Pergamon

Technovation 23 (2003) 291–296

technovation

www.elsevier.com/locate/technovation

In search of innovative techniques to evaluate pharmaceutical R&D projects

William F. Jacob [a], Young Hoon Kwak [b,*]

[a] *Human Genome Sciences, 9410 Key West Avenue, Rockville, MD 20850, USA*
[b] *Department of Management Science, Monroe Hall 403, School of Business and Public Management, The George Washington University, 2115 G Street, Washington, DC 20052, USA*

Abstract

This paper is a conceptual paper that examines a new integrative evaluation approach for pharmaceutical R&D projects. It describes recent changes in the health care economy and the underlying scientific and technological revolution that has markedly altered the business environment in which the pharmaceutical industry operates. Changes in cost and technology resulting from managed care organizations, marketing, generic drugs, new drug development risk, and scientific and technological evolution forced us to think of a new way to evaluate R&D projects in the early phase of the project. These changes have placed increased emphasis on the need for improvements in technology management methodologies. A real options approach, especially when combined with other project risk management processes, offers a significant improvement in project selection and review, and resource allocation decisions.

Keywords: R&D; Project management; Real option models; Risk management

1. Introduction

> While governments and large institutional buyers continued to exert strong downward pressure on drug prices and company earnings, a scientific and technological revolution promised to change the way in which drugs were discovered, developed, and tested, and in the process to expose the industry to a wave of new competitors (Fagan and Hayes, 1998).

The decade of the 1990s has been a period of turmoil for the pharmaceutical industry as it has faced the dual challenges of radical changes in health care economics and in science and technology (Agnew, 2000). Meeting these challenges has brought a major consolidation of the industry through a series of mergers and acquisitions that a few large firms now dominate the industry. However, the cost savings resulting from the elimination of redundant cost centers and the economies of scale achieved by these structural changes are no guarantee of long-term success (Carr, 1998; Kearney, 1997).

These insights have placed new emphasis on the development of management tools and practices to compete more effectively. Adapting and implementing project management tools, techniques and principles will play an important role in this process. The pharmaceutical industry has been using project management techniques and methodologies for some time, but overall its development and impact are behind that of other industries (Byers, 1989; Krusko and Cangemi, 1987; Murphy, 1989; Foulkes, 2000). In large part this has been due to the inherent difficulties in managing R&D projects. The development of new technology has an inherent unpredictability that has kept it outside the domain of conventional approaches to project management (Sheasley, 2000).

This situation is changing as the result of recent efforts to develop improved techniques for technology management. The application of real options analysis to R&D projects has gained support in the last few years and promises to yield a significant improvement in technology management. This paper reviews the recent environments and trends on R&D project management and its impact on the pharmaceutical industry.

* Tel.: +1-202-994-7115; fax: +1-202-994-2736.
E-mail addresses: will_jacob@hgsi.com (W.F. Jacob); kwak@gwu.edu (Y.H. Kwak).

0166-4972/02/$ - see front matter © 2002 Elsevier Science Ltd. All rights reserved.
doi:10.1016/S0166-4972(01)00116-X

2. Cost, technology, risk and environmental changes in the pharmaceutical industry

The pharmaceutical industry has faced intensifying cost pressures through the 1990s. These pressures are expected to continue. The source has been several fold.

2.1. Managed care organizations

Managed care organizations, seeking to control health care costs, have had a major effect on the economics of health care. The number of patients under managed care has increased steadily from 1980, when approximately 5% of patients were covered under managed care organizations, to the early 1990s, when 80% were covered (McGahan, 1994). They have expanded the use of lower cost generic drugs, developed closed formularies, and limited prescription reimbursements. Cost consciousness has been increasing as well in Europe and Japan, which with the US make up the three largest markets in the world (McGahan et al., 1995).

2.2. Marketing

Marketing expenditures have grown as a result of changes in regulations allowing direct advertising to consumers. Now, in addition to marketing to doctors, companies must mount major advertising campaigns on TV and in magazines (Carr, 1998).

2.3. Generic drugs

Prior to 1984, companies introducing generic forms of patented drugs had to wait until the patent expired and then had to do clinical and safety studies before the drug could be marketed. Barriers to the entry of generic drugs have fallen significantly following passage of the Waxman-Hatch Act (1984) which permitted introduction of the generic if it could be shown that it was equivalent to the original without having to go through separate clinical and safety trials. This has significantly reduced the period of time during which a drug is protected by patent and could command premium pricing.

2.4. Drug development: increased cost and complexity

The increasing complexity of drug development has also added cost to the process. A major shift in usage has occurred during the last 20 years. A large and growing proportion of drugs are now prescribed for chronic conditions rather than for short-term conditions (Agnew, 2000). This means that regulators look more closely at a drug's long-term effects. Drugs that will be taken for years for conditions such as hypertension or diabetes have to have very good safety profiles. As drugs are increasingly taken in combinations, it is imperative that drug interactions be eliminated. The standard of performance has been raised so that many new drugs that were marketable 20 years ago are no longer acceptable today.

In addition, new drugs need not only be safe and efficacious they must also be cost effective. They must be significantly better than other therapeutic options. Studies demonstrating cost effectiveness and long-term safety are expensive. Overall, costs of clinical trials account for roughly 40% of R&D budgets, with another 10% going to production and scale-up costs. These costs are expected to increase.

2.5. Risk

Drug development is a research-intensive, high-risk endeavor. Typically, more than 5000 compounds must be screened to produce one marketable drug. Considerable resources must be expended in the early stages of development. Total costs to bring a drug to market are currently between US$350 and 500 million. This figure includes the cost of failed projects. It is not uncommon for drugs to fail in phase III trials. There is a high and unpredictable level of attrition at each stage of the development path such that 40–50 projects are needed at the research stage in order to assure one new chemical entity introduced into the market. In addition, there are uncertainties at the other end. One cannot be sure that a drug will live up to its commercial potential. Other companies may launch similar products at the same time, or unexpected toxicities can lead to curtailment of use or withdrawal (Kaufman, 2000).

2.6. Scientific and technological revolution

At the same time that the industry was trying to cope with the effects of changes in health care economics, the nature of the drug discovery and development process was changing as the result of a revolution in science and technology. Advances in biochemistry and molecular biology have led to "rational drug design", targeting fundamental disease processes. Combinatorial chemistry has dramatically increased the number of compounds that chemists can make, and high throughput screening technology has improved the efficiency of screening those compounds.

Molecular genetics is having an enormous impact on drug development. Not only is it providing a large number of potential new targets for therapeutic intervention, it promises to make therapies that are tailored to the genetic makeup of the recipient. Exploitation of this new knowledge will require much larger R&D programs. One of the major driving forces behind the recent mergers is the need to expand R&D efforts.

The accepted thinking is that size is a key success factor. The largest companies will be the ones able to