Key factors in the rising cost of new drug discovery and development

A presentation by Daniel, Felix, Flurina, Marigona & Merel

Introduction

By: Merel Kuijs

KEY FACTORS IN THE RISING COST OF NEW DRUG DISCOVERY AND DEVELOPMENT

Michael Dickson[⋆] *and Jean Paul Gagnon*[‡]

The public desire for new therapies, their increasing cost and the increased role of government as a payer for innovative new drugs all converge on the issue of the rapidly rising cost of new drug development — now thought to be greater than US $800 million — and highlight the necessity for an efficient use of resources. With this in mind, here we review studies on the cost of developing new drugs and consider how this cost has, and could be, affected by the changing environment for pharmaceutical research and development.

Debate about Drug Pricing: Public vs. Industry

- Drug prices have been increasing steadily
- Pharmaceutical companies have defended escalating prices
- Public dismay and political resistance

Price Change by Condition, 2014-2019

Condition	Price change
Anaphylaxis	+96%
Rheumatoid arthritis	+92%
Diabetes	+58%
HIV	+42%
Asthma	+35%
Birth control	+18%
ADHD	+12%
Erectile dysfunction	+7%
Migraine	+5%
High cholesterol	+5%
Depression and anxiety	-18%
All drugs	+32%

Img: GoodRx

Most Expensive Drug (Per Dose)

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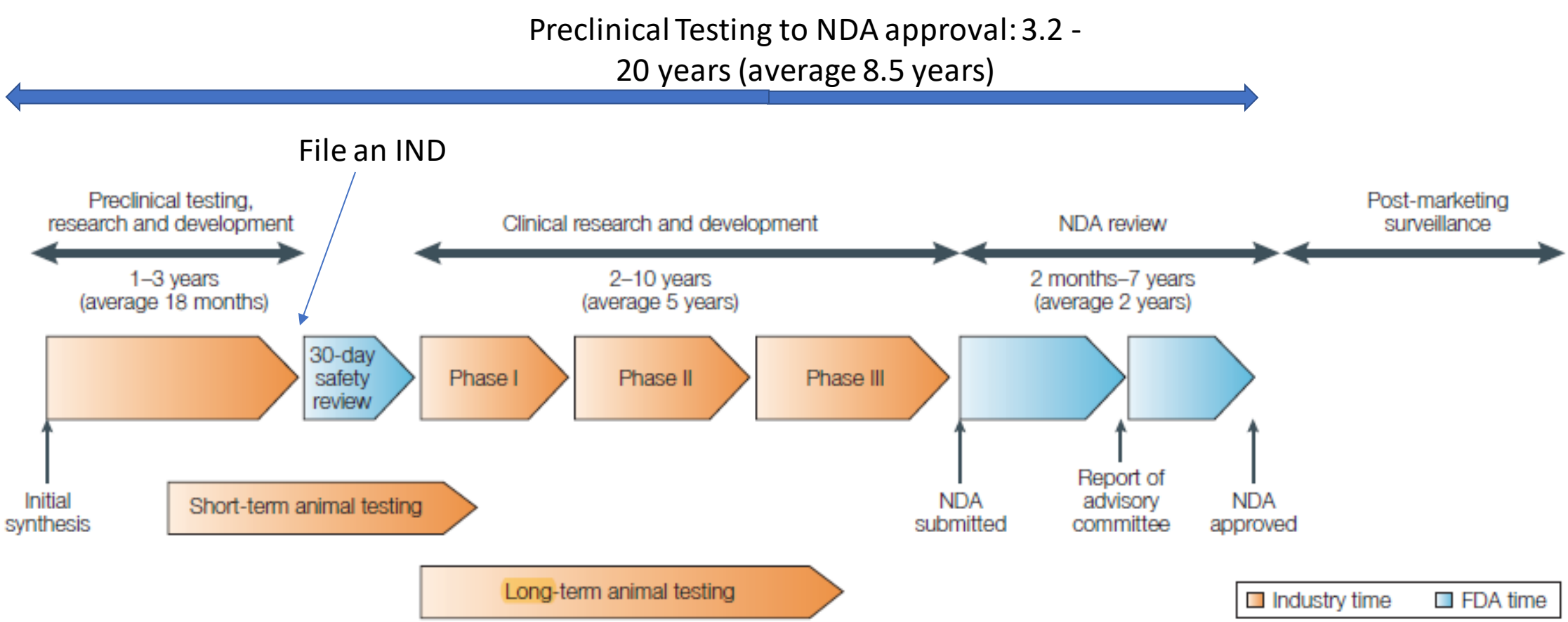
Increased Timespans in Drug Development

By: Flurina Fischer

Drug Approval Process (in US) (1)



IND: Investigational New Drug Application
NDA: New Drug Application

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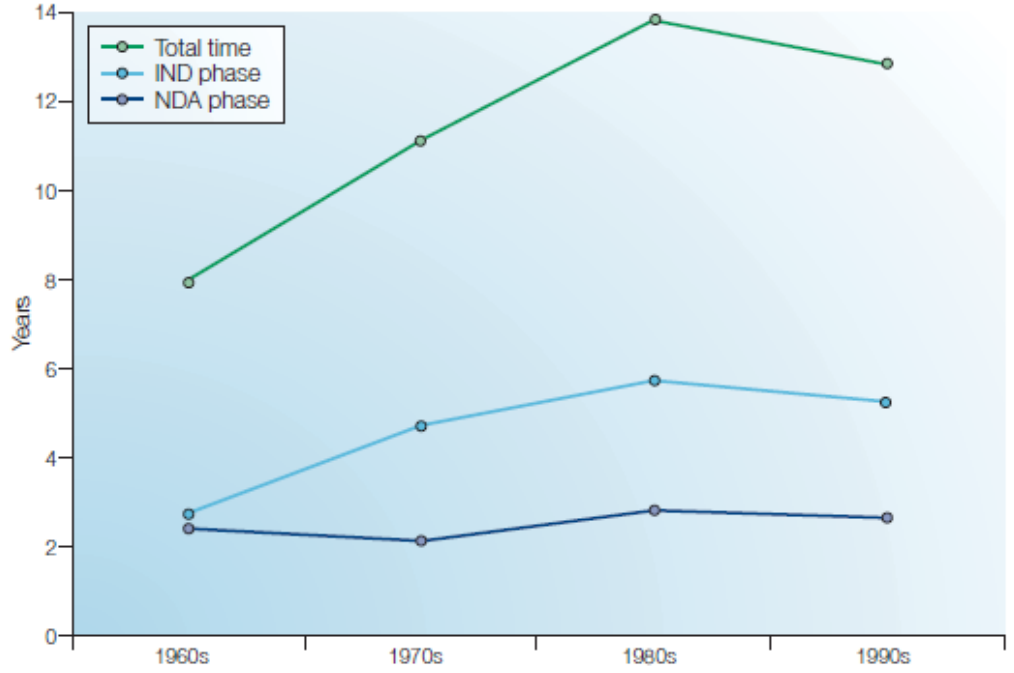
Drug Approval Process (in US) (2)

- Trend: needs more time --> longer clinical trials
  - Regulatory requirements
  - Number of subjects (--> finding subjects)
  - Chronical diseases
- Note: Clinical trials: most expensive in development
- FDA needs proof of safety and efficacy --> min. 2 clinical trials
- Similar processes in EU and Japan

From Synthesis of Compound to NDA approval:
10 – 20 years
(average 9 – 12 years

Situation of FDA Approval Process

- Since 1992 (PDUFA) time FDA needs: decreasing
- Concern: FDA recources diverted --> review time suffers
- Rising numbers of safety recalls
- Decreased numbers of approved drugs
- Fear: rising approval time



PDUFA: prescription drug user fee act

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Many Factors

- Focus on chronic diseases
- Competiton and increased risk
- More requirements and restrictions
- Overall higher standards:
  - Data collection
  - Manufacturing
  - Testing

Chronic Conditions and the Drug Discovery Process

By: Felix Guntlisbergen

Changing Environment

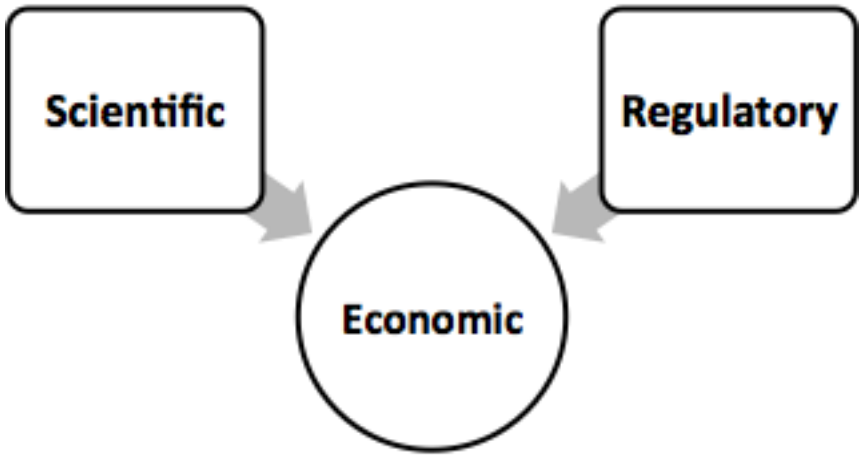
- Trends in the type of new drug development
- Treatment of chronic diseases
- Cardiovascular disease (CVD), cancer and stroke
- Improved drug therapies

Chronic Conditions

- Increase time for clinical trial --> Increase drug development time
- Longer time periods to demonstrate desired effects
- Low success rates for antineoplastics and immunological drugs

Risk in the Pharmaceutical Industry

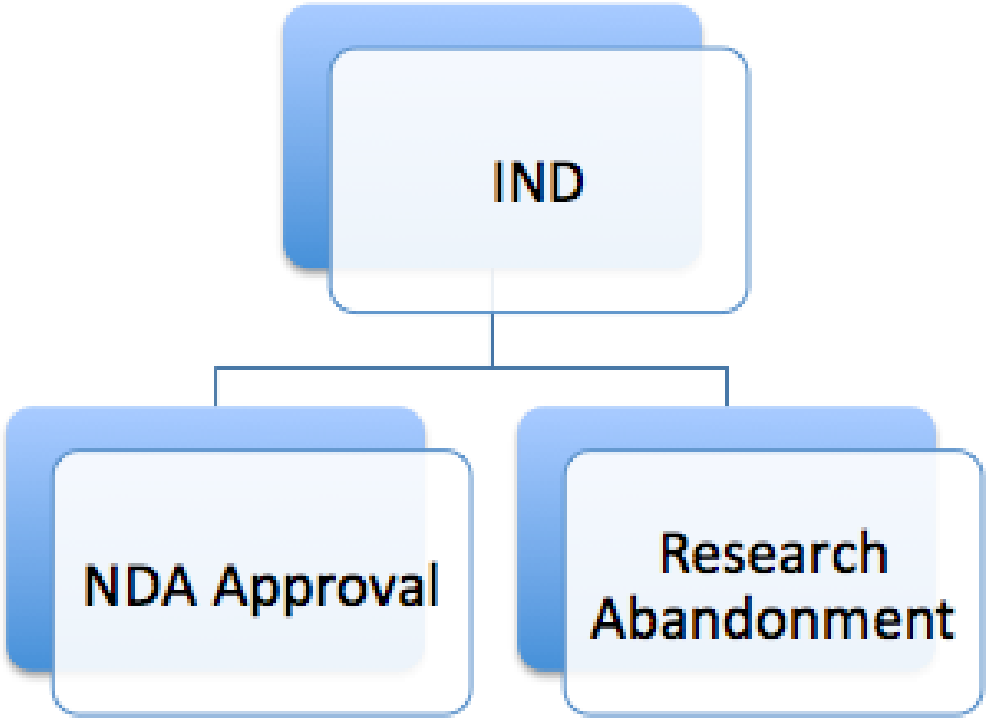
By: Marigona Ramadani-Hoti



Risk in the pharmaceutical industry is the result of *scientific* , *regulatory* and *economic* uncertainty.

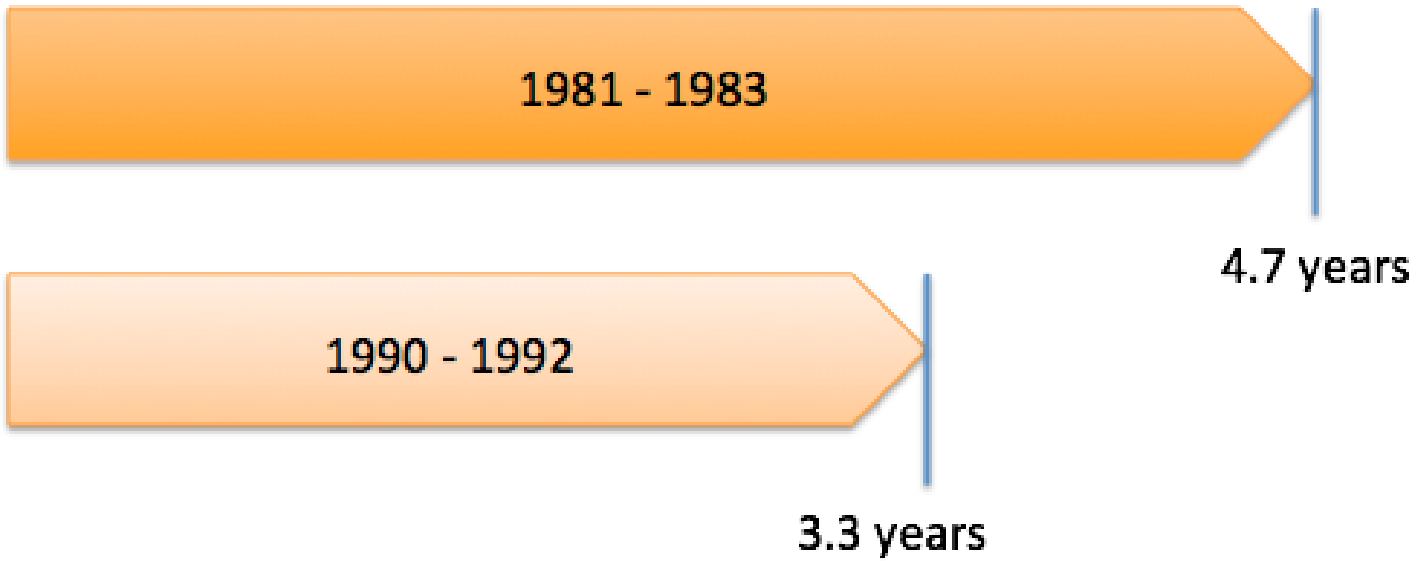
The scientific and regulatory risk create the lengthy development time and thereby economic risk.

- **Risk** is often assessed in terms of the time from filing an IND application to NDA approval or abandonment of research on an NCE.



Average time to *research abandonment*

- This reduction of 30% indicates that pharmaceutical firms were attempting to reduce risk by making earlier decisions to discontinue work on less promising compounds.



Summary

Long times from discovery to NDA approval

High probability of failure

Unpredictability of Sales

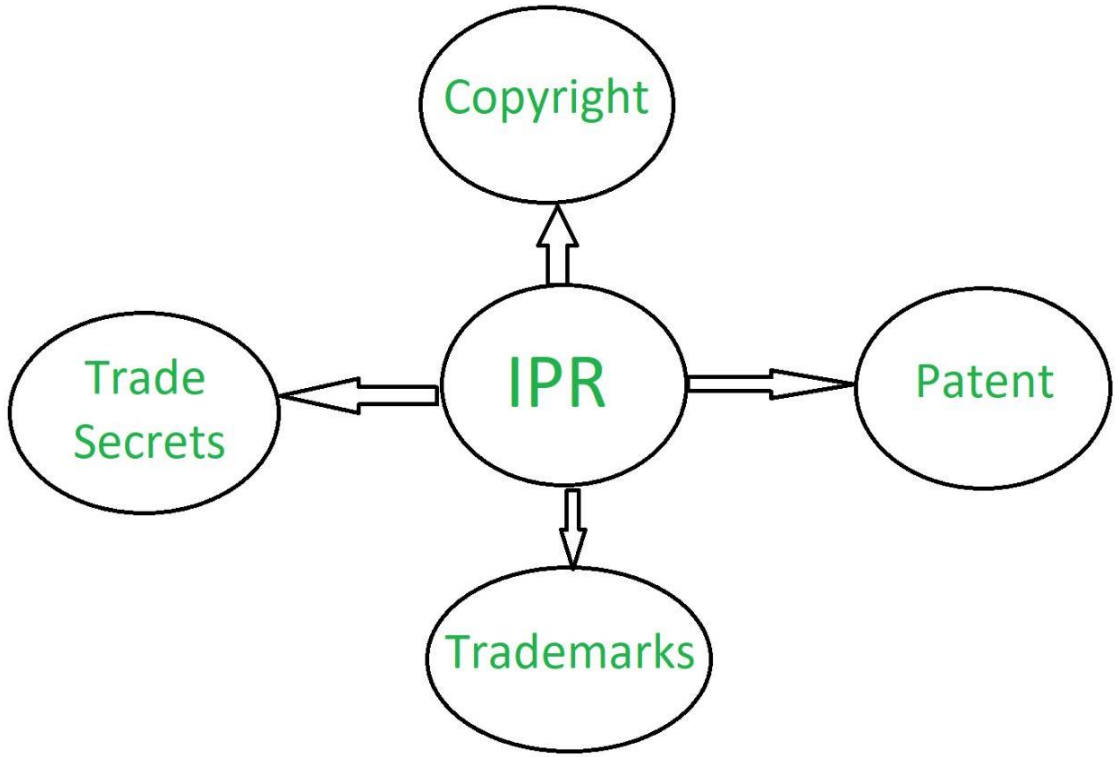
Risky business environment

The Fierce Market of Drug Development

By: Daniel de Wilde

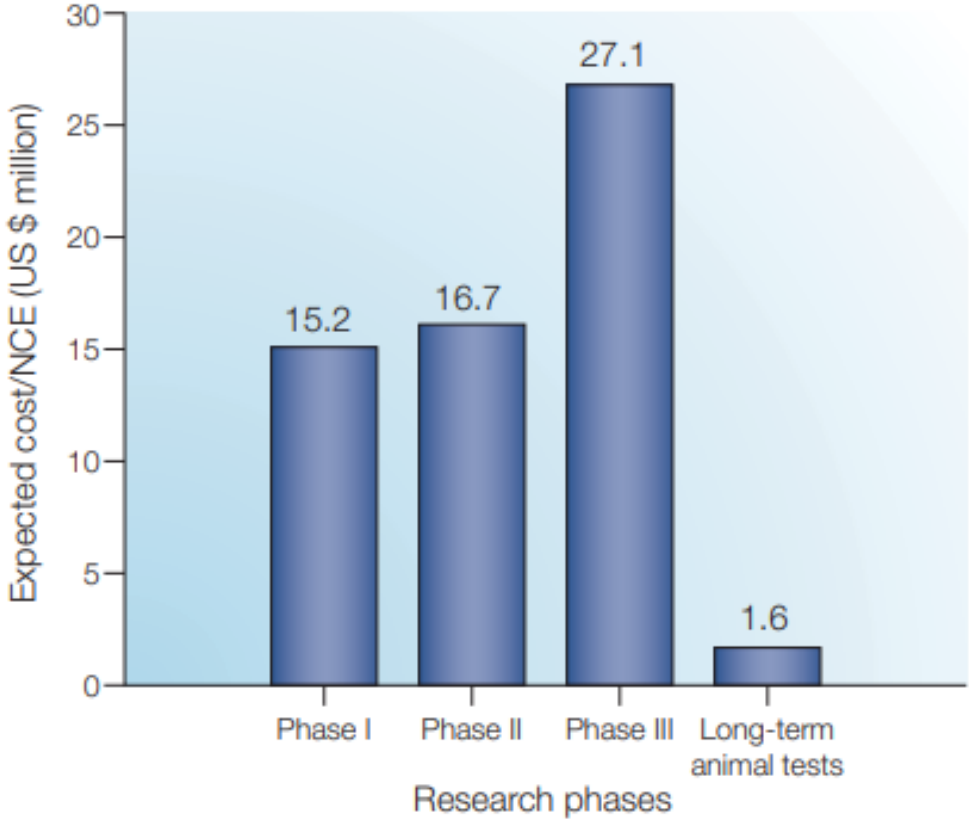
Protection of Intellectual Property

- Patent laws -> 20 year protection in most countries
- Innovating costs are high while imitation costs are relatively low
- The more significant the patent protection system the more new drugs were approved
- Protection of intellectual property gives people incentive to innovate



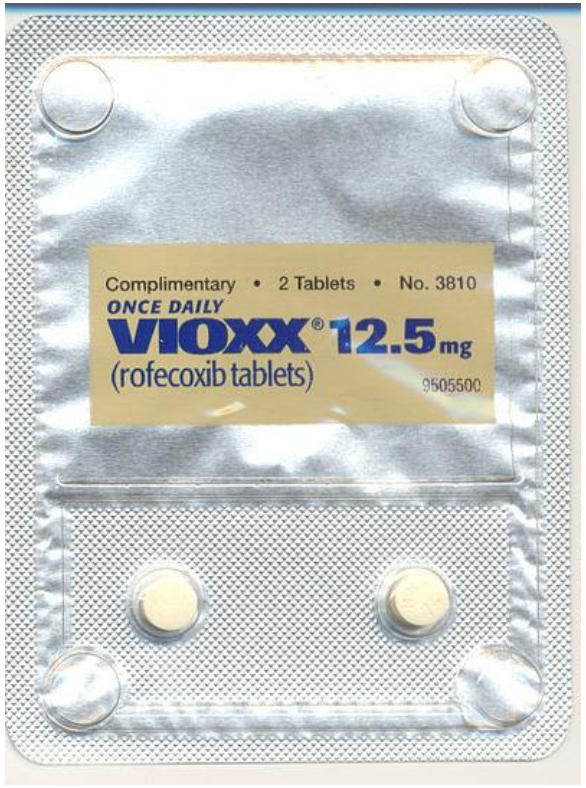
Therapeutic Competition

- The market for innovative new pharma has become immensely competitive
- New compounds are being developed with similar MoA's but different chemical compounds
- Therapeutic competition thus pressures pharma companies even more than before
- There is a significant reduction in market share compared to a market without therapeutic competition



Celecoxib and Rofecoxib

- While ***Celecoxib*** was released in December 1998, ***rofecoxib*** was released in May 1999
- The difference in market entry was merely 5 months
- Celecoxib ⬆ Rofecoxib ⬇



Generic Competition

GENERIC COMPETITION WAS INCREASED IMMENSLY BY THE HATCH – WAXMAN ACT

DECREASE IN THE BARRIERS FOR MARKET ENTRY RESULTED IN SURGE OF GENERIC COMPETITION

6 MONTHS AFTER GENERIC ENTRY, AVERAGE GENERIC PRICE = 46% OF BRAND PRICE

Summary

- Protection of intellectual property gives innovators sense of safety
- Therapeutic and generic competition pressures companies
- Higher competition in the market results in higher risk for drug development

Discussion

By: Merel Kuijs

Discussion points

- R&D costs and the profit margin
  - How high should the profit margin be?
- Trend: acquisition of smaller, specialized companies by large pharmaceutical companies
  - More efficient?
- Severe lack of price transparency
- Different prices in different countries