



BERKELEY CENTER  
FOR HEALTH TECHNOLOGY

# **Innovation and Affordability in Biomedical Technology**

**Cal Day 2012**

**Professor James C. Robinson  
Leonard D. Schaeffer Professor of Health Economics  
Director, Berkeley Center for Health Technology**



# OVERVIEW

- What is the biopharmaceutical industry?
- Life cycle of drug innovation, assessment, purchasing
- Challenges facing the industry
- Value and pricing
- Insurer strategies for managing costs
- Impact of health care reform?



## How Biologics Differ from Traditional Pharmaceuticals

	Pharmaceuticals	Biologics
Type of molecule	Organic chemistry-based small molecules	Biology, protein-based large molecules
R&D investment	13% total revenue	25% total revenue
Distribution	Typically wholesale distribution	Typically specialty distribution
Product Administration	Usually Oral	Mostly injectible
Benefit Design	Usually pharmacy benefit (Medicare Part D)	Medical or pharmacy benefit (Medicare Part B)



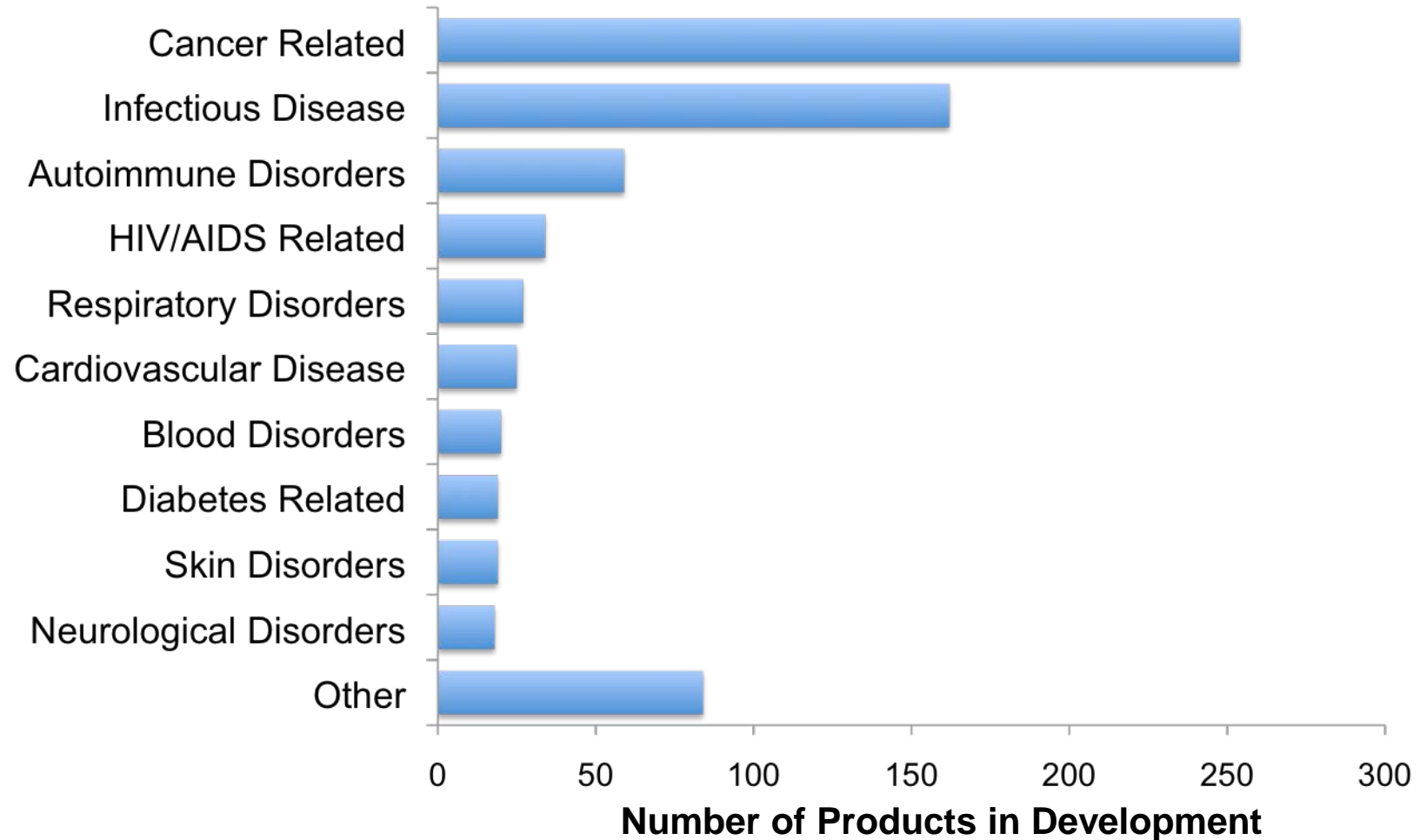
## Dynamism of Biomedical Innovation

- Industry maintains impressive R&D spend with a large number of medicines in development
  - 2,950 compounds in 2010 vs. 1,800 in 1999
- Drug development timeline: 10-15 years
- Development costs:
  - Biologic (in 2005): \$1.2 billion
  - Drug (in 2005): \$1.3 million vs. drug (in 2001): \$802 million
- Generic share of the market increasing
  - 49% in 2000 to 74% in 2009



# Biopharmaceuticals in Development by Therapeutic Category

## Biopharmaceuticals in Development by Therapeutic Category



## California as a Leader of the Biomedical Industry

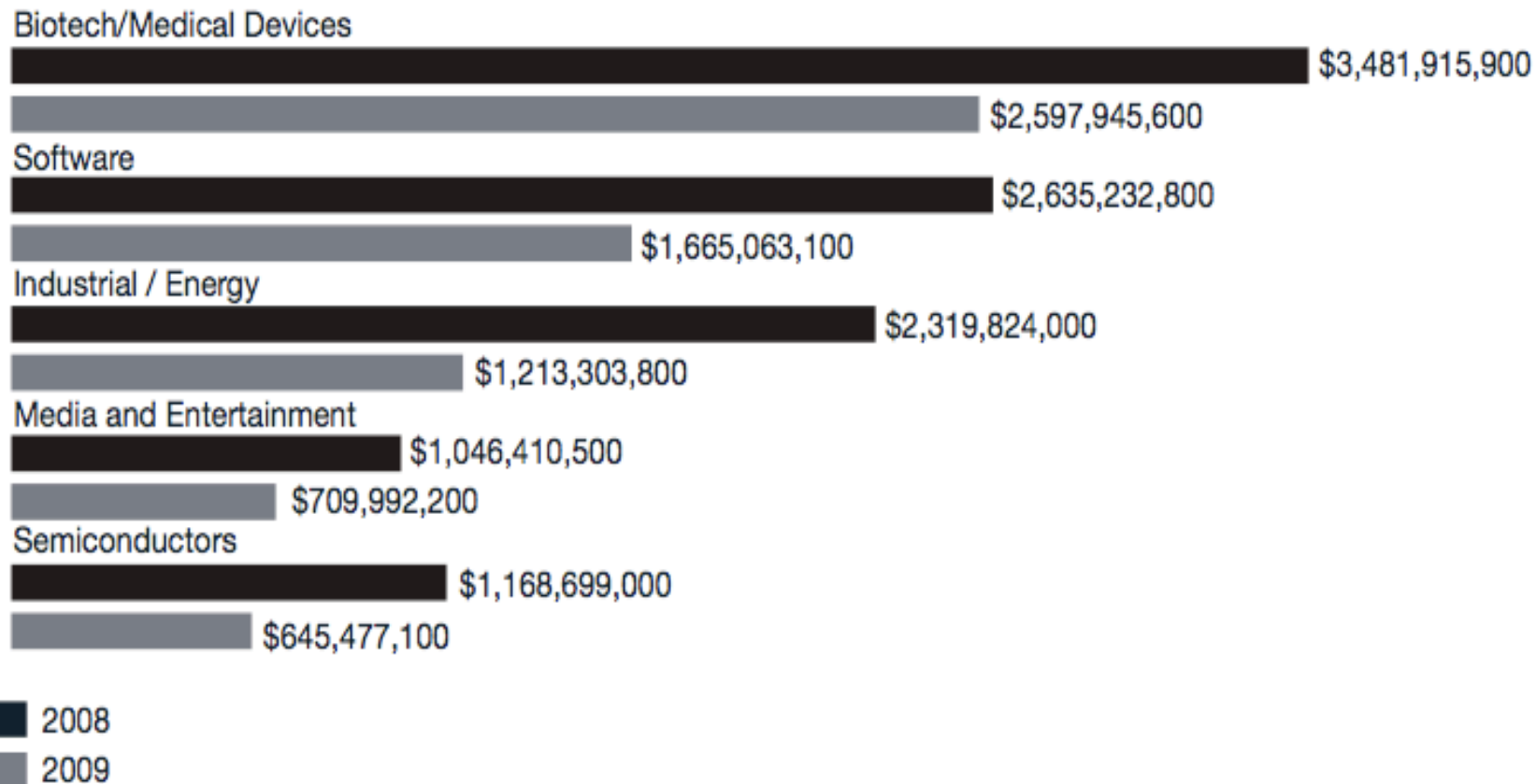
- World headquarters for biomedical R&D
- Largest concentration of companies and employment in industry
- Home to one in six of the 1.6 million biomedical jobs nationwide

### California Biomedical Industry Highlights

Number of California biomedical companies	2,000
Total estimated revenues	\$75.9 billion
Total estimated employment	274,000
Total estimated wages and salaries paid	\$20.5 billion
Total NIH grants awarded	\$3.15 billion
Total estimated VC investment in CA biotech companies	\$2.6 billion
Total biomedical exports	\$17.5 billion

# Biomedical Leads Venture Capital Investment in California

## Top 5 Industries in California by VC Investment



Source: PricewaterhouseCoopers/National Venture Capital Association MoneyTree™ Report based on data from Thomson Reuters

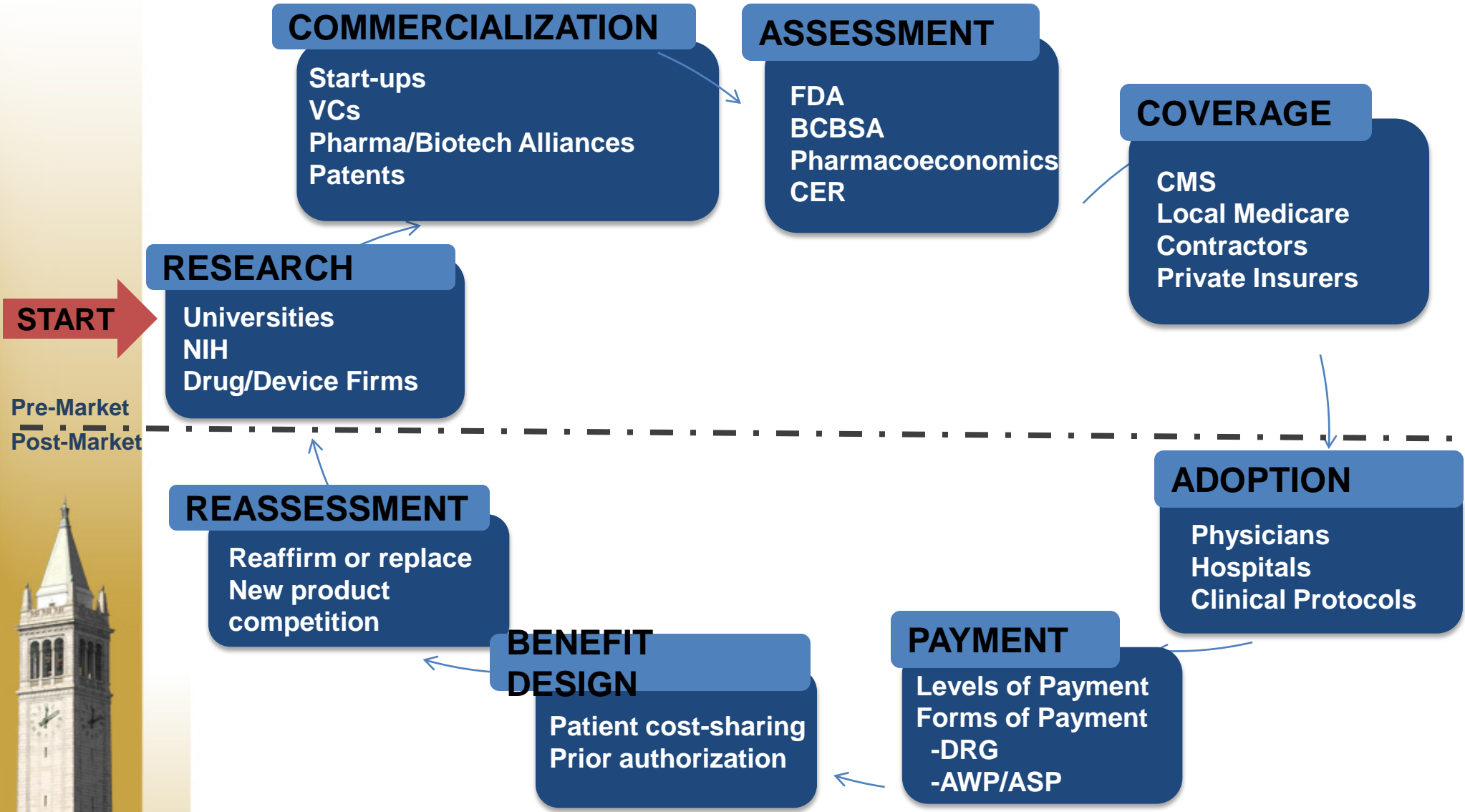
## Challenges Facing Biopharma Industry

- Declining rate of product innovation
  - Increased scrutiny by FDA
  - Global competition from China, India.
  - Debates over patents and biosimilars
  - Debate over inappropriate physician incentives, sunshine laws
- 
- Pushback from insurers on pricing



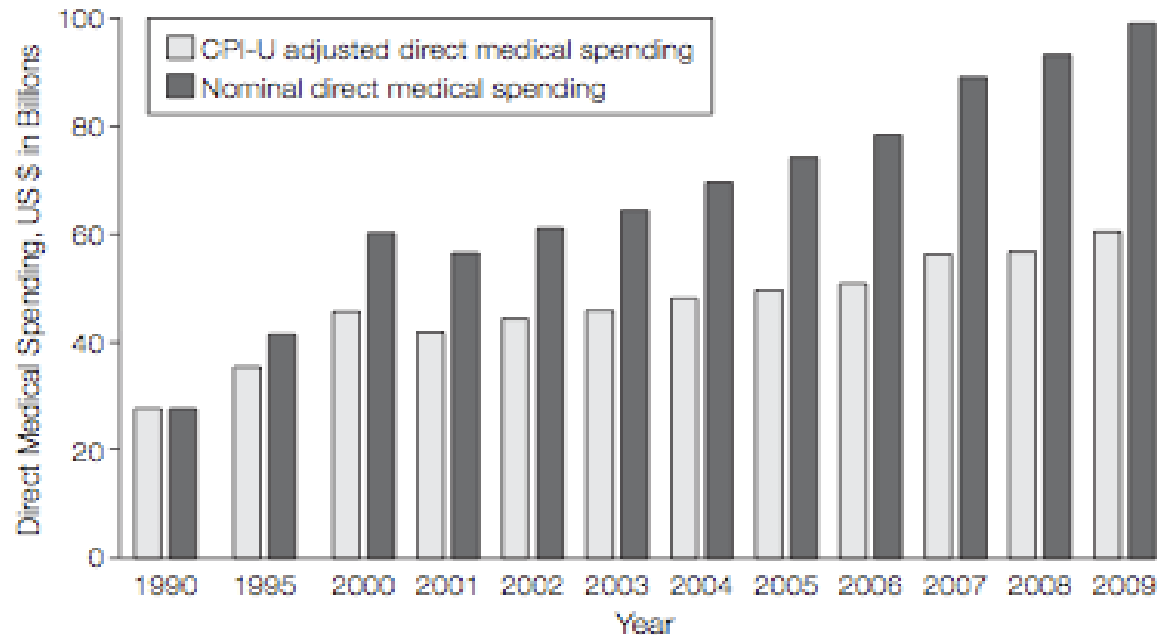


# Cycle of Innovation, Diffusion, Purchasing and Innovation



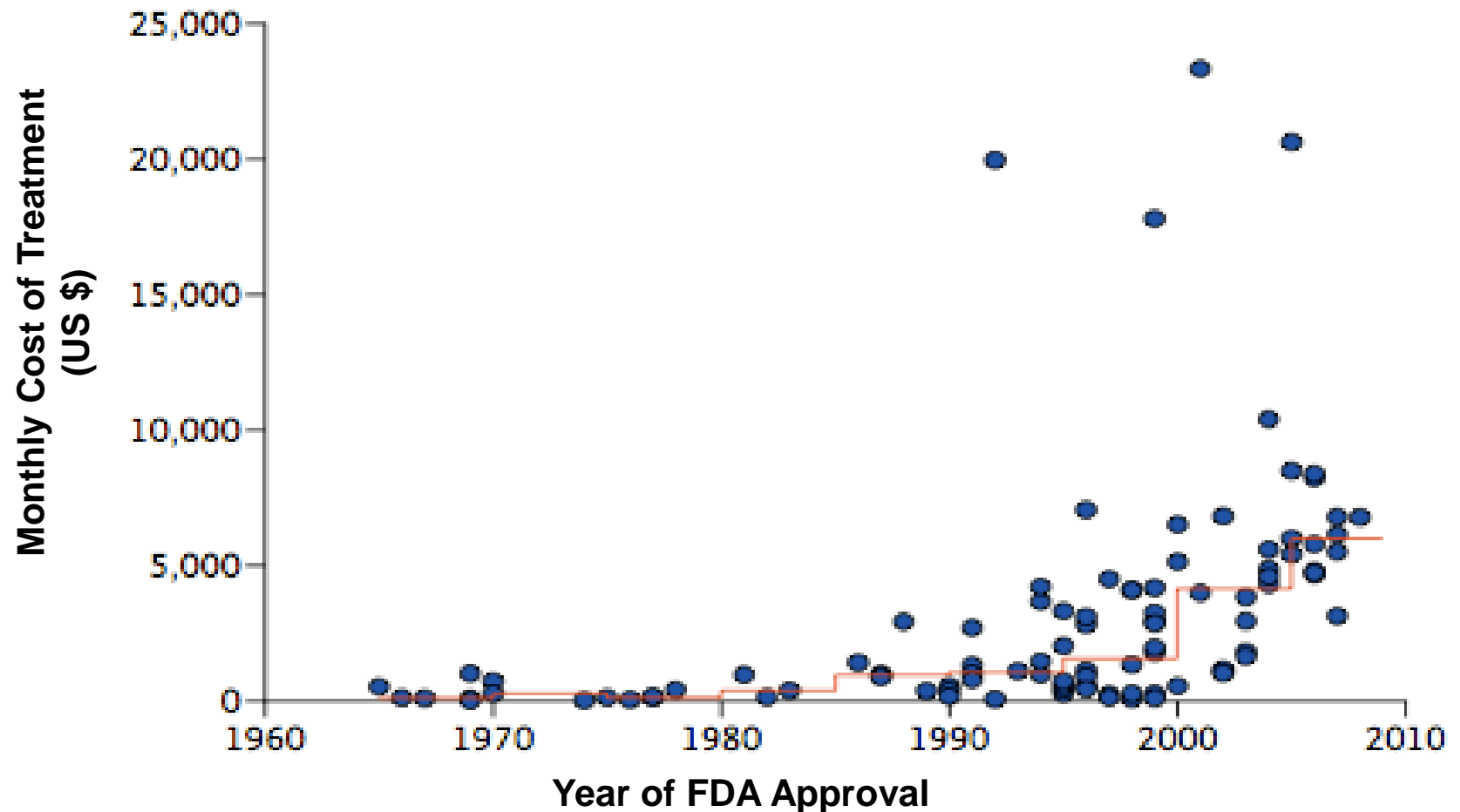
## Oncology Costs Continue to Rise

**Figure.** Nominal and Inflation-Adjusted Direct Medical Spending Attributed to Cancer, 1990-2009



Direct costs are personal health care expenditures for hospital and nursing home care, drugs, home care, and physician and other professional services. Sources for the 1990-1995 estimates are from Brown et al<sup>1</sup>; 2000-2009 estimates are from the National Heart, Lung, and Blood Institute and are based on data from multiple sources, applying the 1995 fraction of direct medical costs attributable to cancer to annual national health expenditure estimates.<sup>2</sup> CPI-U indicates Consumer Price Index for all urban consumers.

## Costs of Cancer Drugs at the Time of Approval by the FDA, 2009



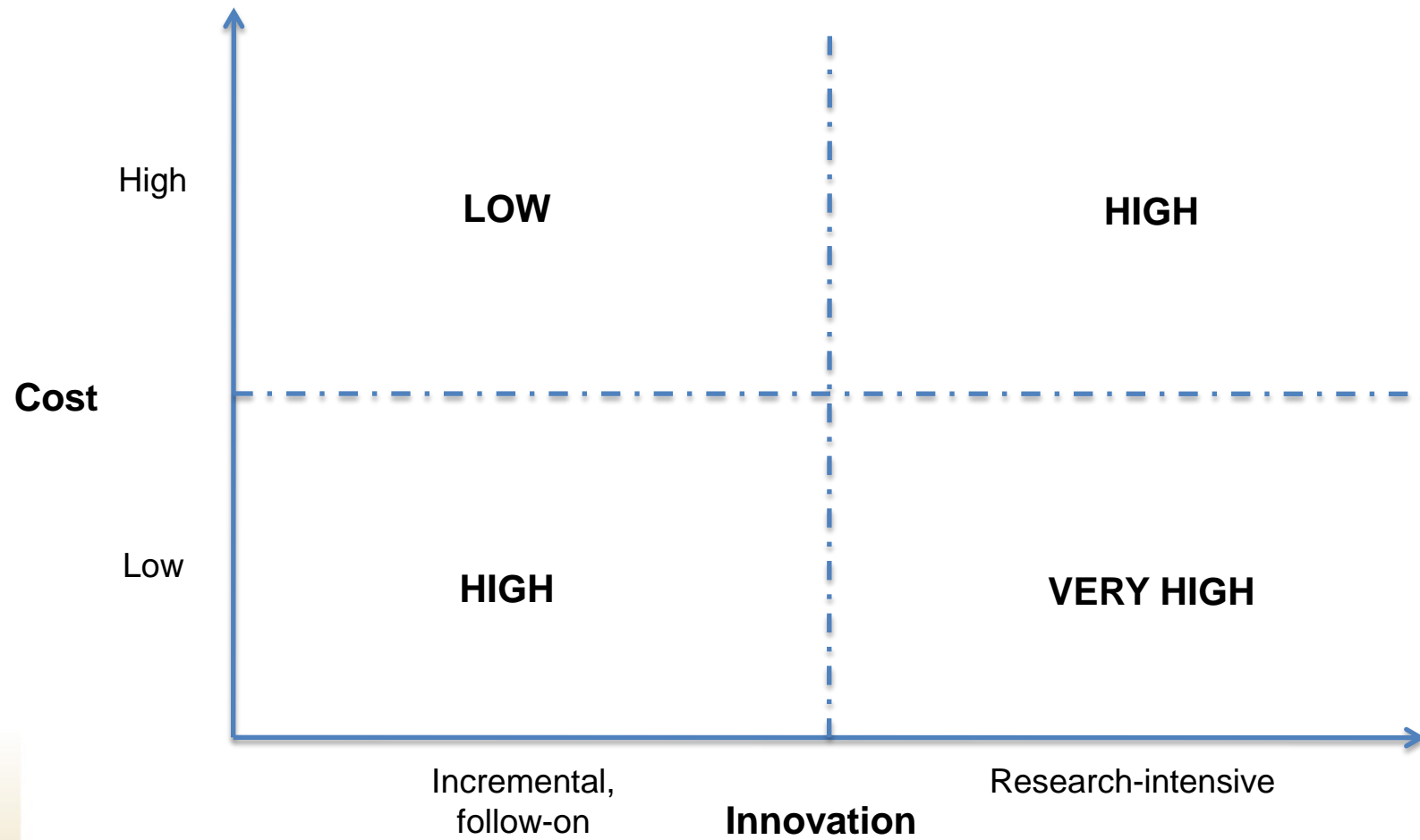
Note: Costs are shown for 1 month of cancer treatment for a person who weighs 70 kg or has a body-surface area of 1.7 m<sup>2</sup>. The red line indicates median prices during a 5-year period. Prices have been adjusted to 2007 dollars and reflect the total price for the drug at the time of approval, including both the amount of Medicare reimbursement and the amount paid by the patient or by a secondary payer.

# Promoting Value in Technologically Dynamic Sectors

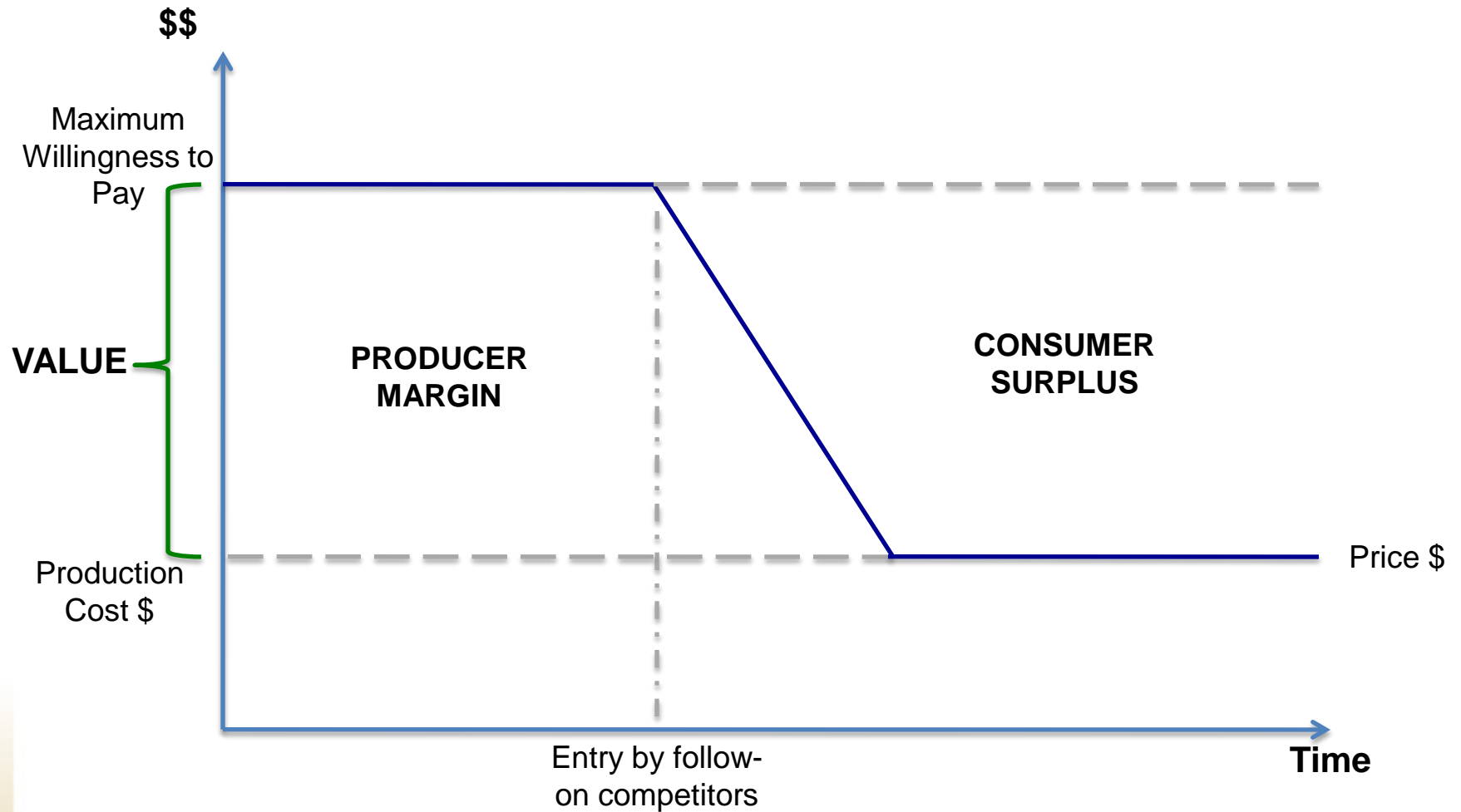
- Value=performance/cost
- Dividing the gains from innovation:
  - Consumers and this generation of patients
  - Producers and the next generation of patients
- Over-investment and under-investment
- Patterns of prices and value allocation over time
- Cost increasing and cost decreasing innovation



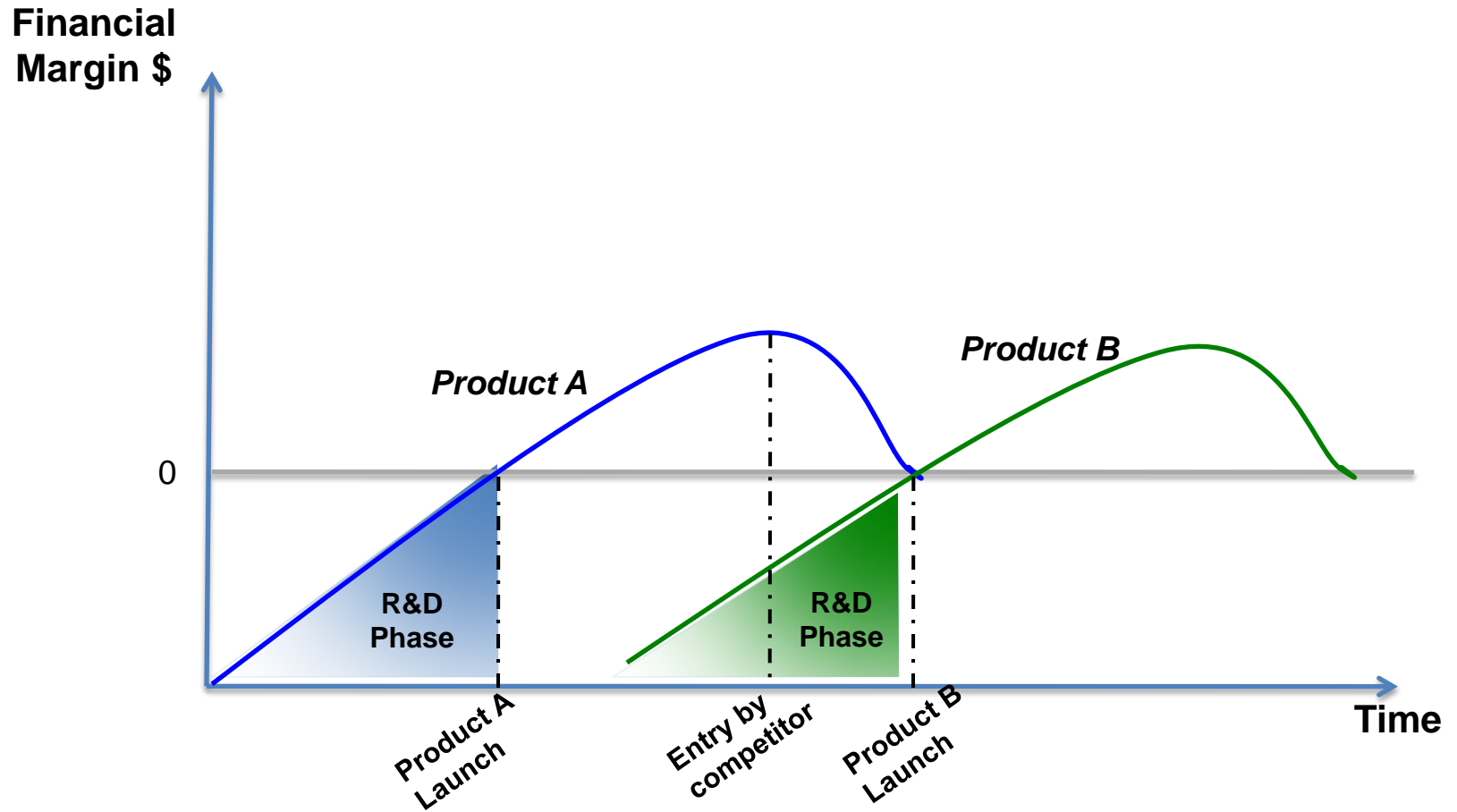
## Value Depends on Type of Innovation and Level of Cost



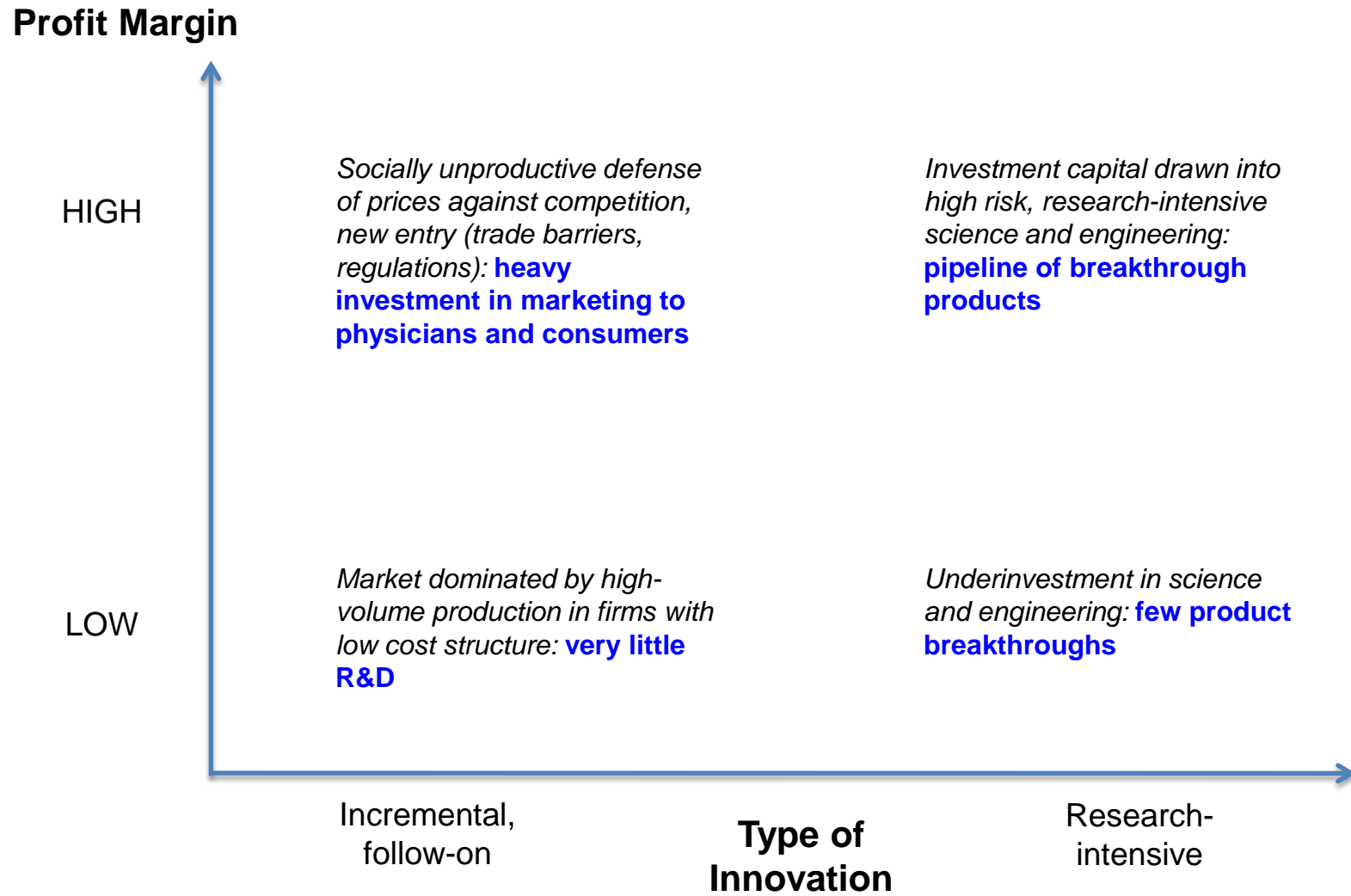
# Producer Margin and Consumer Surplus in Technologically Dynamic Industries



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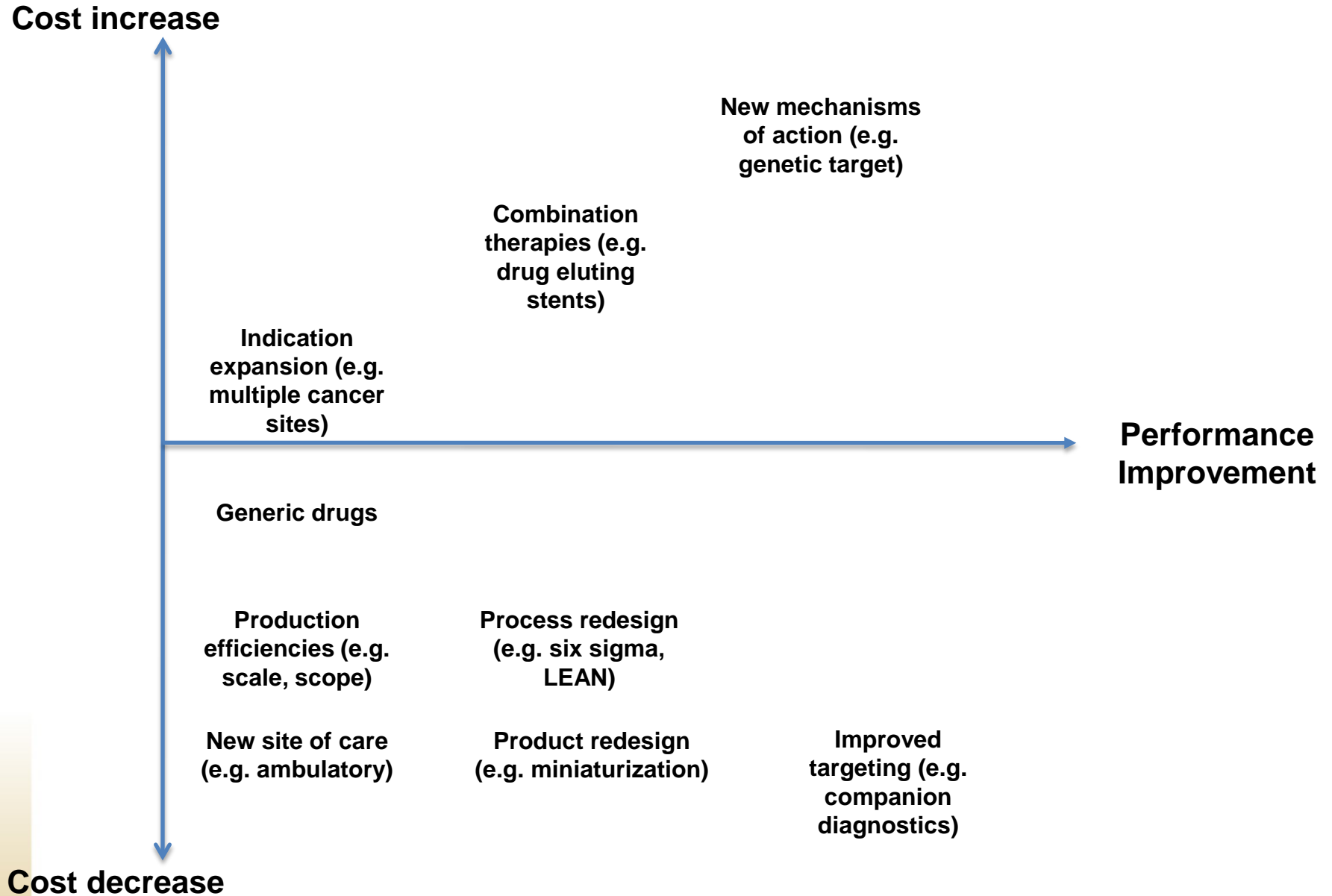


# Profit Margins & Investments in Innovation





# Cost-Increasing and Cost-Decreasing Innovation

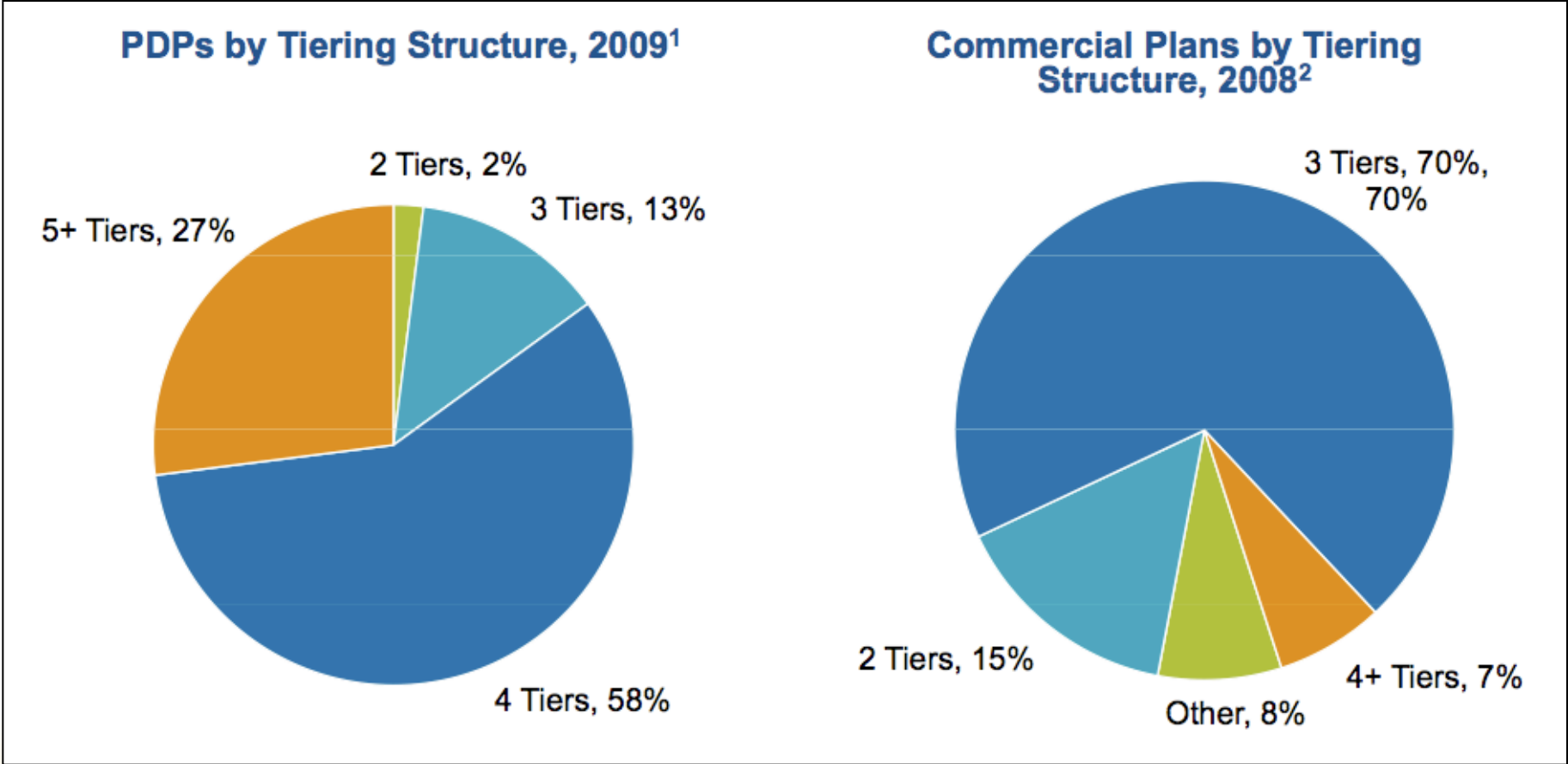


# Insurer Strategies for Managing Drug Costs: Benefit Design and Consumer Cost Sharing

- **Formulary management**
  - Plan P&T reviews clinical benefit and comparative efficacy
  - Plans cover FDA approved indications: debate over off label use
- **Attempt to contain costs and impact treatment decision-making through benefit design**
  - Tier structure (multi-tier plans, varying copay levels, coinsurance)
  - Utilization management tools (prior authorization, step therapy)



# Tiering in Medicare and in Commercial Insurance



**Avalere Health**  
DataFrame, an Avalere Health proprietary database of Medicare Part D plan features, and 2009 PDP data released by CMS on September 25, 2008.

# Insurer Strategies: Prices and Distribution

- Negotiate prices and formulary placement
- Limit physician mark-up
  - Encourage use of oral drugs and self administered vs. infused
  - Shift towards specialty pharmacy and away from “buy and bill”
- Use of third party guideline and benefit management organizations (P4, iCore)
- Develop risk-sharing or outcomes-based pricing and payment arrangements



# Insurer Strategies: Paying for Outcomes

## Performance-Based Coverage and Reimbursement Schemes in the United States

Disease area	Product	Manufacturer	Payer	Description
High cholesterol	simvastatin	Merck	Patients and insurers	Merck promised to refund patients and insurers up to 6 months of their prescription costs if simvastatin plus diet did not help them lower LDL cholesterol to target concentrations identified by their doctors. <sup>10</sup>
Breast cancer	Oncotype Dx	Genomic Health	United-Healthcare	UnitedHealthcare agreed to reimburse the Oncotype Dx test for 18 months while it and Genomic Health monitor the results. If the number of women receiving chemotherapy exceeds an agreed upon threshold, even if the test suggests they do not need it, the insurer will negotiate a lower price.
Type 2 diabetes	sitagliptin; sitagliptin + metformin	Merck	CIGNA	Merck has agreed to peg what the insurer CIGNA pays for the diabetes drugs sitagliptin and sitagliptin + metformin to how well type 2 diabetes patients are able to control their blood sugar.
Osteoporosis	risedronate	Proctor & Gamble, sanofi-aventis	Health Alliance	Two companies that jointly sell the osteoporosis drug risedronate agreed to reimburse the insurer Health Alliance for the costs of treating nonspinal fractures suffered by patients taking that medicine.

# Impact of Health Reform ?

- Health insurance reform (employer and individual mandates)
  - Increases number of insured lives with prescription drug coverage
- Creates approval pathway for biosimilars (12 year exclusivity)
- Increases manufacturer rebates to Medicaid from 15.1% to 23.1% and expands rebates to Medicaid managed care plans
  - Increases number of 340B Hospitals, which also receive rebate
- Tax on branded drug manufacturers based on each company's share of sales to federal government programs
- Provides tax credits to small biotech companies suffering from tight credit markets
- Physician Payment Sunshine Act- requires financial disclosure
- Creates a federal research institution to fund and direct comparative effectiveness research