to correlate their organizational structure and behavior with the outcome of their activities. Part of her work has been documented in her well-known "case reports." She lectures extensively in management courses for members of pharmaceutical and consulting companies and serves as a consultant for pharmaceutical and diagnostic companies worldwide.

Moreover, I asked Volker Eid, a distinguished teacher in ethics. He is a member of a considerable number of committees on ethics, a frequently sought-after consultant for all partners in the health care system and an advisor to the German Government as well as the European Commission.

Both agreed without hesitation and enthusiastically participated by contributing their excellent knowledge in their subjects and by inspiring and reviewing each other's contribution. Accordingly, this book emerged as a truly interdisciplinary and integrated joint work.

We have been delighted with help from the following people as well:

Petra Netter, a medical doctor as well as a prominent psychologist, contributed her knowledge and advised us on all aspects of psychology.

Many suggestions arose from numerous discussions with many of our colleagues, especially in various pharmaceutical companies. In particular, Jürgen Reden (Dr. rer. nat., Head of Research, Hoechst Pharmaceutical Division), Ulrich Delvos (Dr. med., Head of Research and Development, Behringwerke AG) and Hans Dohmen (teacher in ethics, Marburg) contributed with their proposals for designing the outline of this book. Hans Moser (Dr. rer. nat., Behringwerke AG) gave a lot of his time in reading our manuscript. With his critical mind he was able to point out gaps in our arguments and unclear conclusions.

All parts of the manuscript, all figures were compiled, typed and retyped by Manuela Rogala, who with her extraordinary skill significantly contributed to the successful outcome.

All in all, this book is the result of the work and contribution of many persons with different activities and occupations. This fact illustrates the fact that neither the whole book nor any part of it is the expressed opinion of organizations, institutions or companies the authors and advisors have been cooperating with or are employed in.

The book describes the needs of the pharmaceutical market (chapter I), and considers the various ethical obligations to patients, animals and the environment (chapter II and X), and how R&D projects can be evaluated and compared with each other. Moreover, it outlines the main R&D areas, goals, and strategies

in view of the strengths and weaknesses of a company, the threats it is subjected to as well as the opportunities it is offered (chapter III). It points out what measures can be taken to reduce risks (chapter IV); how projects can be managed (chapter V); and how the company can keep pace with the progress in technology (chapter VI).

The essential conditions for successful management for innovation and of projects are described, - taking leadership (chapter VII), motivation, culture, and organizational systems into account (chapter VIII); and last but not least, the social and political influences on innovation are discussed (chapter IX).

It is our hope that this book can be of help to scientists who come into contact with strategic planning in drug research and development; that it can inform them of the methods needed to elaborate strategies; and that through it they will become aware of the numerous managerial, organizational, social, and political parameters and forces, which must be considered in order to successfully implement a formulated strategy.

H.-Harald Sedlacek
Marburg, October 1995

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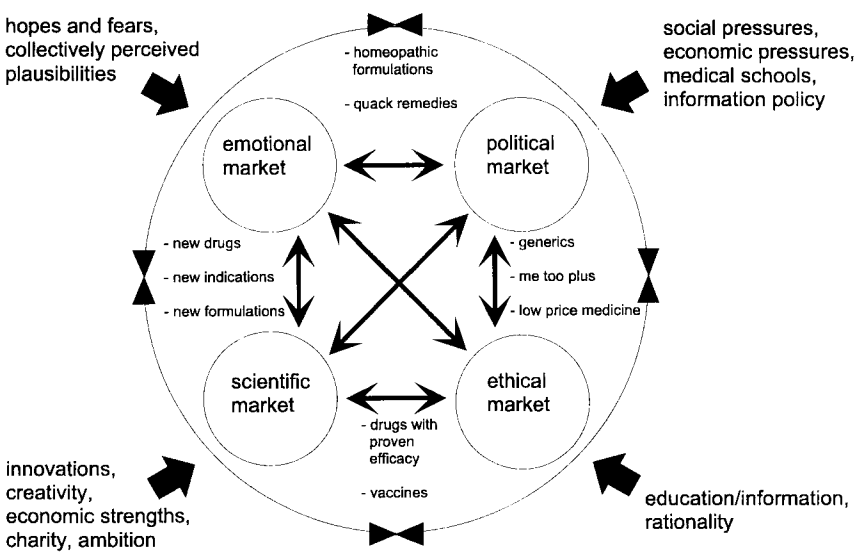
CHAPTER I

Introduction

A Characterization of the pharmaceutical market

THE FOCUS of all strategic planning and management of pharmaceutical R&D projects is the pharmaceutical market. Its definition and knowledge of the main driving forces for its future development form the context of the planning effort.

Figure I/1. The world market for drugs is very heterogeneous and influenced by extremely different driving forces.



The most important characteristic of the pharmaceutical market is the extreme heterogeneity of its components (Figure I/1). Partly because of this heterogeneity, its real size is unknown. Attempts to estimate the size by commercial sale audits are mostly based on sampling, which is not identical with actual sales figures.

Sales figures are also significantly influenced by the local characteristics and conditions found in the various countries, with respect to the kind of products, the various types of outlets, distribution organizations, coverage of health insurance, prices, and discounts. Such characterists can only be estimated.

Figure I/2. Rough estimation of the pharmaceutical world market and its classes of products turnover (billion DM) in 1994

class of products	natural products			synthetic compounds	all products
	isolates	chemical derivatives	recombinant proteins		
drugs	30	88	12	245	375*)
plasma proteins	4	<1	<1	-	6
vaccines	3	<1	1	-	4
total	37	89	14	245	385

*) Schneider 1994; Scrip 2026, 1995

The size of the current (1995) ethical pharmaceutical world market is in the order of about 260 billion US $ (or 385 billion DM, Figure I/2), but this figure could be as much as 10–20% below actual sales.

Most sales in this market occur in pharmacies (Campbell and Mahan 1992), with about 30% occurring in hospitals and other institutions (e.g., home health agencies, physicians' offices, out-patient care centers).

The main territories are North America, Europe and Japan. This triad seems to cover more than 80% of the known and recorded world market. More importantly, more than 95% of all major global drugs had their origin in those countries in the period from 1970 to 1992.

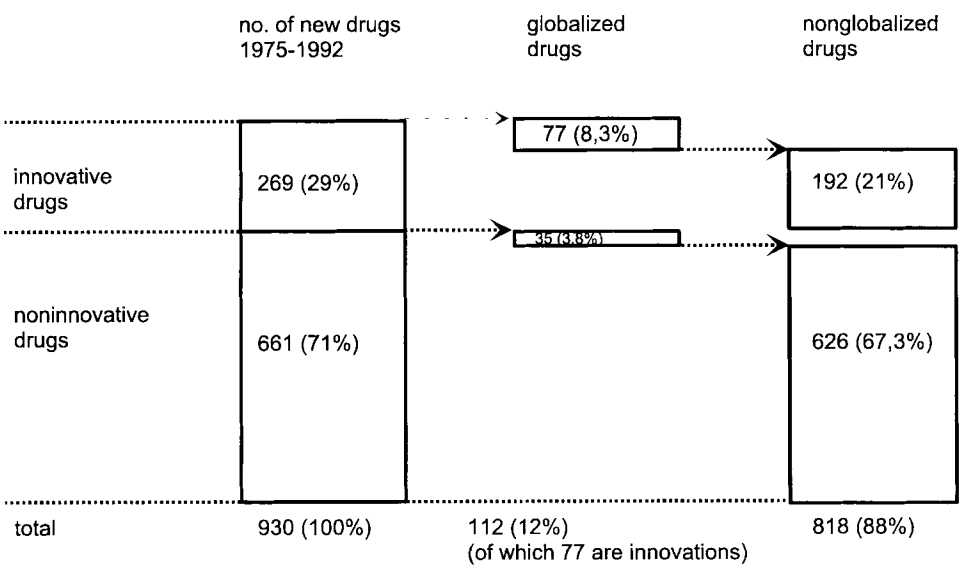
During the past 30 years, the size of the pharmaceutical market has increased in waves but nevertheless continuously. The yearly overall growth rate, as far as can be estimated, has been between ±0% and 15%.

Figure I/3. Success of pharmaceutical R&D investment (1970 - 1992) (number of major global drugs)*

world-wide	USA	Europe								Japan	Rest of World
		European Union					other				
		D	UK	F	I	other	CH	S	East		
265 (100%)	113 (43%)	24 (9%)	24 (9%)	14 (5%)	9 (3%)	11 (4%)	20 (8%)	11 (4%)	5 (2%)	29 (11%)	5 (2%)
				82 (30%)							
						118 (44%)					

*) of the 453 internationally accepted drugs (registered in at least 4 of the world's 7 leading markets USA, J, D, F, I, UK, SP) 265 drugs were defined as "major global drugs" because of their postclinical stage in at least 6 of these markets (Redwood 1993)

Figure I/4. Nearly 70% of the globalized drugs are innovations



Barral 1992, Redwood 1993

Most of this growth can be attributed to innovations, be they only slight or be they considerable therapeutic or technical improvements of products, or new and unique therapeutics for untreatable or insufficiently treatable diseases (Figure I/3). These innovations accounted for about 70% of all drugs that could be globalized between 1970 and 1992 (Figure I/4).

The tools used to develop these innovations were new achievements in organic chemistry, in protein chemistry, in recombinant DNA technology, in cell culture techniques. In addition, new insights into the complex mechanisms of organ function—as a result of improved diagnostic approaches to evaluate the interactions among mediators, receptors, transmitters and recipient molecules inside and outside of cells—also catalyzed innovation.

Today, pharmaceuticals consist of natural products, chemical derivatives of natural substances, new synthetic compounds, and recombinant proteins (Figure I/2).

B Driving forces for the future

In spite of the considerable success of new drugs, only some of the diseases affecting populations can be cured by treatment. A considerable number of diseases remain which are not only insufficiently treatable, but also a tremendous financial burden on the health care and social security systems of nations. Such hitherto untreatable or insufficiently treatable diseases represent a huge potential global market for present and future therapeutic innovations (Figure I/5).

Thus, it is understandable that the number of compounds developed in such top therapeutic categories is extremely high (Figure I/6). Only a minority will succeed in showing therapeutic advantages over the respective standard treatments. However, the underlying reason of the therapeutic advantages will be, without exception, a high degree of innovation.

In recent years new technologies, excess capacity in hospitals and an increasing number of medical doctors, as well as excess demands due to intensification, broadening and socialization of treatment have led to an explosion in health care expenditure, which in turn provoked drastic cost containment measures, affecting pharmaceuticals as well. (Drug budgets, however large, still represent only a small proportion, between about 8% and 20%, of total health care spending (Watts 1994). Nevertheless, they are a prominent target for cutting back on expenses). Reimbursement lists, fixed prices, regulation of margins, fast track registration of generics, and restricted registration of "me too plus" preparations are examples of responses to curtail expenditure on drugs. The pharmaceutical industry reacted with price cuts, generic competition, and improved drug formulations. Moreover, health care providers, such as health

Figure I/5. Potential targets for R&D of drugs for treatment of most frequent diseases

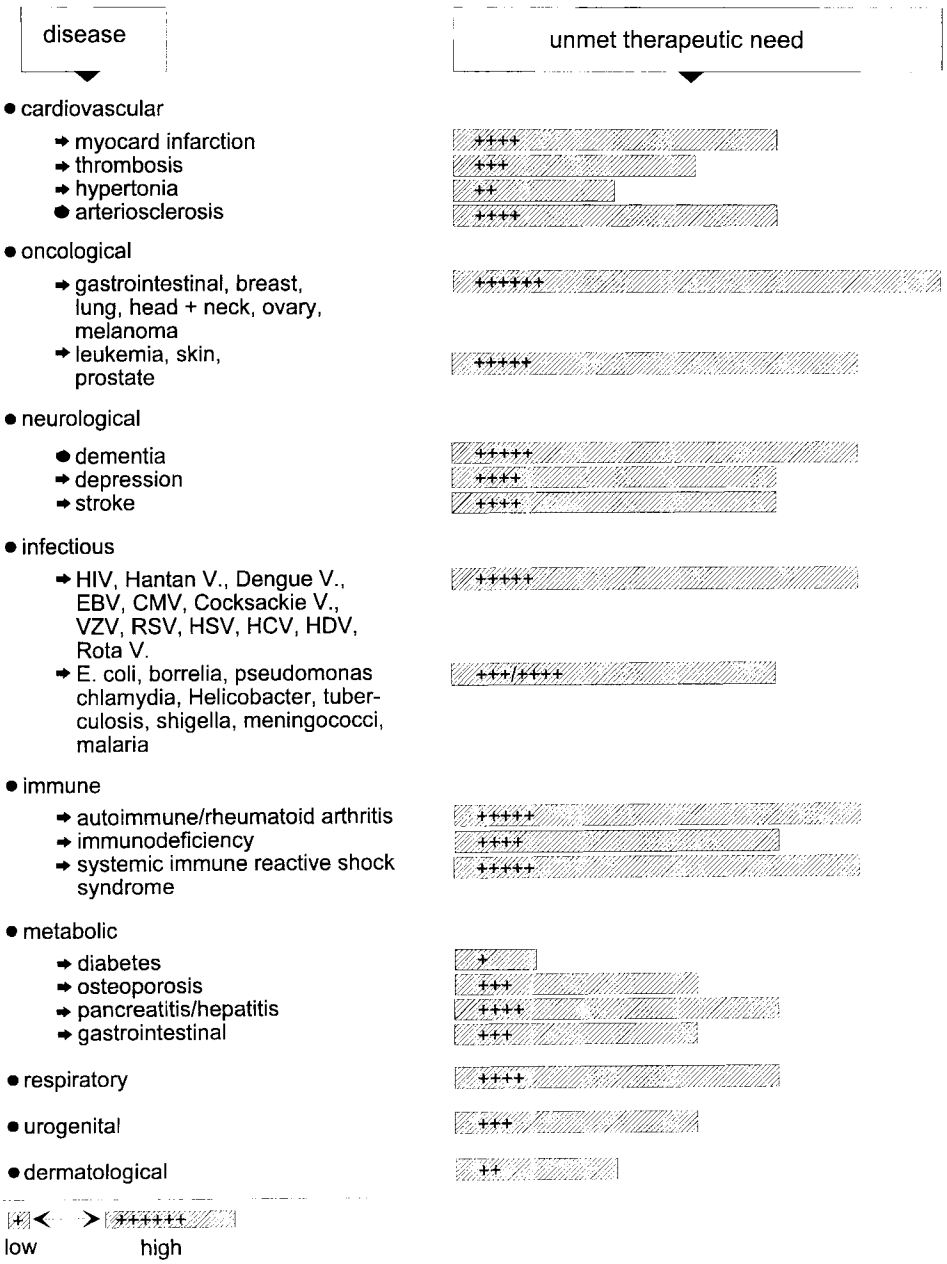
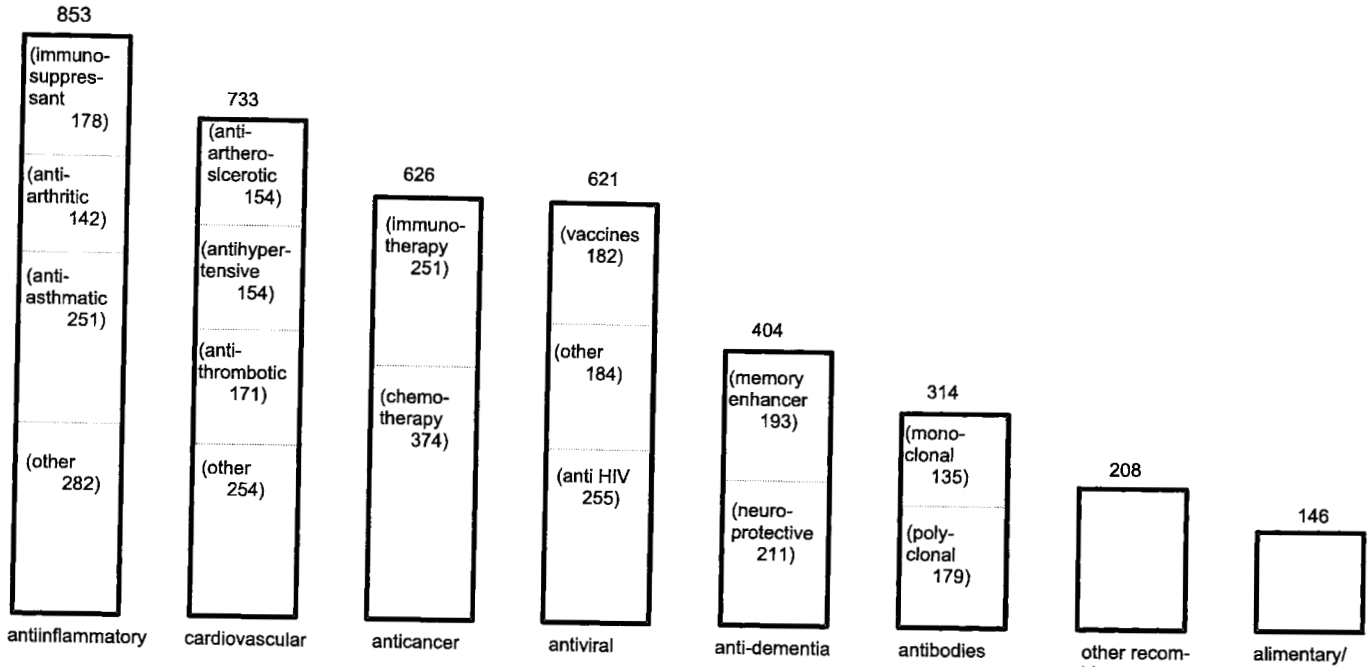


Figure I/6. Number of R&D compounds in the top therapeutic categories (12/1994)



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maintenance organizations, hospital chains and state government institutions, have adopted a strategy of "managed care." These groups with great purchasing power are now demanding the most cost-effective medical therapies and have provoked intense price competition among pharmaceutical companies. This development has been promoted by the fact that, during this decade, more patents of prescription pharmaceuticals have expired or will expire than at any other time, opening the door for companies to market less expensive generic drugs (Watts 1994).

Consequently, in addition to therapeutic innovations leading to new or improved products, price reduction of pharmaceuticals is already and will remain the second strongest global driving force influencing the pharmaceutical market. As a result, new strategies and measures to reduce costs by new methods of synthesis and by more efficient production and distribution systems will be of increasing importance for pharmaceutical companies in order to gain a competitive edge in the global market.

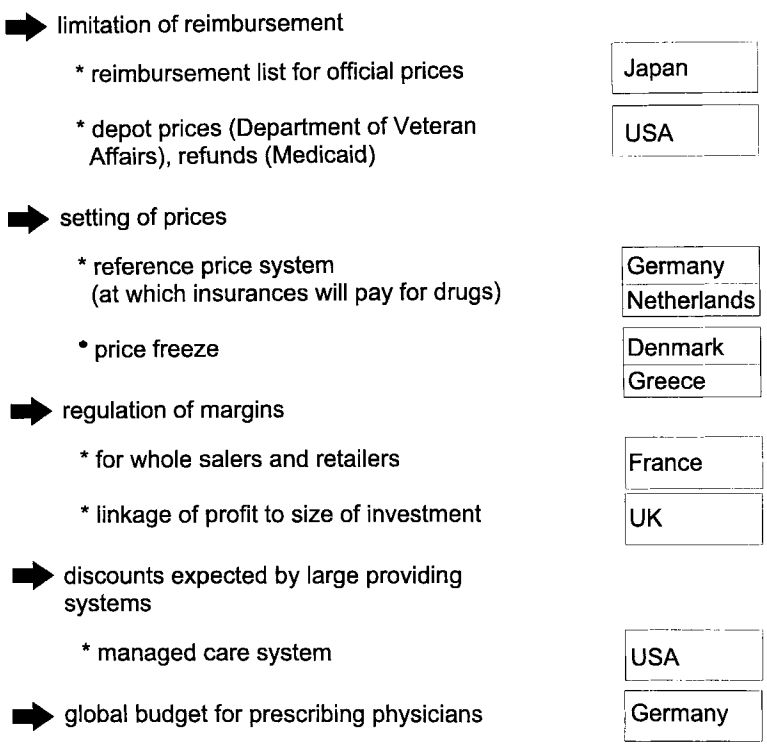
In addition to these global forces, every region is subject to different political influences and social pressures. Each region has different medical schools; registration and prescription laws; methods, degree, and policies of providing information through the media; as well as the hopes, fears, and feelings of patients and the prescribing attitudes of physicians.

Obviously, such local driving forces represent a mosaic of parameters. Companies that can adapt to local characteristics and conditions and simultaneously ensure that the resulting regionally scattered activities add up to a global strategy are in the possession of a strong competitive edge.

C Controls on pricing

As already outlined, regulations and strategies to reduce the price of drugs are significant driving forces in the pharmaceutical market. Wherever governments pay for drugs they exert some form of control on drug pricing (Figure I/7). In Japan, the Ministry of Health and Welfare publishes a table listing the official prices at which drugs will be reimbursed. Since the early 1980s, when pharmaceuticals accounted for nearly 40% of national health care expenditures, these prices have been continuously and selectively reduced. Germany legislates a reference price system. This sets the prices of drugs which are charged to the health insurance companies. This system is intended to stimulate price competition among drug manufacturers. France, on the other hand, regulates the margins of wholesalers and retailers, as a means of controlling drug prices. The UK links manufacturer profit to the size of the firm's investment in Great Britain. Prices of individual drugs are not regulated, but the government has instituted across-the-board price reductions as well as a price freeze.

Figure I/7. Controls on pricing of drugs



Despite being in force for a number of years, such pricing schemes have met with mixed success. A recent comparison of prescription drug price controls in Germany, France, Sweden, and the United Kingdom concluded that control effectively kept individual drug price increases below overall inflation. However, such price controls "have not completely contained the rise in drug spending" (USA General Accounting Office, 1994). One response, in Germany, has been to set fixed budgets for prescribing physicians. If total drug spending exceeds the fixed budget, the physician is financially responsible for the surplus.

In the United States, the government exerts control over drug prices only for those purchased by the Department of Veterans Affairs (VA); those reimbursed by the federal/state system of Medicaid, which pays for the health care of the indigent; and those reimbursed by Medicare, which pays for the health care of those over 65 years (and currently pays for inpatient drugs, but only for outpatient drugs used in end-stage renal disease, such as erythropoietin). The VA requires manufacturers to sell at a sizable discount, called the "depot price."

Medicaid requires manufacturers to return an amount of money equal to the difference between the drug price as of October 1990 and the current average wholesaler's price, if the latter rose faster than inflation. Medicare, on the other hand, examines both the cost and effectiveness of drugs, diagnostics, and medical devices. The price of erythropoietin, for example, was set by Medicare after the government had completed an analysis of the internal cost data from the drug's manufacturer and determined a "fair" price.

Even more control over prices is exerted by so-called managed care plans in the United States. These are organizations that provide both health care and health insurance, giving them an incentive to manage expenditure by carefully managing care. Because these plans are now so widespread and such powerful buyers, it is important to understand what pressure they have exerted on drug prices.

Although manufacturers publish an average wholesalers price, the actual price (that is, the revenue the company actually receives) depends on the distribution channel. As an April 1993 study by the Boston Consulting Group showed, managed care channels accounted for nearly half the US prescription drug volume and extracted sizable discounts for that volume (Figure I/8).

In addition to managed hospital and retail pharmacies, managed care plans also make use of mail order pharmacy, especially for drugs used in the case of chronic illness. The volumes of drugs distributed through managed care channels—and the size of the discounts—are expected to increase.

Figure I/8. Cost controls expected by new managed care channels

distribution channel	% US market accounted for by channel	average discount by channel
mail order pharmacy	5 %	30 %
managed hospital pharmacy	15 %	30 %
managed retail pharmacy	35 %	25 %
traditional hospital pharmacy	5 %	5 %
nursing homes, other	15 %	5 %
traditional pharmacy	25 %	0 %

Boston Consulting Group 1993

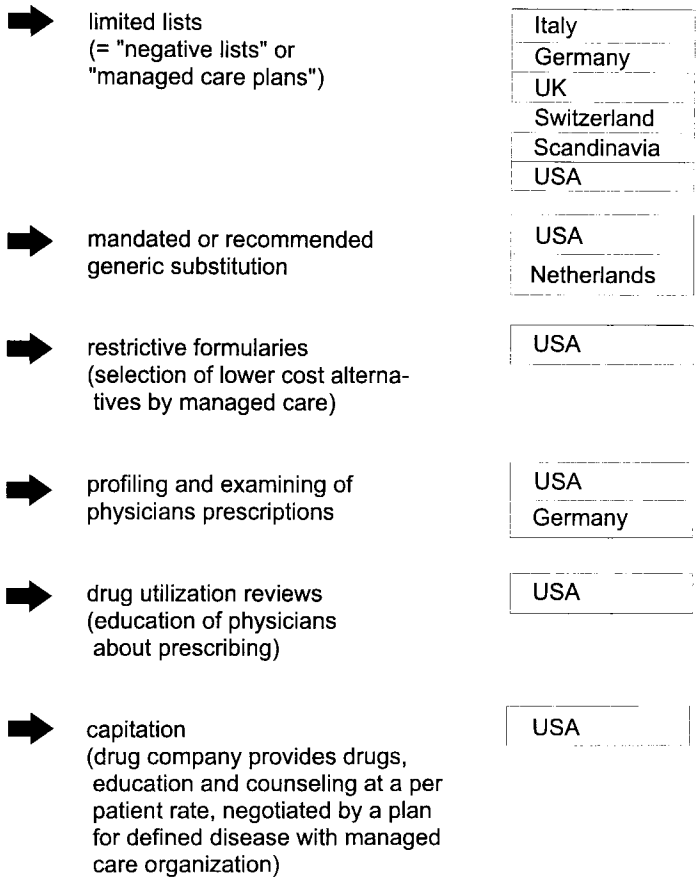
Managed care plans are watching the development of biotechnology drugs, such as erythropoietin, very carefully, because of the enormous price tag such drugs carry. For example, tissue plasminogen activator (tPA) is priced at about $ 2,000 per administration; Factor VIII at $ 25,000 per year; growth hormone at $ 8,000 to $ 30,000 per year; and treatment for Gaucher's disease at $ 100,000 per year. In one managed care organization, six to ten biotechnology drugs accounted for nearly one-third of the total formulary budget (the formulary itself listed several hundred drugs). When a biotechnology drug is a therapeutic innovation, e.g. the only agent available to treat a condition, it is likely to be included in a managed care formulary. However, "system savings" must be clear in managed care plans (in other words, the drug must also, for example, reduce hospitalization associated with the disease), in order that the drug be kept on the formulary.

D Control on utilization

Various methods have been developed to control the utilization of drugs (Figure I/9). They include limited lists, common in Italy, Germany (known as "negative lists"), the UK, and Scandinavia, among others. Mandated generic substitution and strict formulary management are common utilization controls in the United States.

In managed care plans, the "formulary" (like the limited list in Europe) has come to mean those drugs that will be paid for by the plan. If a physician writes a prescription for a drug not on the formulary, the patient pays for all or a portion of the cost out of his own pocket. Restrictive formularies are likely to become even more restrictive. In many managed care organizations, a formulary committee comprising a group of physicians and pharmacists, regularly reviews each therapeutic class of drugs, examining both the clinical outcome data and expenditure on the major prescription drugs. For equivalent clinical quality among drugs, the decision of which to include in the formulary is made by the committee in favor of lower cost. If a drug is removed from the list, or taken off the formulary as a consequence of that review, physician prescribing patterns can change almost completely within as short a period as 3 months. Such formulary committees will even tolerate some patient inconvenience and minor side effects if the overall cost of care is reduced. Thus, for a company to promote a drug because of its advantages (in galenic formulation, application frequency and/or reduced minor intolerability) may not be sufficient for the formulary committee to vote in its favor, unless the company offers the drug at a price that allows it to be chosen for the formulary. Under these conditions, compensation for drug research, development, and marketing costs becomes difficult.

Figure I/9. Controls on utilization of drugs



One of the largest managed care organizations in the US is planning other utilization controls, such as conducting physician profiling—examining, in other words, how each physician prescribes in comparison with other physicians—and ensuring that physicians do not prescribe non-formulary drugs excessively. The organization is planning drug utilization reviews, with concomitant education of physicians about prescribing for certain indications. The savings in drug spending from utilization reviews are expected to far outweigh the savings this plan has already achieved from aggressive discounting (see above).

A control on both price and utilization that is expected to become widespread is capitation, in which the drug manufacturer bears much of the financial risk of treating a particular disease. Managed care plans will "carve out" one or more

Figure I/10. Disease management initiatives in the USA

	cooperation with pharmacy benefits manager						stand alone activities			
care program	PCS/ IDM	Medco	Value Health	DPS	SDMS	Salick	pharmac. company	specialty provider	pharmacy benefits manager	health management organization
AIDS/HIV	-	-	-	-	-	-	-	Chronimed QDM	Caremark	US-Healthcare
Alzheimer	-	-	-	-	-	-	W.-Lambert	-	-	-
asthma	Lilly	MSD	Pfizer	SKB	-	-	Schering-Pl. Glaxo	QDM	Caremark	US-Healthcare
cardiovascular	-	MSD	Pfizer	-	Zeneca	-	W.-Lambert	Nat.-CV-NW	Caremark	US-Healthcare
depression	Lilly	MSD	Pfizer	SKB	-	-	-	-	Caremark	-
diabetes	Lilly	MSD	Pfizer	-	-	-	Boehringer Mh. Upjohn Bayer	Chronimed	Caremark	US-Healthcare
tumor	-	-	Pfizer	-	-	Zeneca	-	Axion	-	US-Healthcare
gastric ulcers	Lilly	MSD	-	-	-	-	-	-	-	-
renal disease (end stage)	-	-	-	-	-	-	-	-	-	US-Healthcare
epilepsy	-	MSD	-	-	-	-	W.-Lambert	-	-	-
infertility	-	-	-	-	-	-	-	-	-	US-Healthcare
liver disease	-	-	-	-	-	-	-	-	-	United Healthcare
haemophilia/ multiple sclerosis	-	-	-	-	-	-	-	QDM	-	-
CNS injuries	-	-	-	-	-	-	-	Paradigm	-	-

Scrip 2028 (1995)

diseases and contract with a manufacturer to provide drugs, education, counseling, and so forth, at a per patient ("capitated") rate that has been negotiated by the plan. If the manufacturer takes care of these patients for less money than the negotiated rate, the difference can be kept as extra profit. But if the cost of care exceeds the negotiated rate, the drug manufacturer bears total financial responsibility.

Such company-led disease management programs offer considerable potential benefits to pharmaceutical companies as well as to health maintenance

Figure I/11. The main driving forces for the future pharmaceutical market