# Chapter 10

## 제약(약물)경제학
## (Pharmacoeconomics)

# A. 개요

Economics of technological change recap:

> Expenditures on pharmaceuticals now represent an increasing proportion of total medical expenditures. This component has increased from about 5% to over 10% of aggregate medical care spending in the United States between 1990 and 2000.

This increase is in part due to technological change which has caused substitution of pharmaceuticals for other medical treatments and in part due to increases in prices.

# B. 지적재산권(IPR)의 문제

We have considered the protection of intellectual property rights as an important reason why U.S. firms innovate as much as they do.

Why is this particularly important in the case of the pharmaceutical industry?

The extremely high cost of developing new drugs (NCEs) makes patent protection especially important.

# B. 지적재산권(IPR)의 문제

1. Does patent protection create temporary monopolies?

The answer depends upon our definition of a monopoly.

A patent grants a monopoly over the production and sale of a drug. However, most NCEs have at least some close substitutes that can be used as alternatives in treating the same disease or illness. Thus, it is better to think of the market for on-patent drugs as **oligopolistic** or **monopolistically competitive**, with product differentiation.

The large pharmaceutical firms are generally classified as oligopolies, but with increased competition between these firms and smaller bio-tech companies, the market has become more competitive.

# B. 지적재산권(IPR)의 문제

## 2. Between- and Within-patent Competition

During the time that a drug is patent protected (on-patent), only between-patent competition is allowed in the U.S. and other countries where patent law is upheld.

Between-patent competition exists when a close substitute, but one that is chemically different, is available in the market.

Within-patent competition exists when generic versions of a brand-name drug become available in the market.

# C. 미국 식약청의 규제내용

The pharmaceutical industry is subject to a great deal of government regulation compared to most other industries, even those which produce other medical products, such as medical devices.

Federal regulation of pharmaceuticals came into being with the Pure Food and Drug Act of 1906. It was strengthened and extended by the Kefauver-Harris Act of 1962.

Before 1971, the chief concern of FDA regulation was consumer safety. In 1971, proof of efficacy was added as a criterion for FDA approval of an NCE.

# C. 미국 식약청의 규제내용

Typical Timetable for New Drug Development

- I. Discovery
- II. Preclinical Animal Testing
- III. Application for Human Testing Authorization [ 3.5 years]
- IV. Phase I Clinical Testing: Healthy Sample [15 months]
- V. Phase II Clinical Testing: Larger Sample [2 years]
- VI. Long-Term Animal Studies [concurrent with IV-V]
- VII. Phase III Clinical Testing: Efficacy/Side Effects [3 years]
- VIII. New Drug Approval Process [2.5 years]

# C. 미국 식약청의 규제내용

The Prescription Drug User Fee Act of 1992 has caused some speeding up of the drug approval process. The Act gives the FDA the authority to collect fees when pharmaceutical companies file applications that are accepted.

Important Policy Questions:

1) Is there too much, too little, or just enough regulation, and how do we go about deciding?

2) How risk averse should a public policy be?

To answer these questions we need to apply cost/benefit analysis:

# C. 미국 식약청의 규제내용

Cost/Benefit Analysis of FDA Regulation

Possible FDA Decisions:

| | Safe Drug | Unsafe Drug |
|---|---|---|
| **Accept** | **Correct decision** | **Type II error** |
| **Reject** | **Type I error** | **Correct decision** |

Note: You may want to review basic statistics: Type 1 and Type 2 errors

# C. 미국 식약청의 규제내용

Instances in which the criteria for the marketing of NCEs may be relaxed.

- The case of orphan drugs.
  These are drugs used to treat rare diseases, defined as those with fewer than 200,000 diagnosed cases

The problem of “salami slicing” -- claiming a drug which has multiple uses is an orphan drug if one uses it for the treatment of rare diseases.

- The compassionate use of experimental drugs.

# D. 기타 규제: 처방약

Another form of regulation is the requirement of obtaining a physician's prescription in order to purchase a drug.

(Drugs that are not restricted in this way are called, "over-the-counter" drugs).

Rx regulation is stricter in the U.S. than in many other countries, including Canada. It is a controversial policy in cases where drugs are neither habit-forming nor dangerous.

# E. 약가정책 (Drug Pricing Policy)

1. There are significant differences internationally in the pricing of pharmaceutical products.

International price differences are related to national regulations about re-importation or “parallel importing” of drugs manufactured abroad. They are also related to whether international patents are enforced and whether governments set drug prices.

The TRIPS agreement and why it is important to the pricing of drugs in the global market:

- It is an agreement to honor patents of other countries and is a requirement for membership in the World Trade Organization.
  Ex) Korea-U.S. FTA

# E. 약가정책 (Drug Pricing Policy)

2. Another basis for price differences is the distinction between **brand-name (**상품명 처방약**)** and **generic drugs (**성분명 처방약**).**

Generic versions of an NCE may only be produced and sold in the U.S. after the NCE comes off patent protection. They also are subject to FDA approval. In the 1970s, the government liberalized the process for the approval of generic versions of drugs.

In the U.S., brand-name drugs tend to be higher priced than in other parts of the world, but generic versions are often cheaper.

# E. 약가정책 (Drug Pricing Policy)

A puzzle: Why are  brand-name drugs often priced higher after they come off patent protection? What factors determine whether a drug price will be raised after its patent protection expires?

Hint: Think about what happens to the demand for the drug, including the price elasticity of demand.

The demand for the brand-name drug decreases as generic drugs are introduced as substitutes.  However, the demand also becomes more price-inelastic as the more loyal consumers remain.

# E. 약가정책 (Drug Pricing Policy)

3. The third category of price difference is related to insurance coverage.

> Insurance carriers may reimburse only certain drugs or reimburse different drugs at different rates, depending upon whether the drug is brand-name or generic, and whether it is on their formulary list.

Note that Managed Care has greatly increased the market for generic drugs, since many insurers (including Medicaid) will only reimburse for generic versions of drugs, when available.

Does this threaten the rate of innovation of pharmaceuticals?

# E. 약가정책 (Drug Pricing Policy)

4. Another basis for price differentials is related to advertising.

There are two key types of advertising for drugs:

- "Detailing": Involves active advertising to physicians. Physicians are regularly visited by sales representatives of pharmaceutical companies who provide them with free samples, treat them to lunch, etc.

- Direct advertising to consumers: This may result in an increase in demand and/or reduction in the price elasticity of demand for drugs which, in turn, may affect drug prices.

# E. 약가정책 (Drug Pricing Policy)

5. 접근성의 문제: OTC(over-the-counter) drug에 대한 약국독점의 폐해

6. 신약개발(high-risk and high-return)에 대한 정부의 지원

   Pharmaco-investment should be made on activities, not on plan itself.