

# **The Price of Innovation: Internal R&D Decisions**

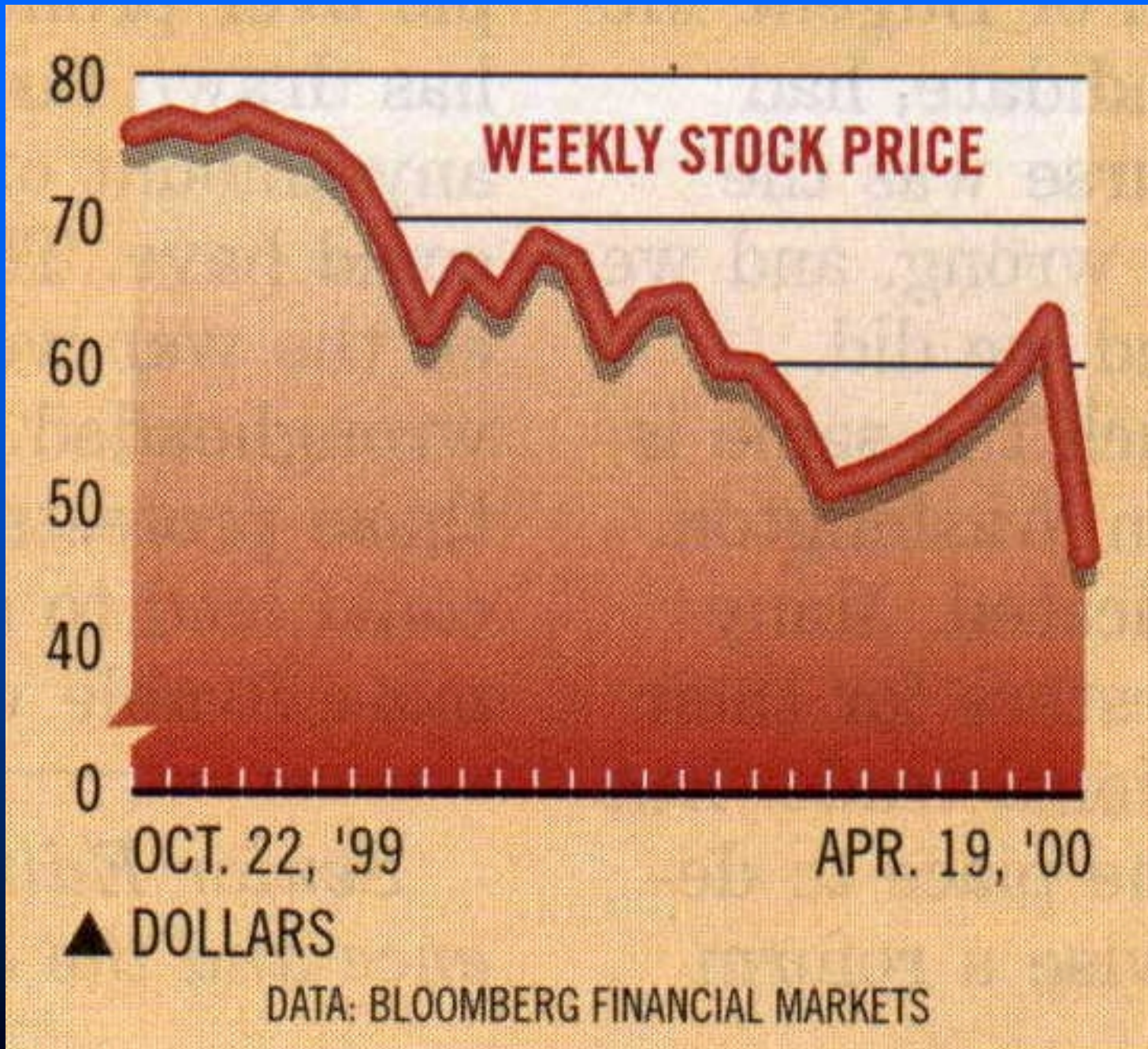
**Glenna M. Crooks, Ph.D.**

Presented at National Health Policy Forum Session,  
“Pharmaceutical Marketplace Dynamics,”

May 31, 2000

# Corporate Culture

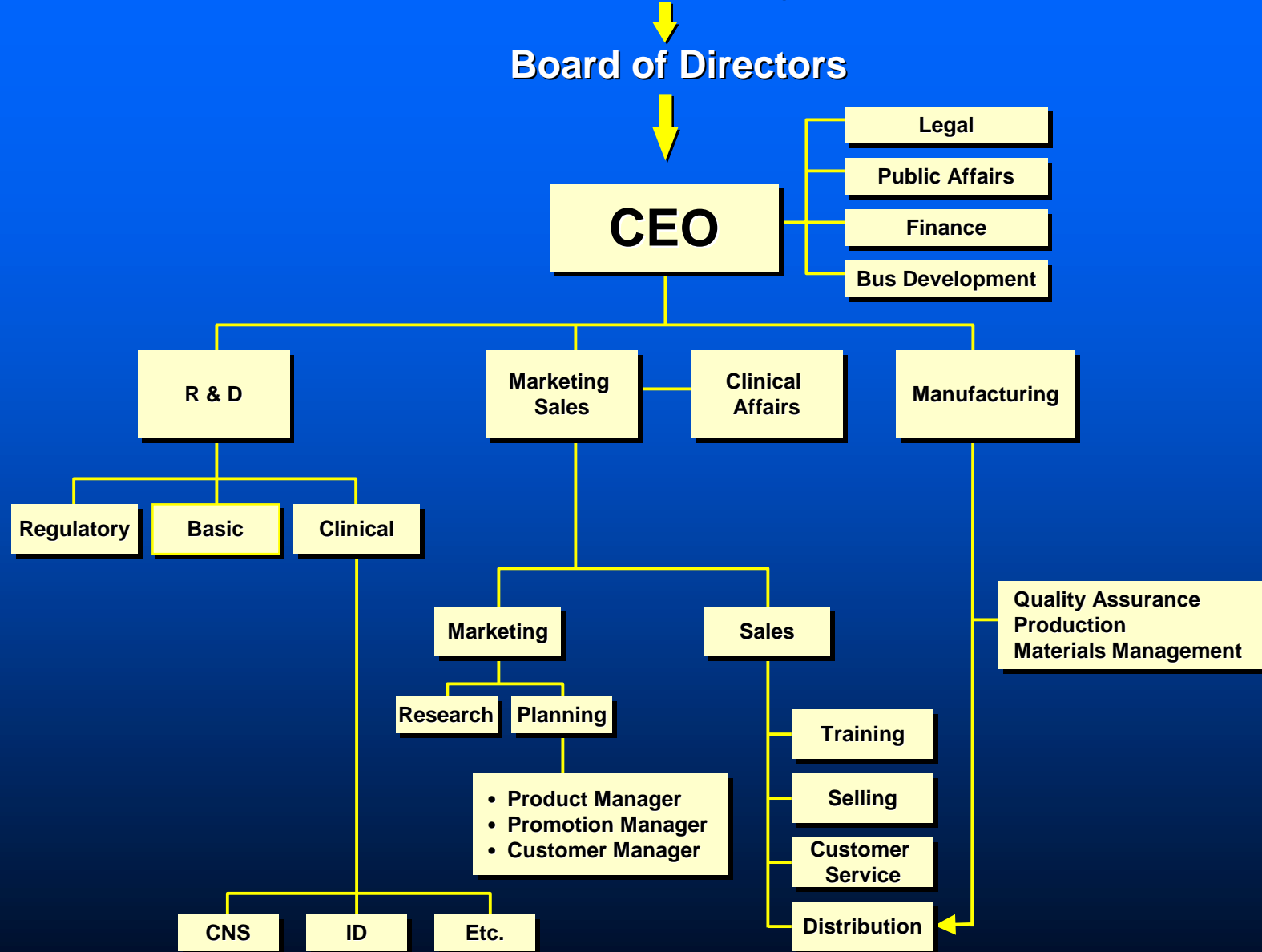
- ◆ Mission-driven
  - Discovery, development, education of prescribers, patients and caregivers, adherent use
  - Return to shareholders-equity financed, not debt, tax or philanthropy financed
- ◆ Objectives-focused
  - Measurable, reported quarterly, annually and hourly
  - Direct personal impact on job, salary, bonus
- ◆ Organizational style
  - Hierarchical, multidisciplinary, teams
  - Data driven, risk-balancing, “learning” style
  - Scripted with outsiders: trade secret and legal requirements



# Capital Market Impact

<i>Index</i>	<i>13/3/00</i>	<i>15/3/00</i>	<i>% Change</i>
Biotech Select	579.17	485.62	-16.2
Large cap	426.86	361.02	-15.4
Mid cap	445.85	383.62	-14.0
Small cap	382.14	320.24	-16.2
Genomics	889.46	673.10	-24.3

# Pharmaceutical Company Shareholders



# “Small” Company Shareholders

Board of Directors

CEO

Legal

Finance

Bus Development

R & D

Regulatory

Basic

Clinical

CNS

ID

Etc.

# Discovery and Development

**BASIC  
RESEARCH**



Government  
- NIH

Private Sector  
- Biomedical  
Research  
Companies

- Nonprofit  
Foundations

**Knowledge  
About  
Disease**

**TRANSLATION  
RESEARCH**



Government  
- NIH

Private Sector  
- Biomedical  
Research  
Companies

- Nonprofit  
Foundations

**APPLIED  
RESEARCH  
(Development)**

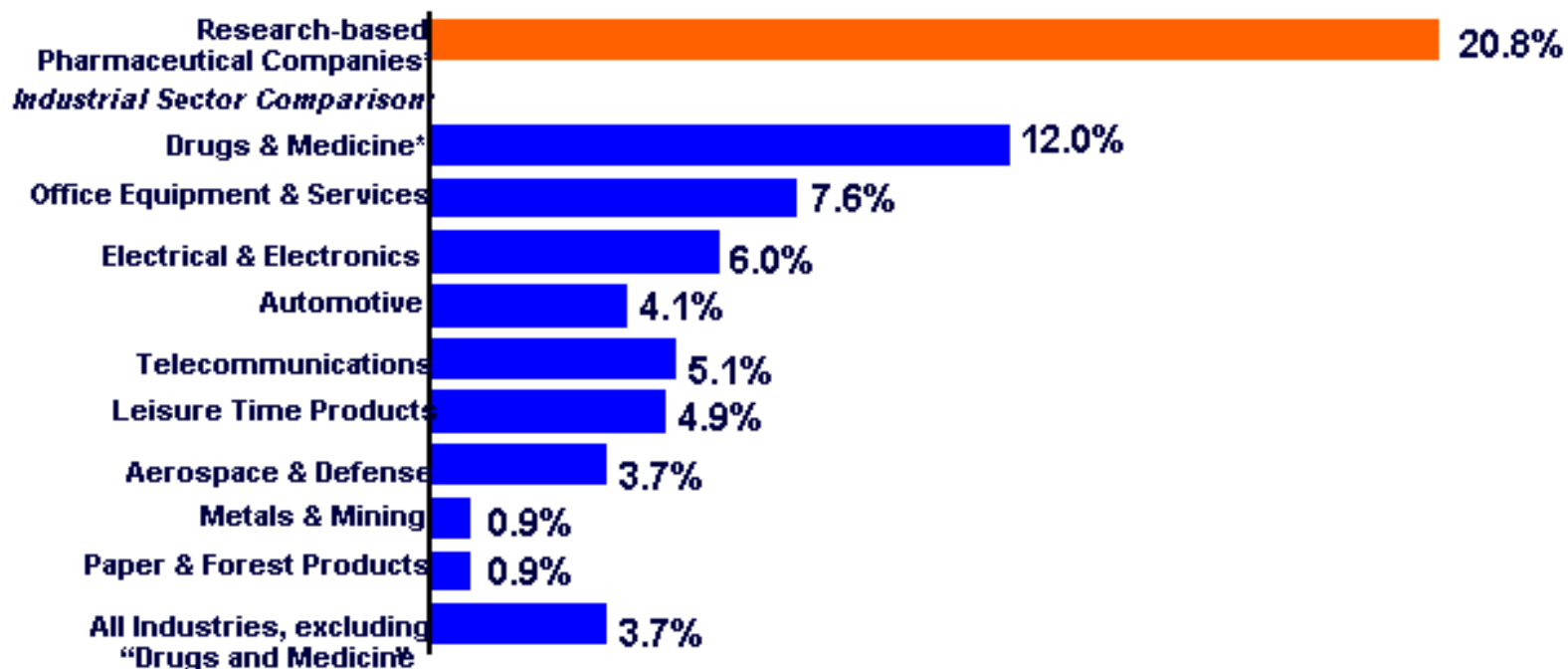


Private Sector  
- Biomedical  
Research  
Companies

**Consumers**

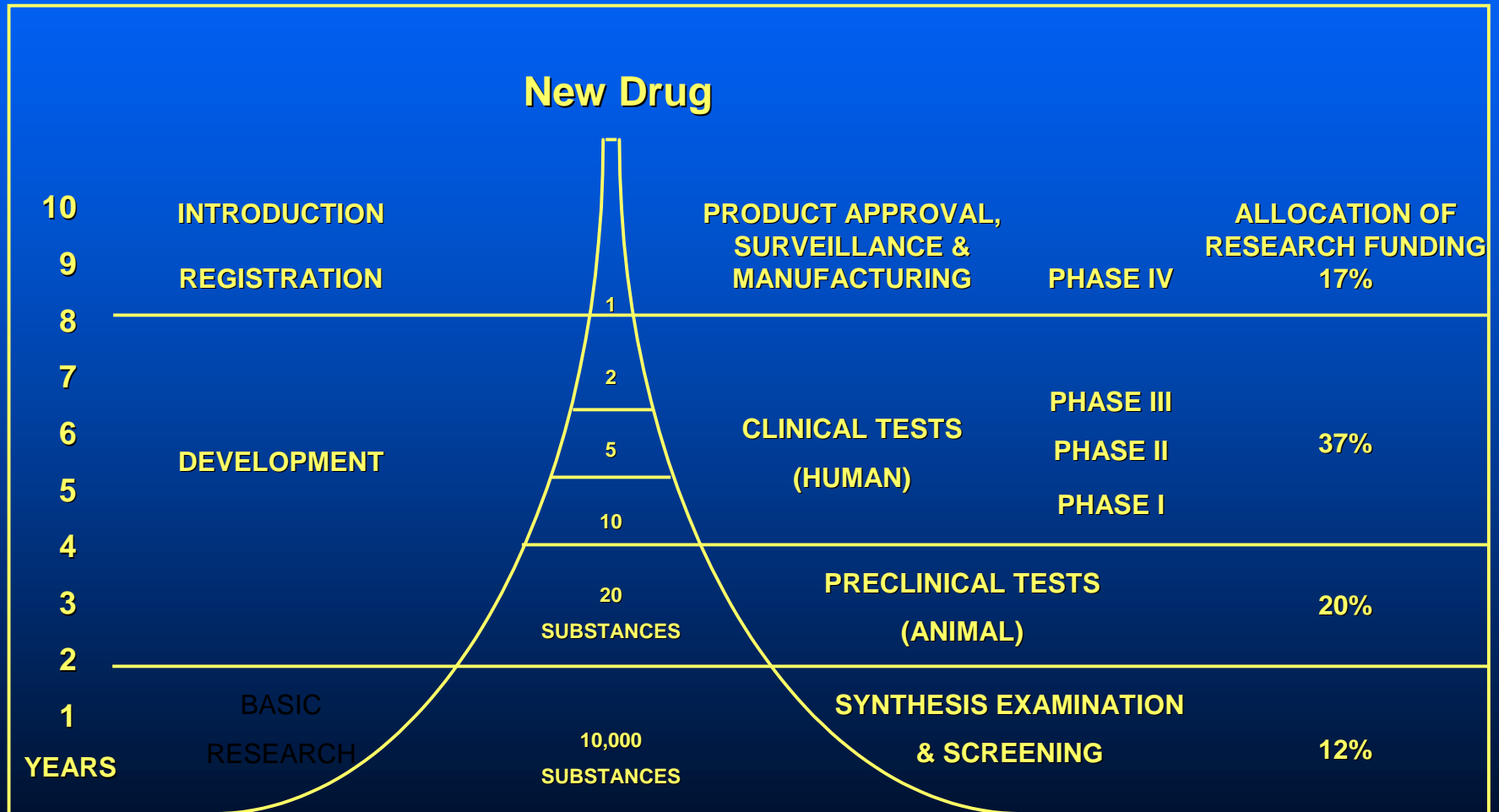
**Cures  
Treatments  
and  
Prevention**

# R&D as a Percent of Sales for Research-based Pharmaceutical Companies and U.S. Industrial Sectors, 1998



\* "Research-based Pharmaceutical Companies based on ethical pharmaceuticals sales and ethical pharmaceutical R&D only as tabulated by PhRMA." "Drugs and Medicine" category based on total R&D and sales for companies classified within the "Drugs and Medicine" sector tabulated by Standard & Poor's Compustat, a division of McGraw-Hill.

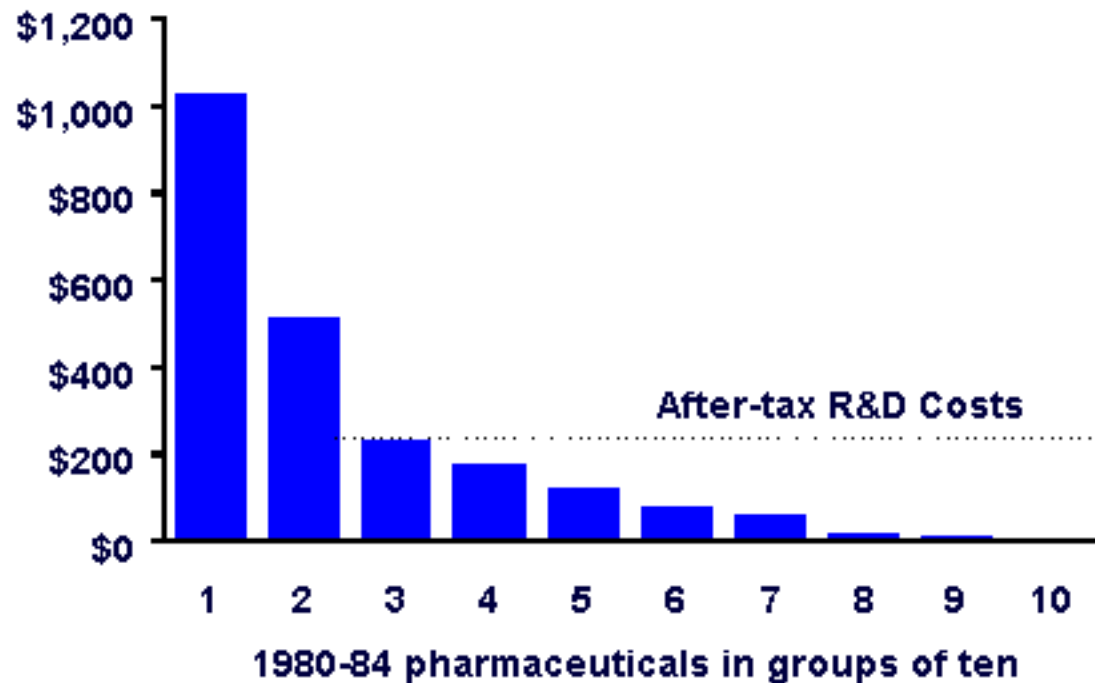
# Development Productivity



*\*Does not add to 100%, 7.9% for other, plus rounding*

# Three of Ten Marketed Drugs Produce Revenues that Match or Exceed Average R&D Costs

Millions of 1990 Dollars

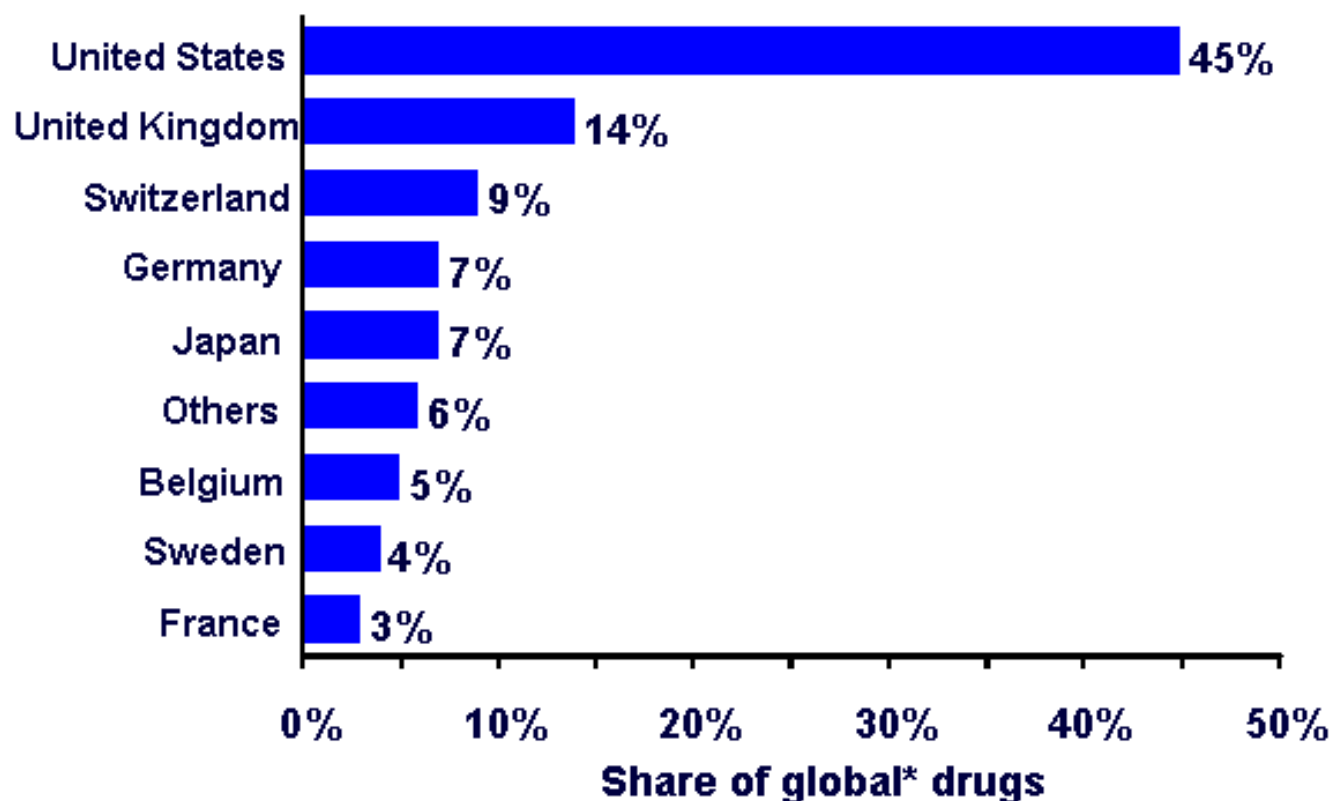


*Note: The drug development cost cited in this chart is after-tax in 1990 dollars for drugs introduced 1960-1984. Based on a separate analysis by the Boston Consulting Group, the pre-tax R&D cost for drugs introduced in 1990 is \$500 million.*

# Science-Related Decision Making

- ◆ Internal resources
  - Research capacity, basic research information, research technology, understanding of disease mechanisms, animals for early tests, raw materials
- ◆ Product features
  - Toxicity, tolerability (AE/other), abuse potential, Hazmat
- ◆ External support
  - Government-supported research infrastructure, available CRO/development partner, patients, investigators
- ◆ Manufacturing challenges
  - Raw material availability, ability to formulate acceptable product, plant capacity, packaging/shipping costs

# Development of 152 Global\* Drugs by Country of Origin, 1975-1994



\*Global drugs: Launched in U.S., Japan, France, Germany, U.K., Italy and Switzerland.  
Source: Barral, P.E., 20 Years of Pharmaceutical Research Results Throughout the World, Rhone-Poulenc Rorer Foundation, 1996.

# Government-Related Decision Making

## ◆ Role

- Controls market entry, penetration, behavior, profitability, business regulation

## ◆ Policy action, analysis and implications

- Authorizes, appropriates, oversights, collaborates, purchases, regulates through FDA, EPA, DEA, DoT, DoD, Commerce
- Enforces/ignores patents, counterfeits
- Sets and shifts policies-R&D and 936 tax credits, technology transfer, market exclusivity

# Customer-Related Decision Making

## ◆ Role

- Controls market access, penetration, behavior, profitability, civil tort liability

## ◆ Policy action, analysis and implications

- Patient demographics, levels of compliance
- Clinical disease knowledge and management
- Willingness to treat (anti-lifestyle bias), definitions of value, desire and/or need for product, patients access to product or product information
- Willingness to pay/reimburse
- Likelihood of litigation

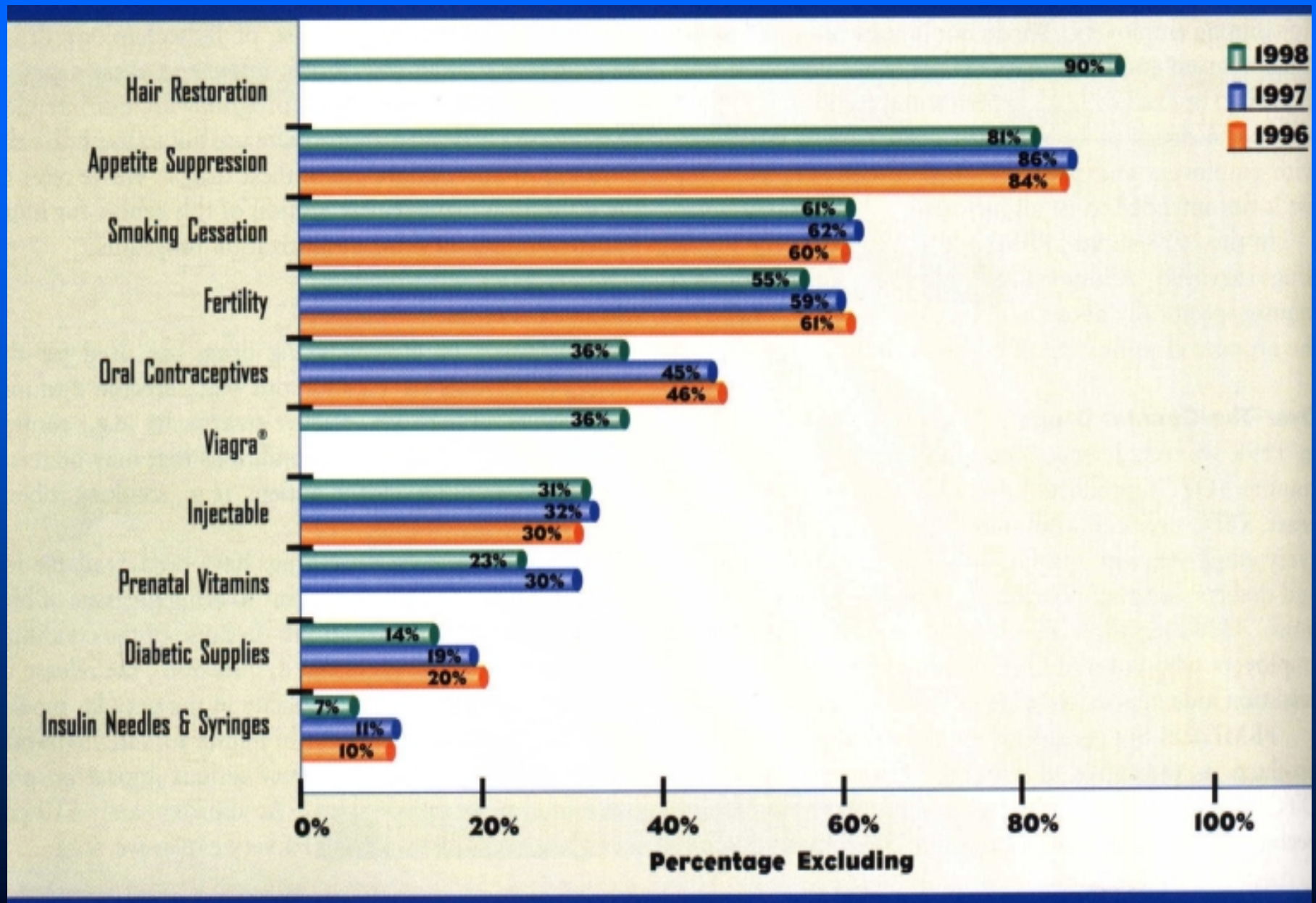
# Channel-Related Decision Making

## ◆ Role

- Controls market access, price, penetration

## ◆ Policy action, analysis and implications

- Special handling and distribution required, training, knowledge and size of prescriber population, special issues in dealing with consumer/patient



Source: Wyeth Ayerst Prescription Drug Benefit Plan design Survey Report, 1999

# Competition-Related Decision Making

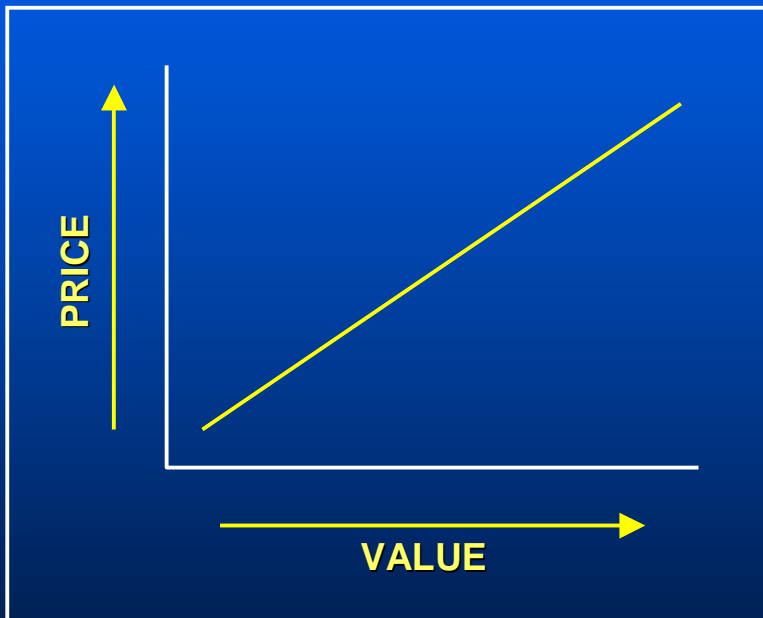
## ◆ Role

- Controls market access/entry, penetration, behavior

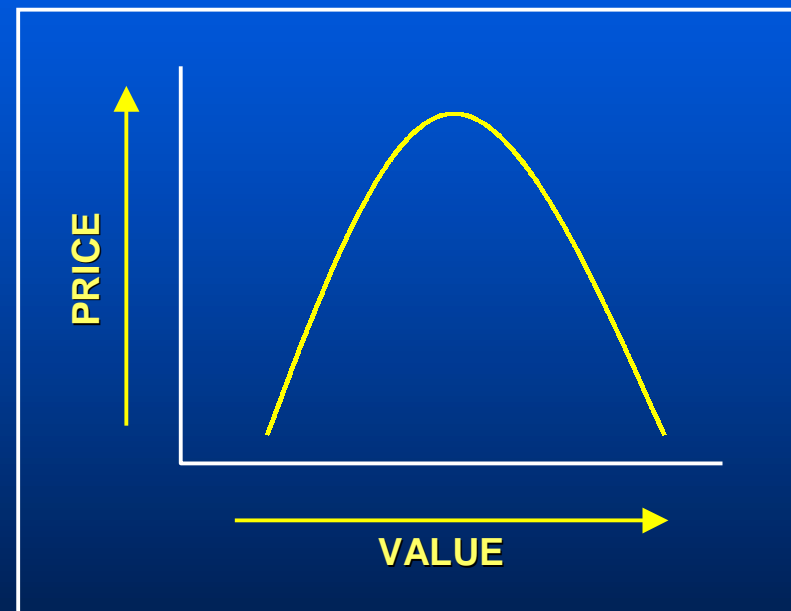
## ◆ Policy action, analysis and implications

- Nature of competitive products, generic and therapeutic substitutes, replacement technologies,
- Nature of promotional costs such as size of competitive sales forces, need for DTC, availability of marketing funds

# Price and Value Considerations



Traditional Assumption



Current Climate

# Image-Related Decision Making

## ◆ Role

- Controls public image, market cap of company, support for regulatory and marketing activities

## ◆ Policy action, analysis and implications

- Level of shareholder interest, founder interest
- “Fit” within corporate mission, contribution to society, impact on image and share price
- Activist support or opposition within regulatory and market arenas, negative press from anti-activists



Source: *The Economist*