

# Medicare Part D and Medicaid: What now?

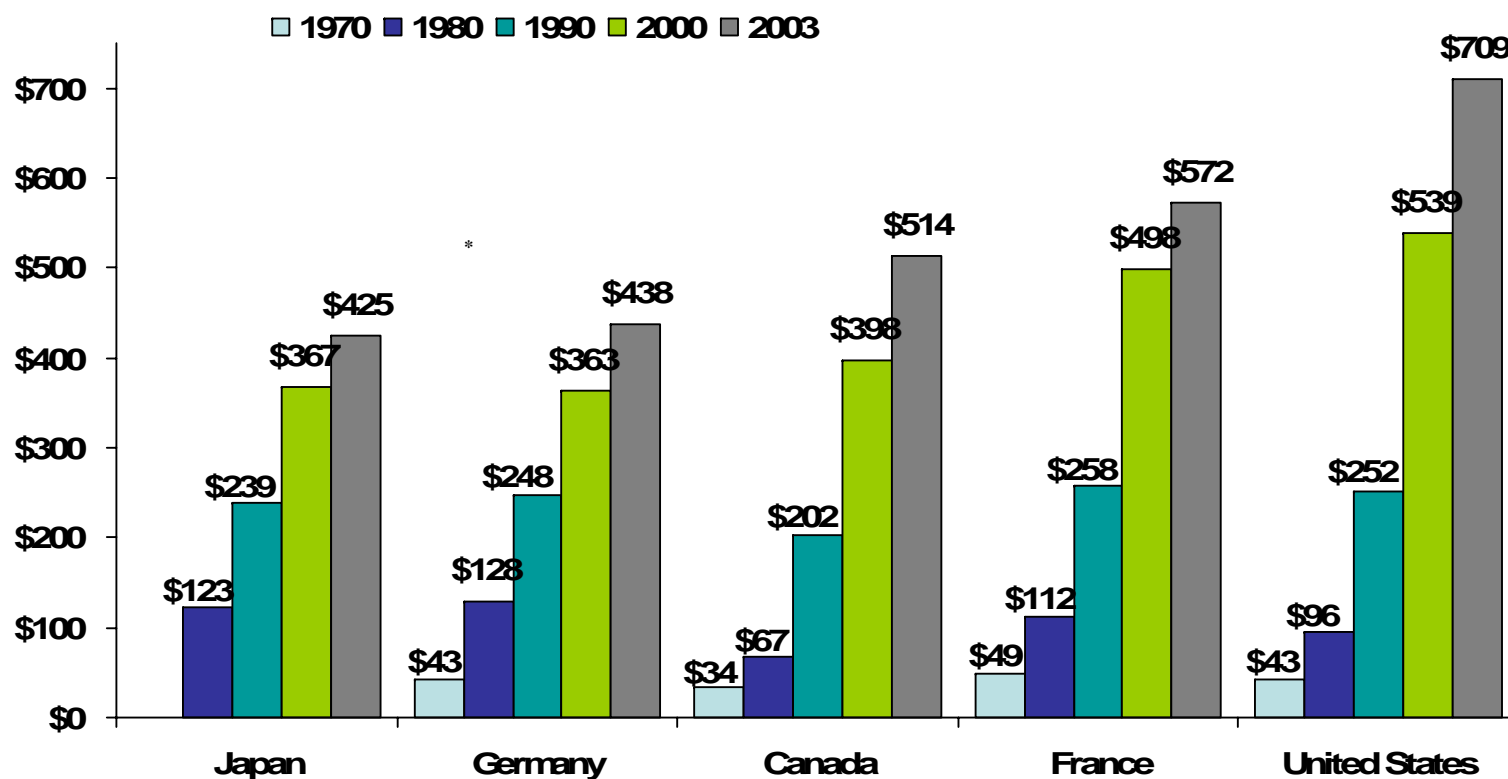
Judith A. Shinogle, PhD., MSc.  
Assistant Professor  
Health Services Administration  
University of Maryland

# Where I am going?

- Current Numbers
- Medicare Part D
- Medicaid
- Issues

**Table 2.7**  
**Per Capita Spending on Pharmaceuticals and Other Non-Durables**  
**by OECD Country, 1970-2003**

*Variation across countries is increasing. Recent growth in North America is most rapid.*



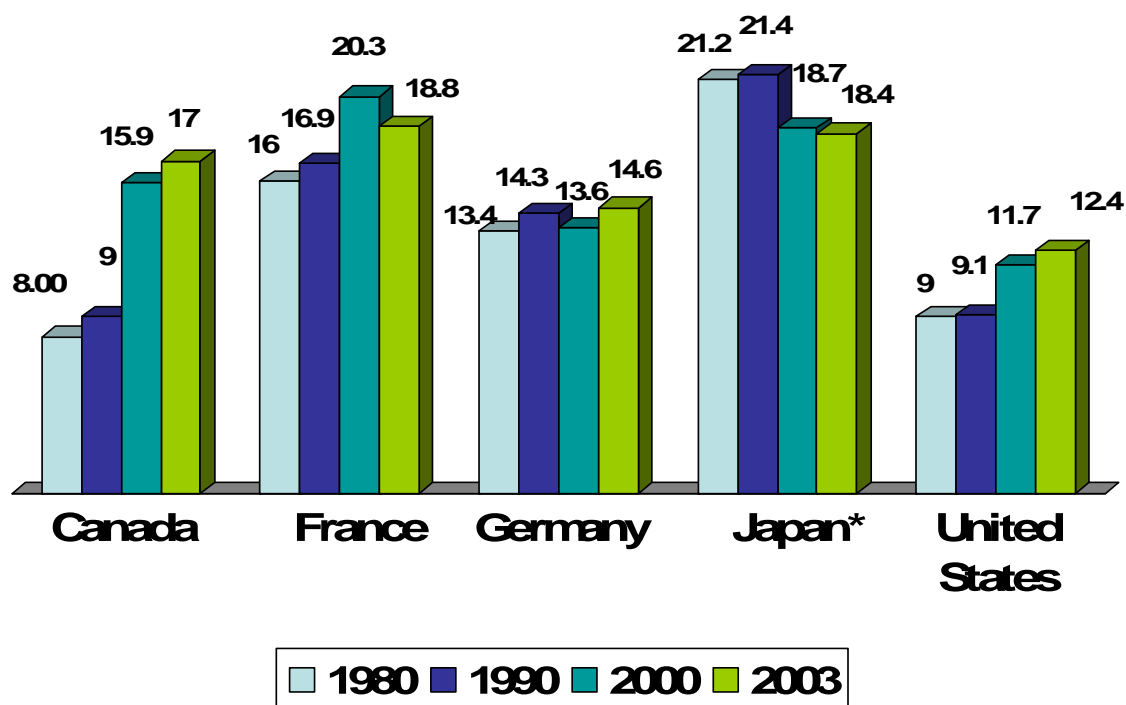
Expenditures in U.S. dollars using purchasing power parity rates.

Note: Data is arrayed by spending levels for 2003. Japan not available for 1970.

Source: OECD Health Data 2006.

## Drug Spending as a Percentage of Total Health Spending by OECD Country, 1980-2003

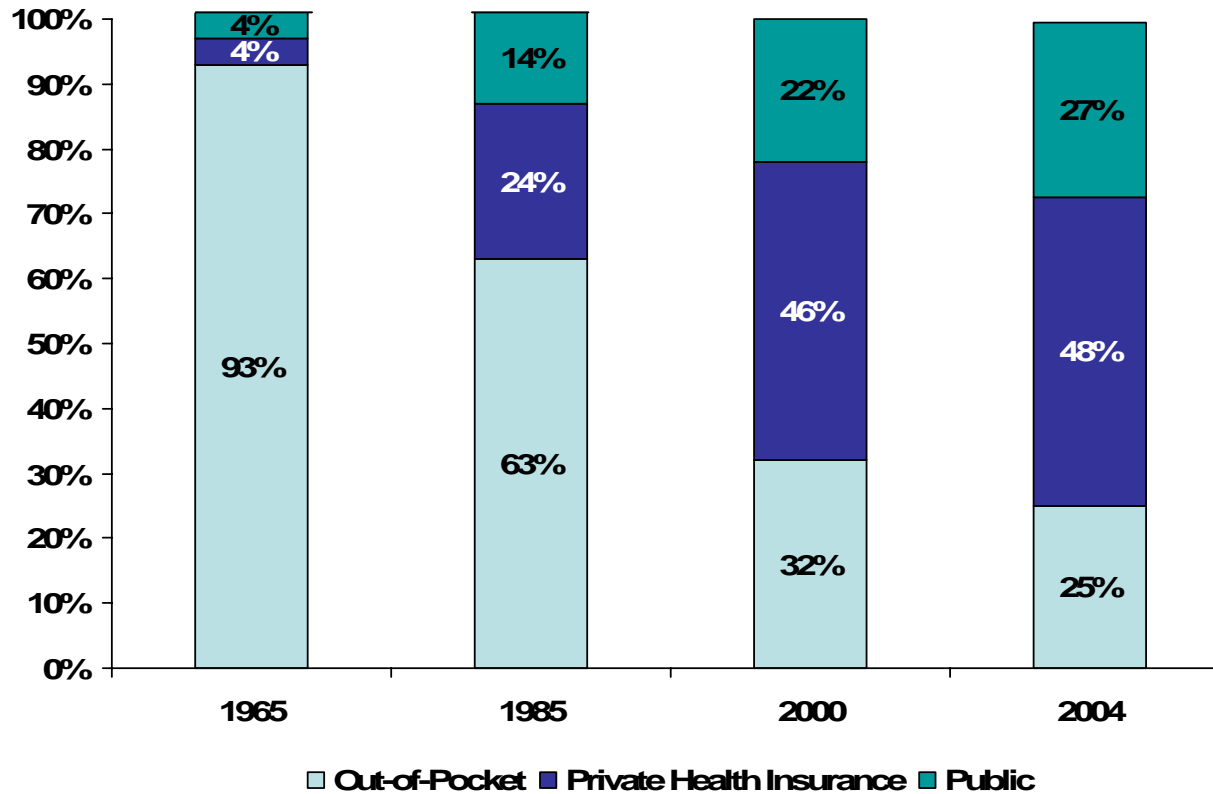
*Although, recent drug spending in the United States on this measure has grown, it is still low compared to other OECD countries*



\*2003 data for Japan is not available; 2002 was used  
Source: OECD Health data, 2006.

**Table 1.10**  
**Prescription Drugs Expenditures by Source of Funds,**  
**1965-2004**

*The share of drug spending covered by public and private sources has grown significantly.*



Note: Percentages may not sum to 100 due to rounding. Drug spending grew from \$3.7 billion in 1965 to \$188.5 billion in 2004

Source: CMS, Office of the Actuary, National Health Statistics Group.

# Private Market Response to Increased Prices

- Increase cost sharing
- Generics
- Preferred drug lists
- Dispensing limits
- Formularies
  - Tiers
  - Open vs. Closed
- Step Therapy
- Therapeutic Interchange
- Physician education
- Mail order
- Pharmacy Benefits Managers

# Dimensions of Pharmacy Benefit Managers

---

## 1. Pharmacy Practice:

- Disease State Mgt
- Mail-Service
- Drug Information
- Academic Detailing
- Patient & Provider Education
- Drug Use Evaluation
- Adverse Drug Event Programs
- Clinical Guideline Development

# Product Cost Controls: Rebates

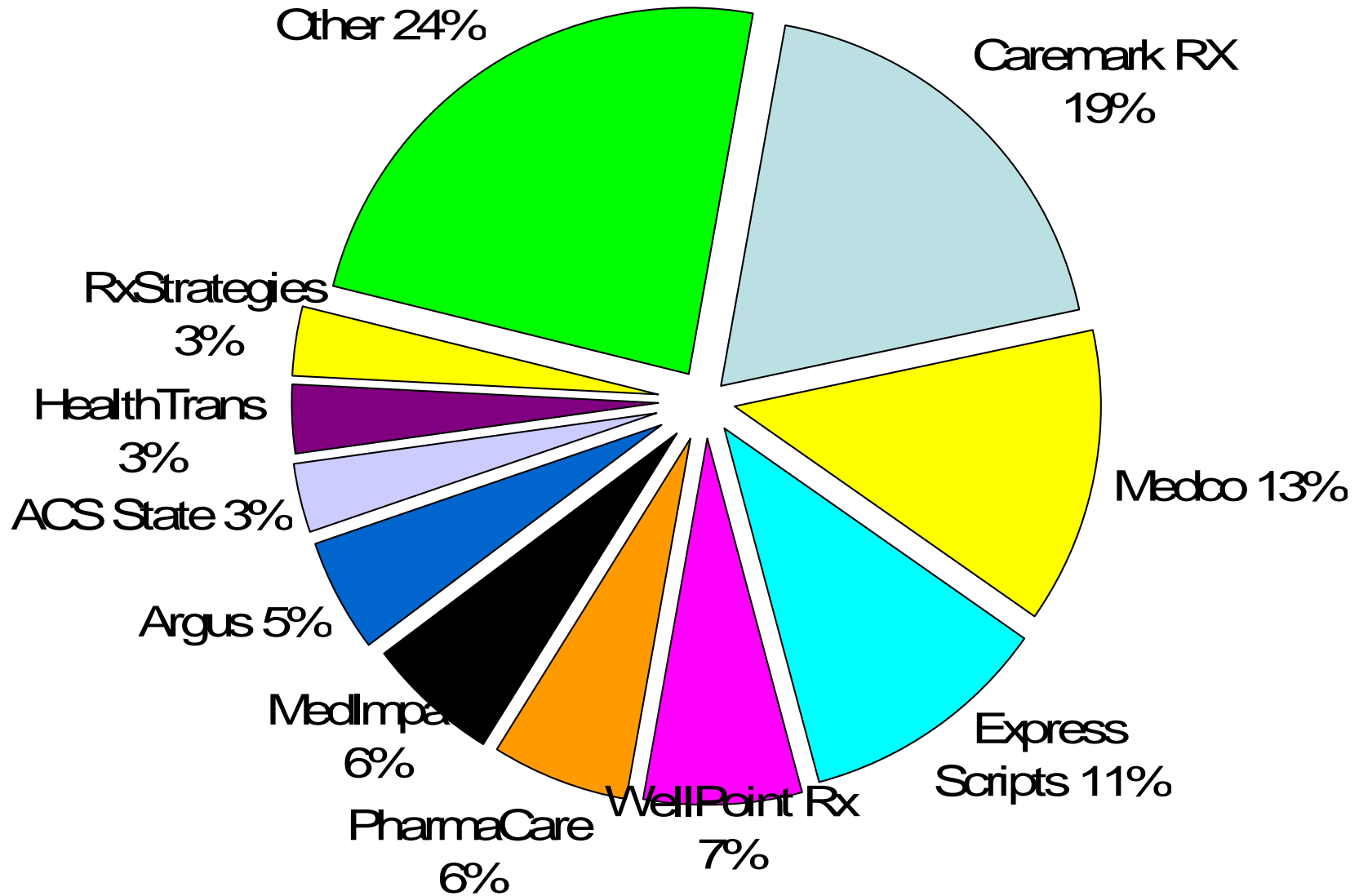
- Manufacturers' repayments for products dispensed and paid for by the 3<sup>rd</sup> party.
- Usually required by the 3<sup>rd</sup> party to have products covered.
- 1990: Medicaid Drug Rebate Program began so that Medicaid pays the "best price".
- "Best Price": equal to or less than prices for wholesalers, retailers, health care providers, managed care, and non-profits.

# Product Cost Controls: Rebates

- “Average Manufacturer’s Price” (AMP): average price paid by wholesalers for products distributed to retailers.
- Rebate formulas:
  - Brands: 15.1% of AMP
  - Generics: 11% of AMP
  - Also, subtract the difference between the AMP and the “Best Price”

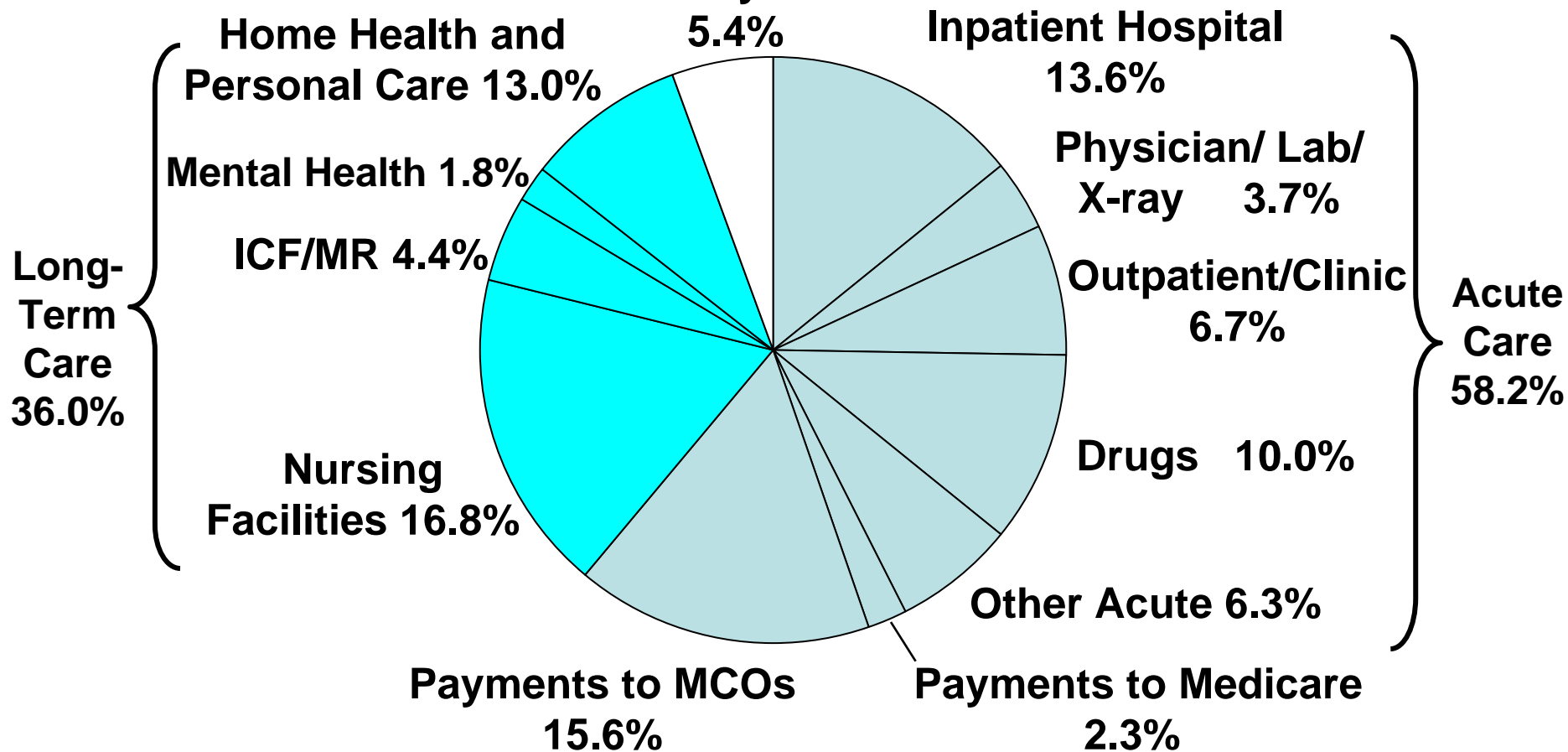
# Leading PBMs

---



# Medicaid Expenditures by Service, 2003

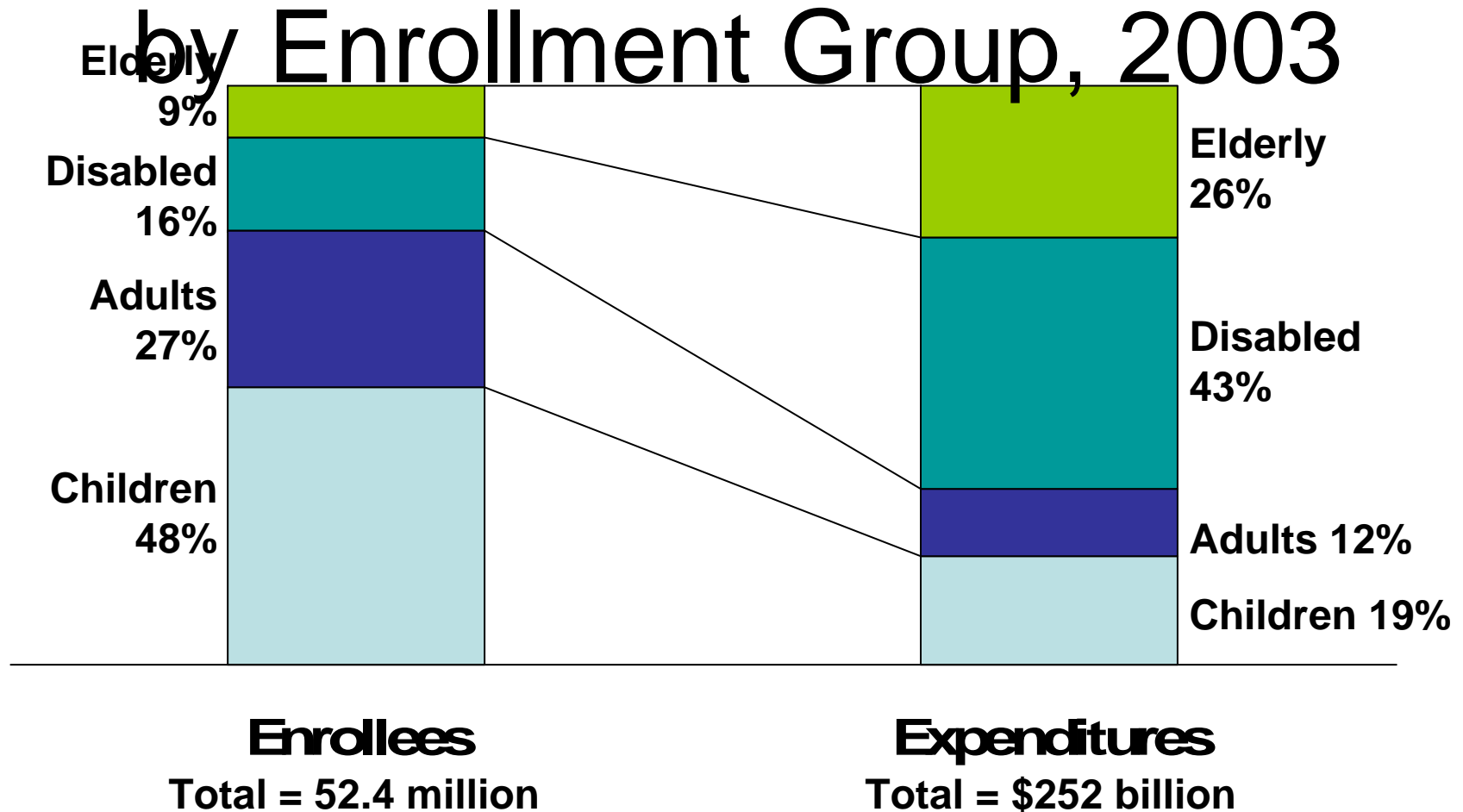
DSH Payments



**Total = \$266.1 billion**

SOURCE: Urban Institute estimates based on data from CMS (Form 64), prepared for KCMU.

# Medicaid Enrollees and Expenditures

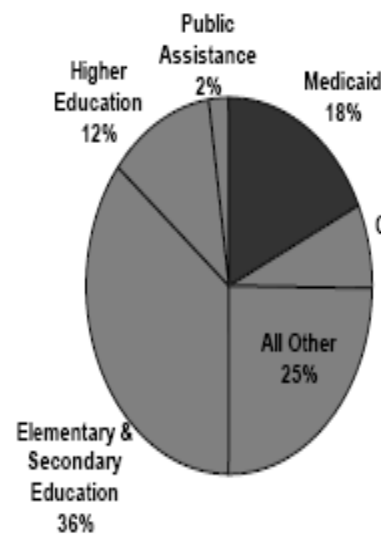


Note: Total expenditures on benefits excludes DSH payments.  
SOURCE: KCMU estimates based on CBO and OMB data, 2004.

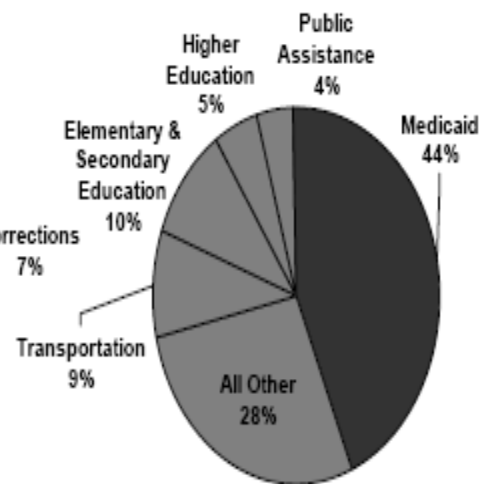
Figure 9

## Medicaid Spending In the States, 2005

State General Fund Spending  
\$536 billion



Federal Funds to States by Program  
\$371 Billion

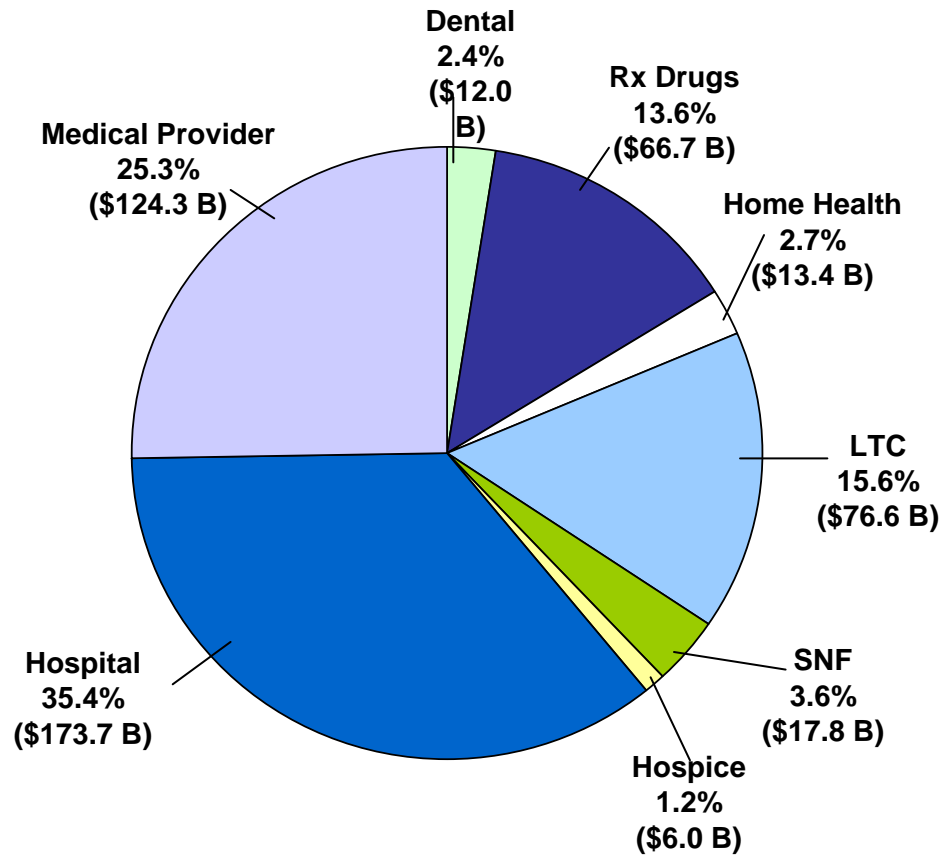


SOURCE: National Association of State Budget Officers, 2004  
State Expenditure Report, 2005.

**KAISER COMMISSION ON  
Medicaid and the Uninsured**

# Medicare Prescription Drug Benefit

**Table 4.11**  
**Total Health Care Expenditures for Medicare Beneficiaries, 2003**  
*Total Health Care Expenditures = \$491 Billion*

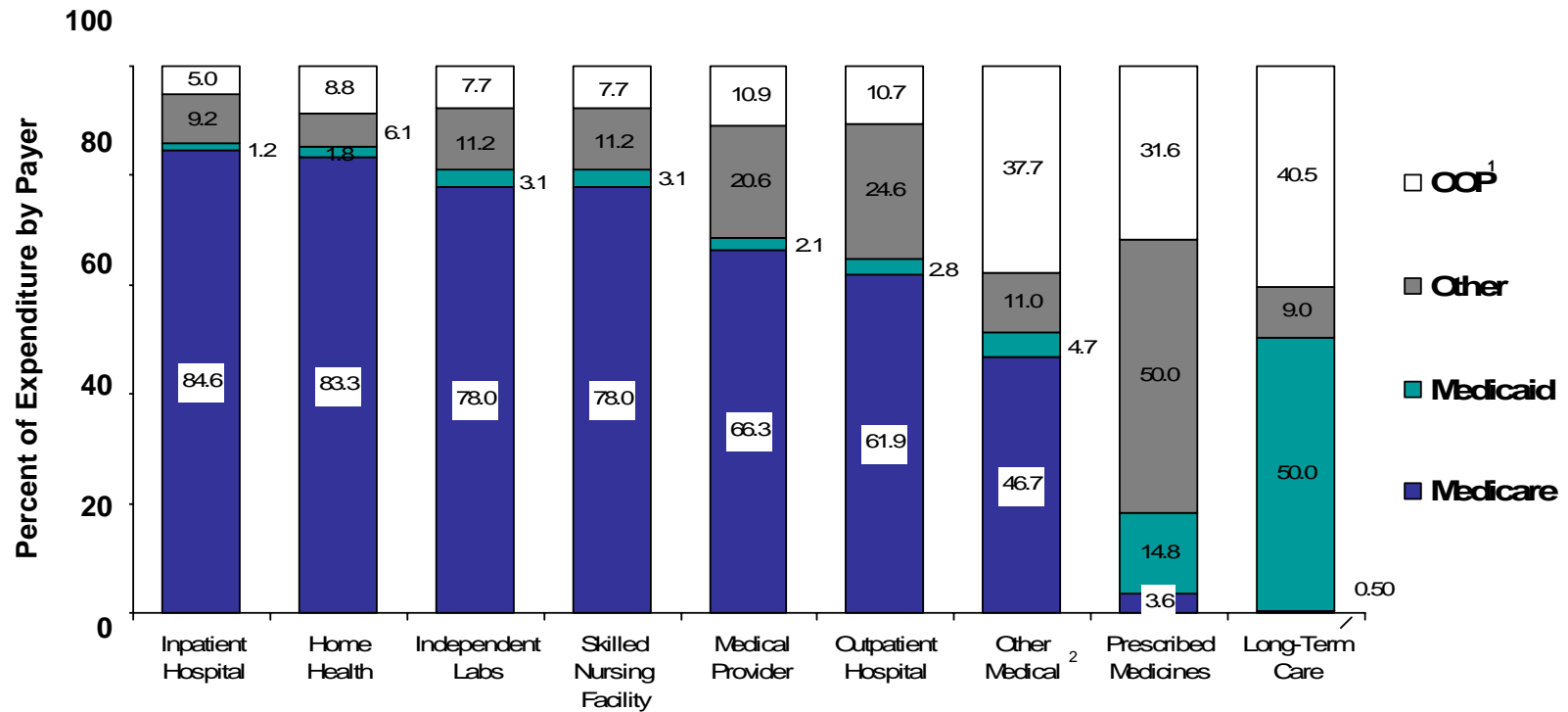


Note: Premium payments are excluded. LTC is long-term care. SNF is skilled nursing facility.

Source: CMS, Office of Research, Development, and Information: Data from the Medicare Current Beneficiary Survey (MCBS) 2003 Cost and Use File.

**Table 4.13**  
**Sources of Payment for Medicare Beneficiaries by Type of Service, 2003**

*Medicare pays a large proportion of the total expenses of services it covers.*



<sup>1</sup> OOP is out-of-pocket.

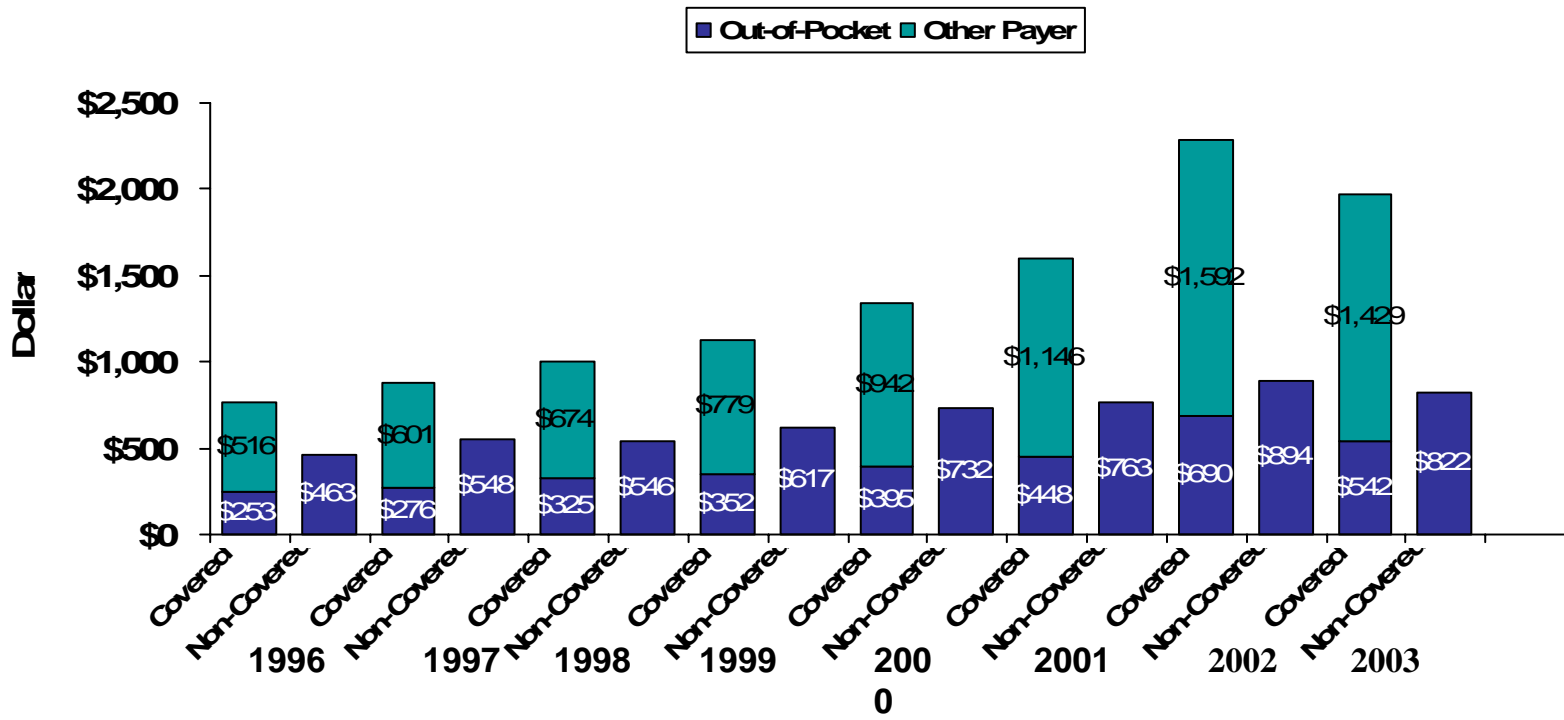
<sup>2</sup> Other Medical includes things such as hospice and durable medical equipment.

Note: Medicare did not generally cover outpatient prescription drugs in 2003.

Source: CMS, Office of Research, Development, and Information: Data from the Medicare Current Beneficiary Survey (MCBS), 2003 Cost and Use File.

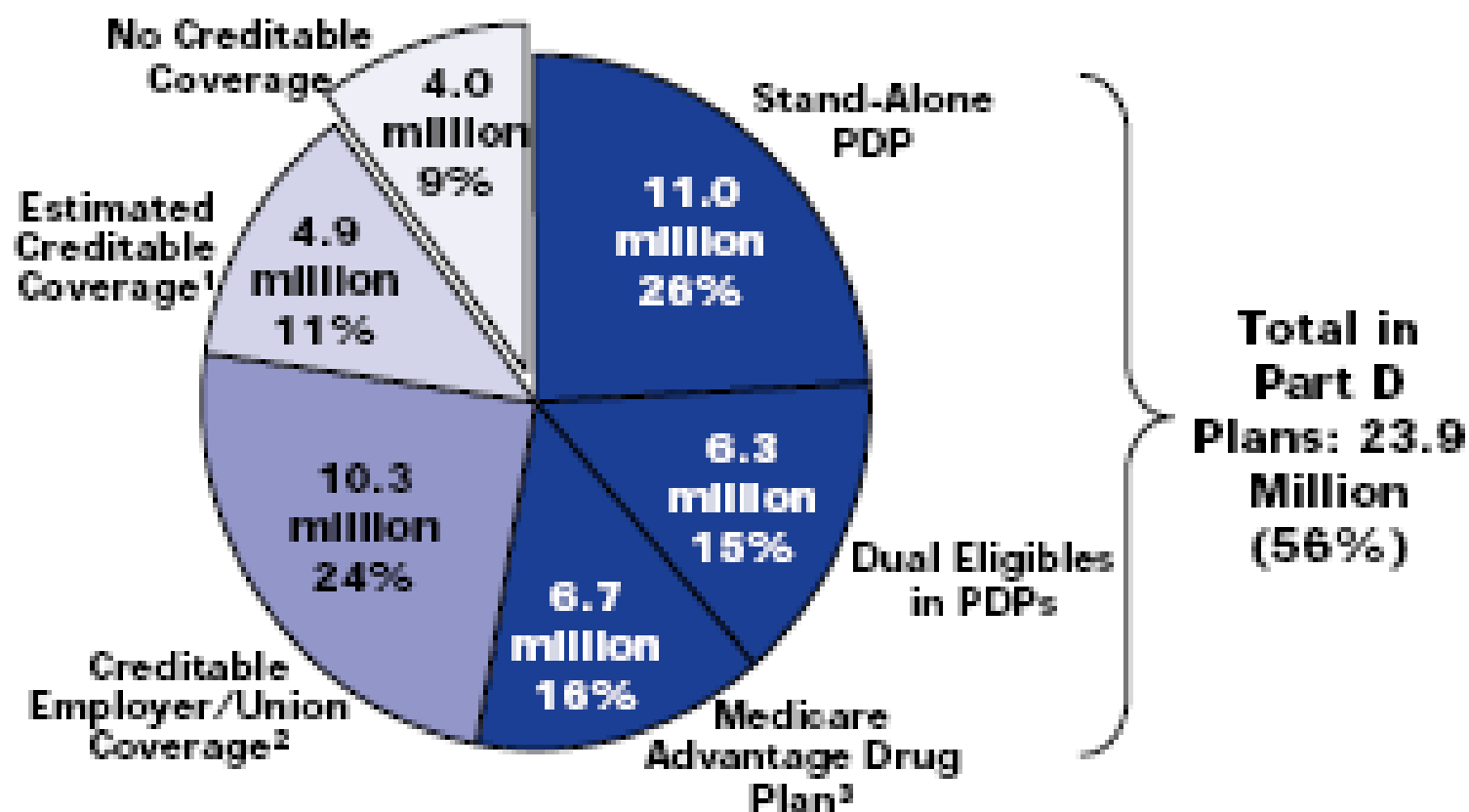
# Total Spending for Prescription Drugs for All Medicare Beneficiaries, 1996-2003

*Total spending for drugs was higher for beneficiaries with drug coverage than without; however, non-covered beneficiaries pay substantially more out-of-pocket costs.*



Note: Does not include beneficiaries in facility care. Does not adjust for underreporting of prescription drugs.  
 Source: CMS, Office of Research, Development, and Information: Data from the Medicare Current Beneficiary Survey (MCBS) 1996-2003 Cost and Use Files.

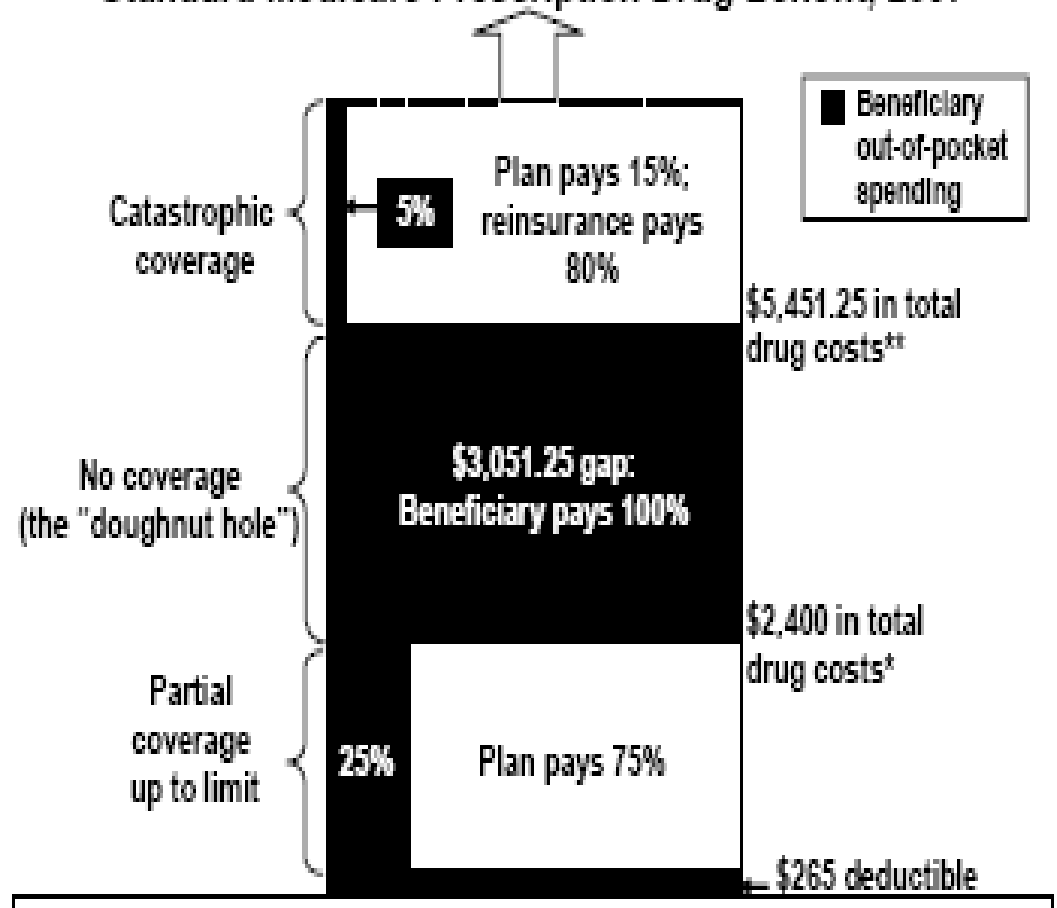
## HHS Estimates of Prescription Drug Coverage Sources Among Medicare Beneficiaries, as of January 2007



**Total Number of Beneficiaries = 43 Million**

Note: Estimates are rounded to the nearest whole number, therefore do not sum to total. <sup>1</sup> Includes Veterans Administration, Indian Health Service, employer plans without retiree subsidies, employer plans for active workers, and state pharmaceutical assistance programs. <sup>2</sup> Includes employer/union, FEHB, and TRICARE coverage. <sup>3</sup> Approximately 0.5 million dual eligibles are enrolled in Medicare Advantage drug plans and are reported in this category. SOURCE: HHS, January 31, 2007. Data as of January 16, 2007.

Figure 1  
**Standard Medicare Prescription Drug Benefit, 2007**



\*Equivalent to \$798.75 in out-of-pocket spending. \*\*Equivalent to \$3,850 in out-of-pocket spending.  
 SOURCE: Kaiser Family Foundation.

Category or income/asset limits	Premium assistance	Deductible	Coinsurance/ copayments	
			Below out-of-pocket threshold	Above out-of-pocket threshold
<b>Full subsidy groups</b>				
Full-benefit Medicaid or Medicare Savings Program beneficiary with income at or below 100% of FPL	100%	\$0	\$1 generic or preferred, \$3.10 other <sup>a</sup>	\$0
Full-benefit Medicaid or Medicare Savings Program beneficiary with income above 100% of FPL	100%	\$0	\$2.15 generic or preferred, \$5.35 other	\$0
Other beneficiary with income below 135% of FPL assets at or below \$6,000 (individual), \$9,000 (couple)	100%	\$0	\$2.15 generic or preferred, \$5.35 other	\$0
<b>Partial subsidy groups</b>				
Income below 135% of FPL, assets \$6,001-11,710 (individual), \$9,001-23,410 (couple)	100%	\$50	15%	\$2.15 generic or preferred, \$5.35 other
Income 135%-150% of FPL, assets at or below \$11,710 (individual), \$23,410 (couple)	Sliding scale, 100%-0%	\$50	15%	\$2.15 generic or preferred, \$5.35 other

<sup>a</sup>No copayments for institutionalized beneficiaries.

<sup>b</sup>135% of the FPG is \$13,784 for an individual and \$17,820 for a couple in 2007.

<sup>c</sup>150% of the FPG is \$18,482 for an individual and \$20,535 for a couple in 2007.

# Medicare & Medicaid Expenditures

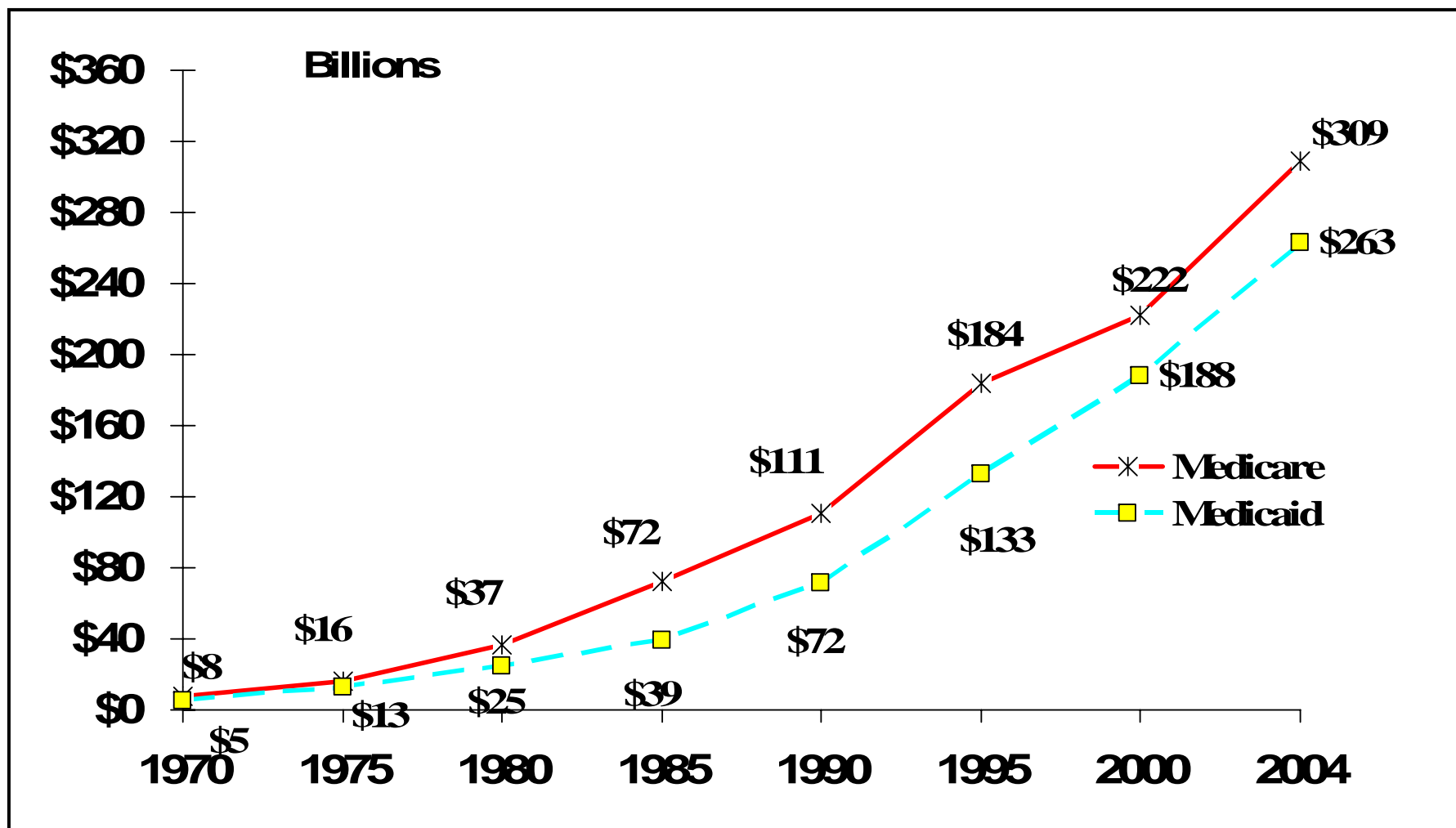
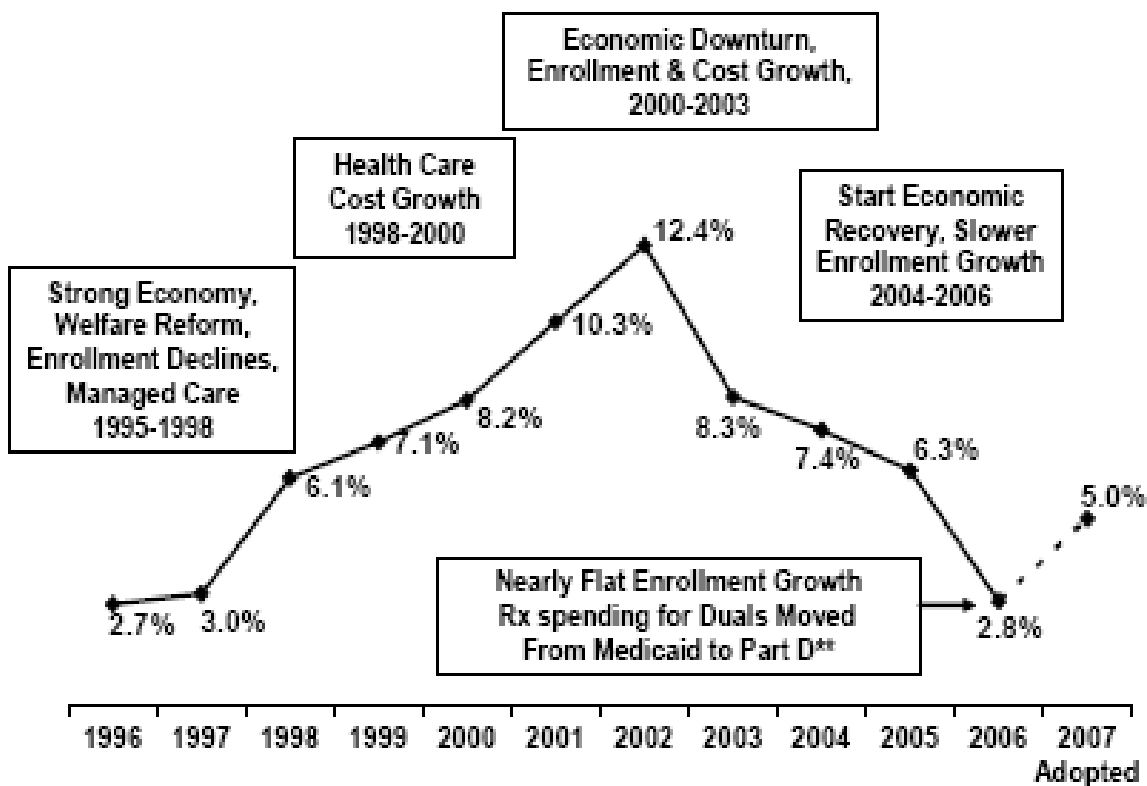


Figure 13

## Medicaid Spending Growth, 1996-2007



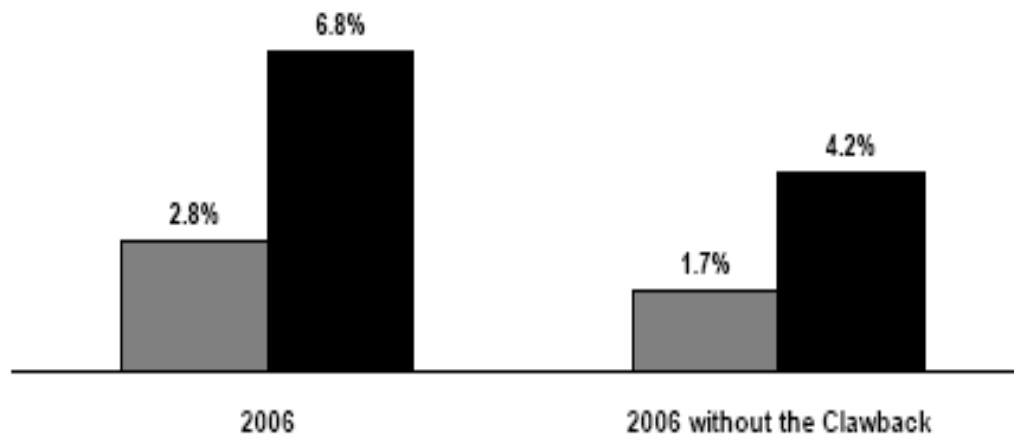
NOTE: Estimates in State Fiscal Year. FY 2007 estimate based on states adopted FY 2007 budget. Clawback payments still counted as state Medicaid payments  
SOURCE: KCMU analysis of CMS Form 64 Data and KCMU / HMA State Budget Survey, 2006

**KAISER COMMISSION ON  
Medicaid and the Uninsured**

Figure 16

## Medicaid Growth Rates Adjusted for Clawback Payments, FY 2006

■ Total Medicaid Growth ■ State General Fund Medicaid Growth

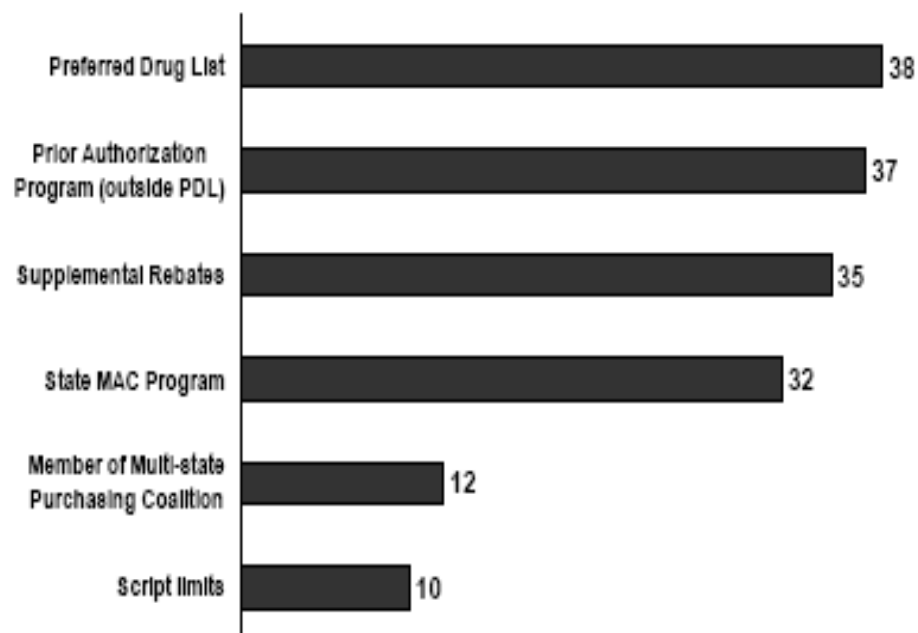


SOURCE: KCMU survey of Medicaid officials in 50 states and DC conducted by Health Management Associates, October 2006.

**KAISER COMMISSION ON  
Medicaid and the Uninsured**

Figure 24

## Medicaid Pharmacy Cost Containment Measures in Place in FY 2006

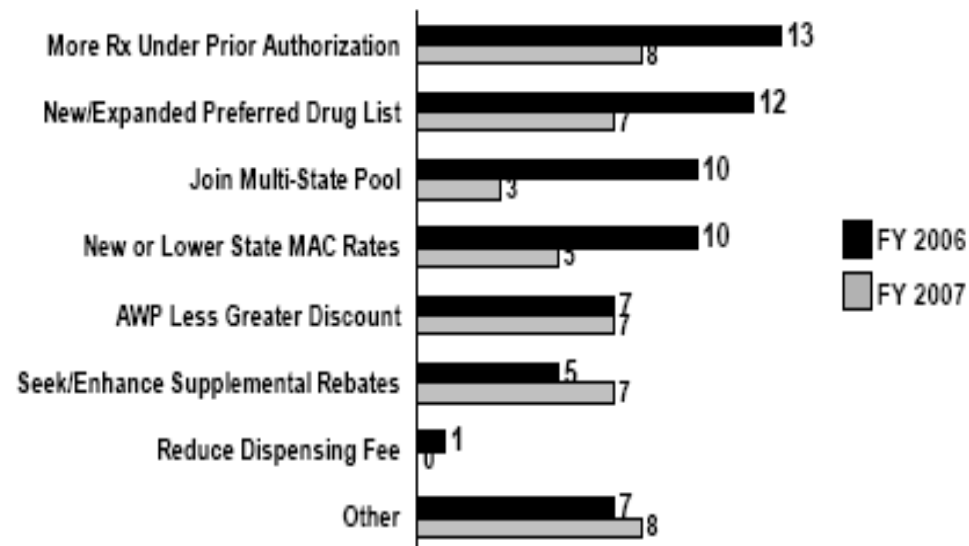


SOURCE: KCMU survey of Medicaid officials in 50 states and DC conducted by Health Management Associates, October 2006.

**KAISER COMMISSION ON  
Medicaid and the Uninsured**

Figure 25

## Medicaid Prescription Drug Policy Changes FY 2006 and FY 2007



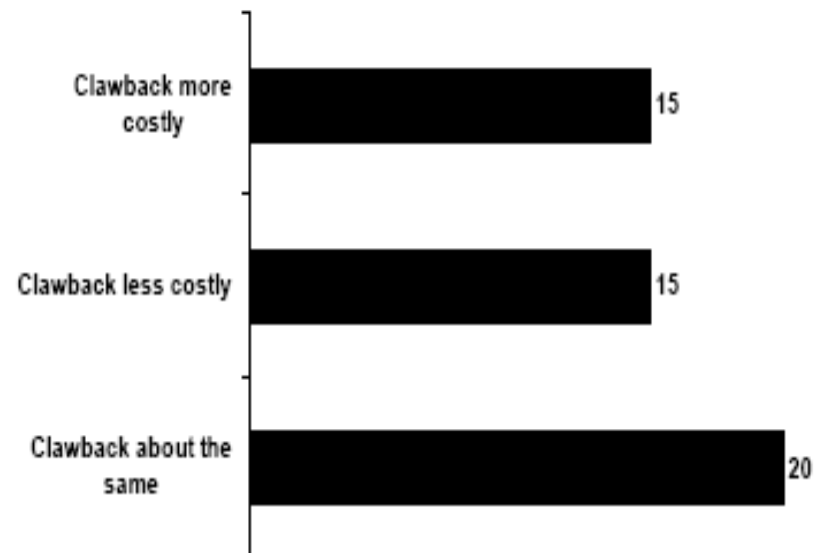
SOURCE: KCMU survey of Medicaid officials in 50 states and DC conducted by Health Management Associates, October 2006.

**KAISER COMMISSION ON  
Medicaid and the Uninsured**

Figure 29

## State Estimates of FY 2007 Clawback Obligations Compared to Cost of Covering Drugs for Duals Through Medicaid

Number of States:

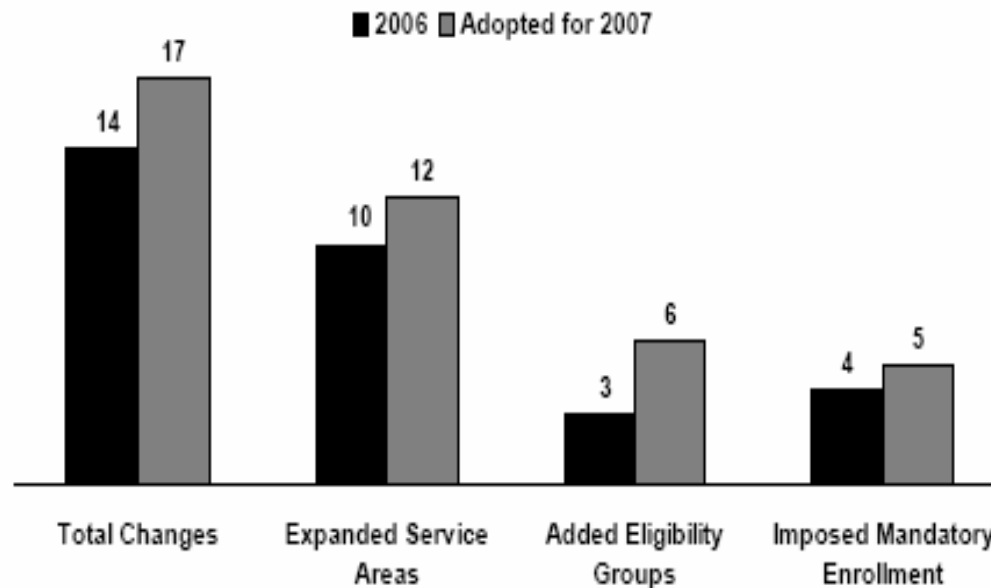


SOURCE: KCMU survey of Medicaid officials in 50 states and DC conducted by Health Management Associates, October 2006. One state reported "did not know"

**KAISER COMMISSION ON  
Medicaid and the Uninsured**

Figure 26

## Medicaid Managed Care Changes Implemented in FY 2006 and Adopted for FY 2007



SOURCE: KCMU survey of Medicaid officials in 50 states and DC conducted by Health Management Associates, October 2006.

**Kaiser Commission on  
Medicaid and the Uninsured**

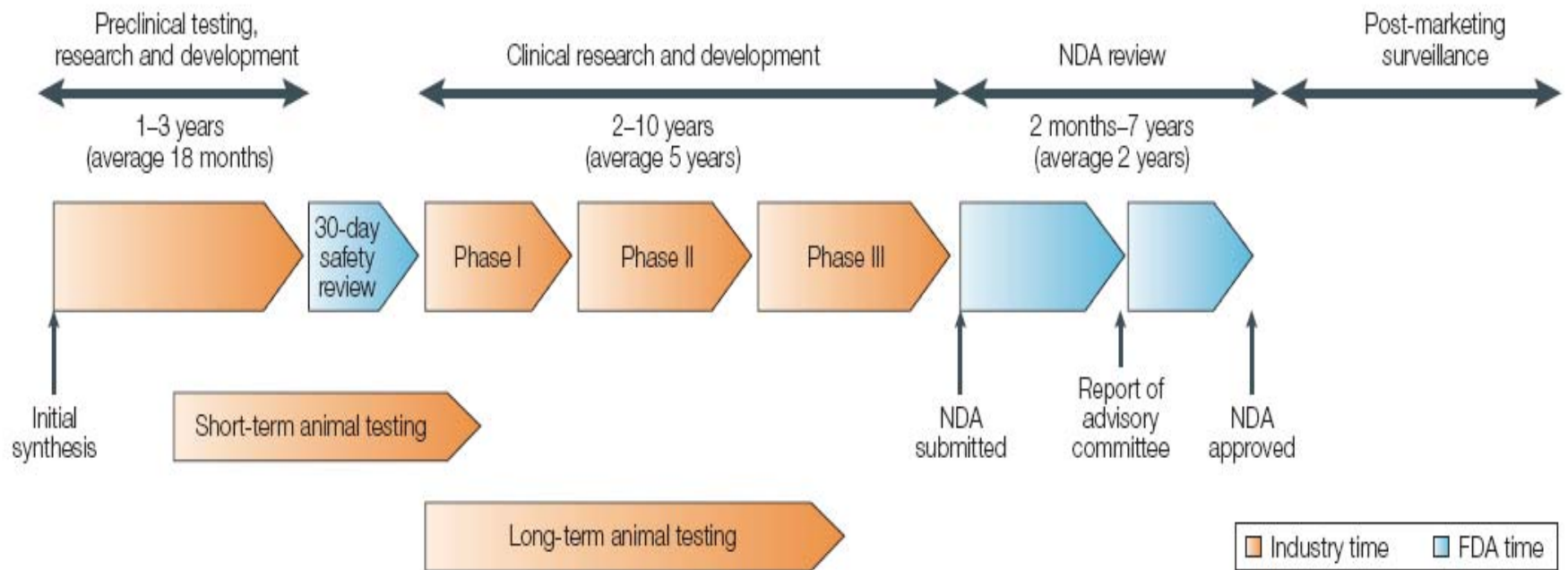
# Issues

- Safety
- Appropriate Prescribing
- Compliance and Persistence
- Pharmacogenomics
- Drug Rebate

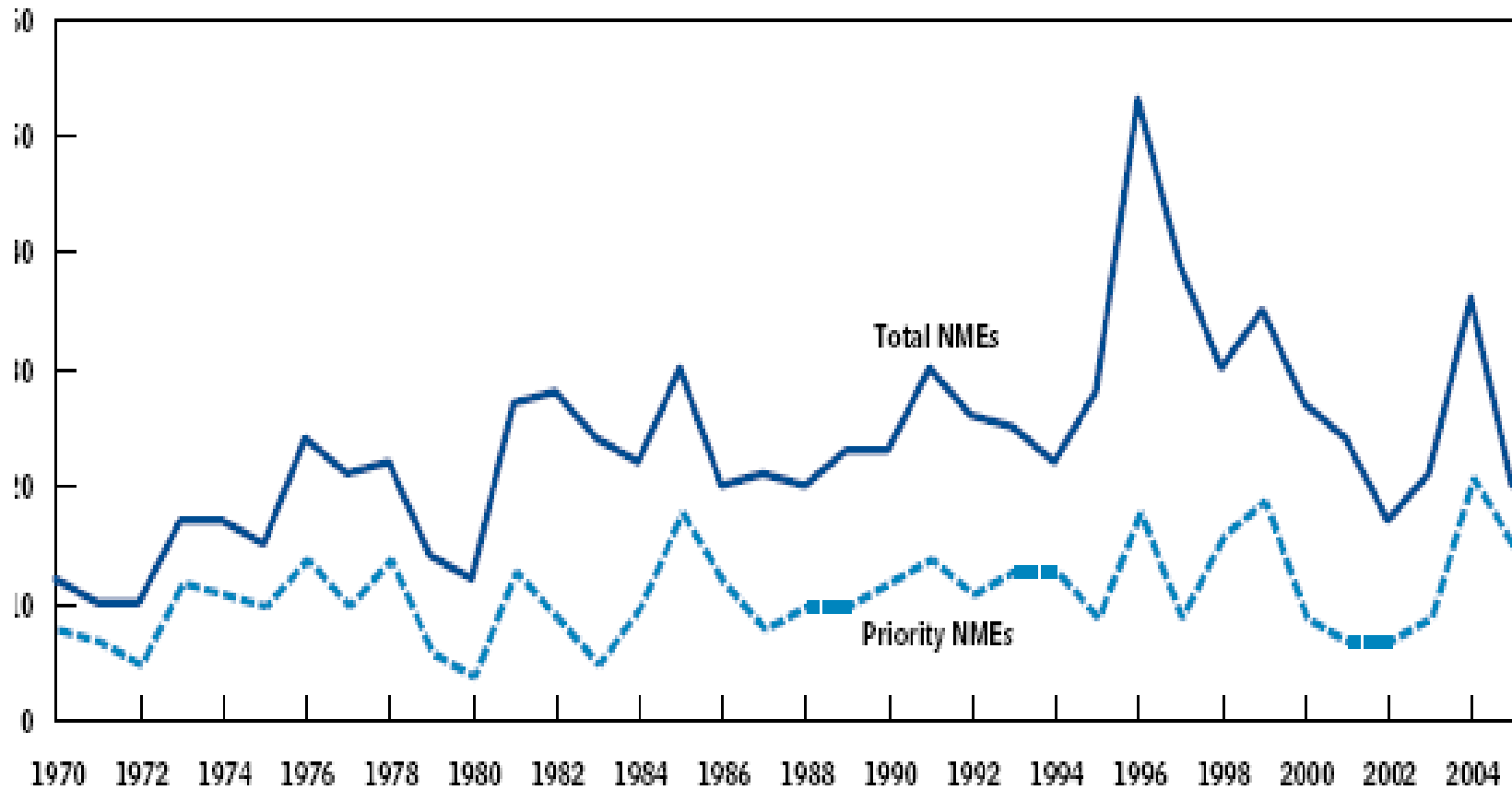
- Extra slides

# Drug Development

- New Molecular Entities
  - About 1/3 new drugs approved
- Basic Research
- Pre-Clinical, Pre-Investigational New Drug
- Phase 1 – safety in humans
- Phase 2 – effectiveness in humans
- Phase 3 – safety and effectiveness
- Phase 4 – post marketing studies

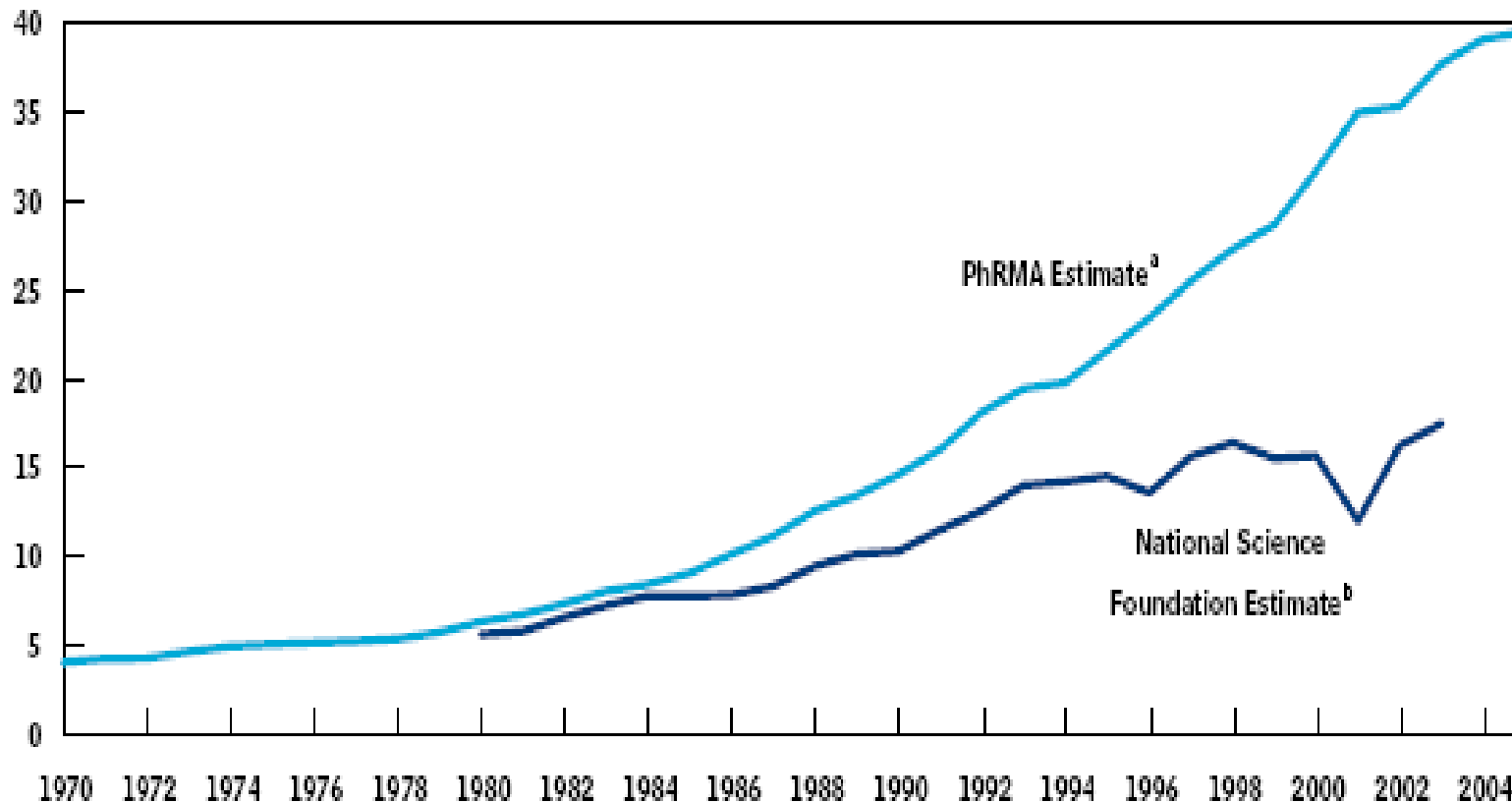


# Number of NME approved by FDA



# Estimates US Drug Companies Spending on R&D

(Billions of 2005 dollars)



# Estimates of Costs

---

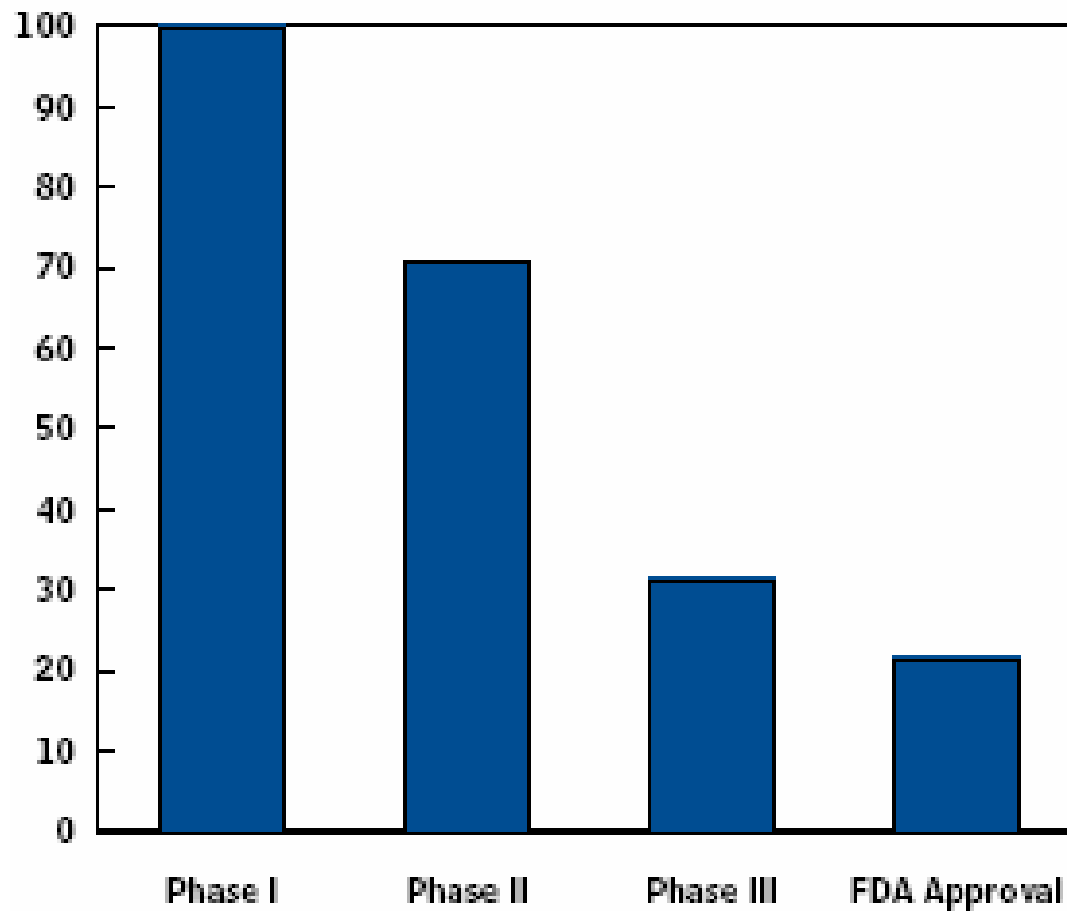
	Average Length of Research Phase		
	Preclinical Phase (4.3 years) <sup>a</sup>	Clinical Trials and FDA Approval (7.5 years)	Total (11.8 years)
Research and Development Costs (Millions of 2000 dollars)			
Direct costs	121	282	403
Opportunity costs <sup>b</sup>	214	185	399
<b>Total Costs</b>	<b>335</b>	<b>467</b>	<b>802</b>

---

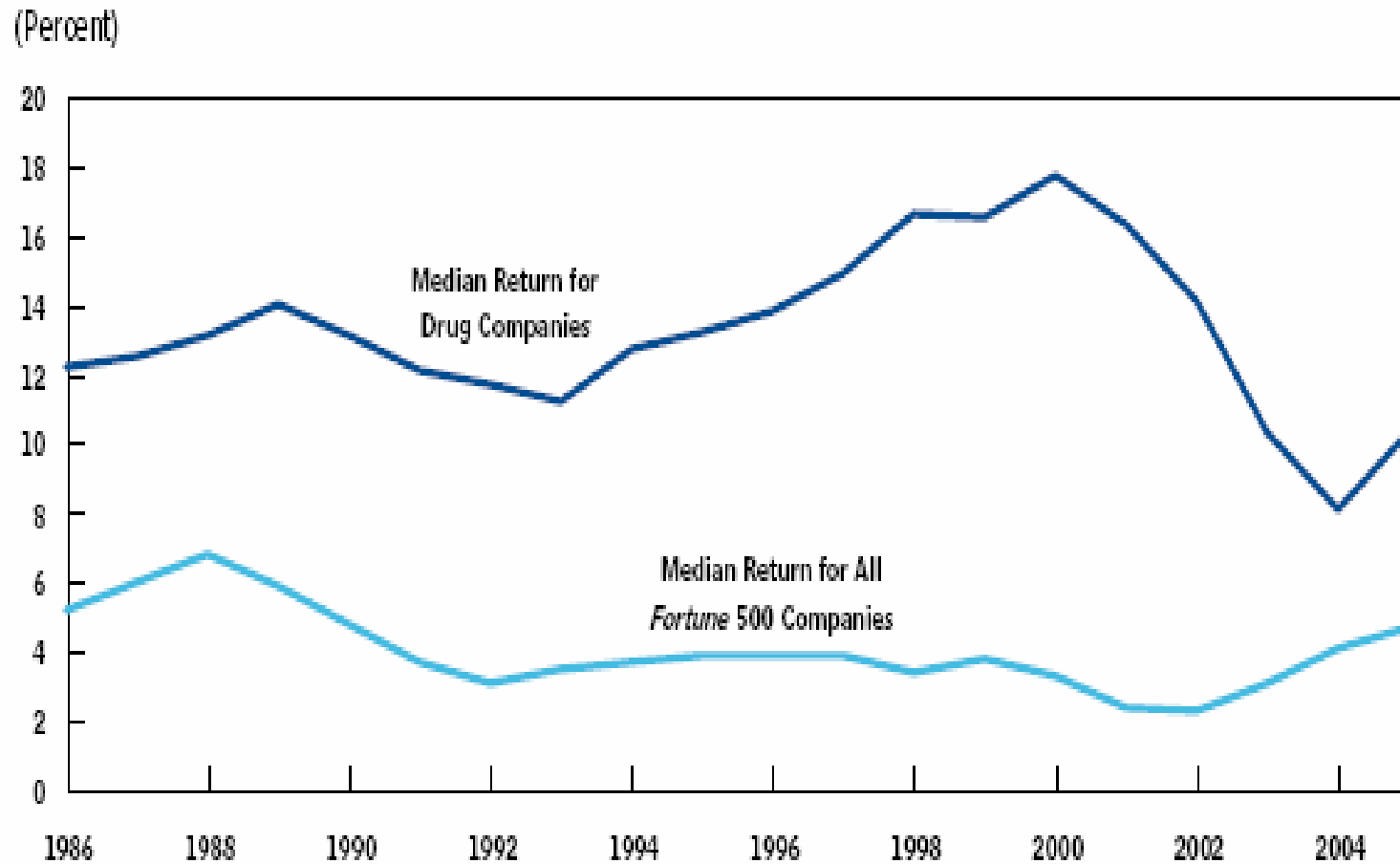
Source: Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, vol. 22, no. 2 (March 2003), pp. 151-185.

## Percentage of New Molecular Entities Entering Each Phase of Clinical Trials

---

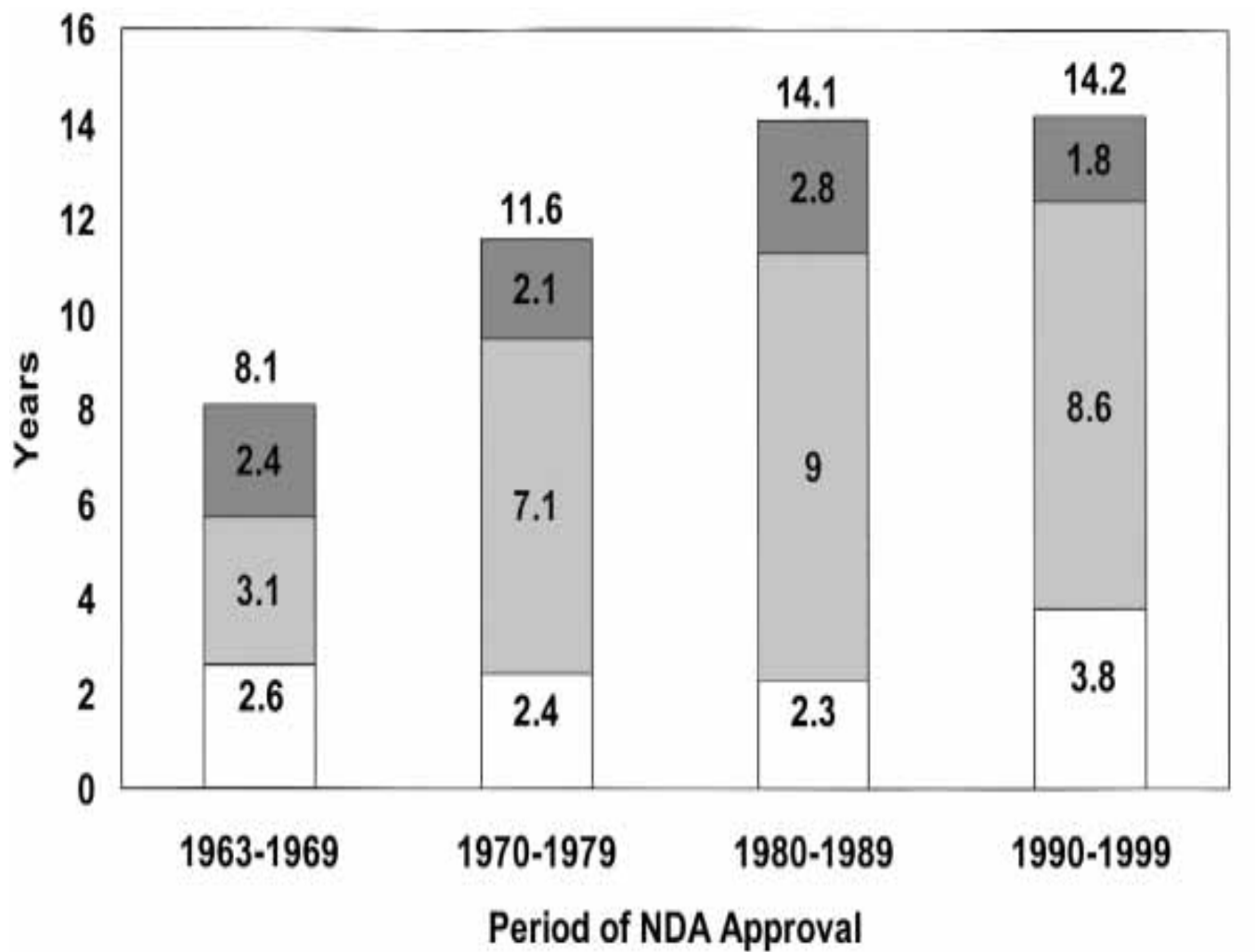


# Return on Assets for Drug Companies versus All Major Companies, by standard accounting



# Why more costly?

- Basic development more costly
- Treating more difficult diseases
- Larger clinical trials
- More competition, quicker
- Market demands more returns
- Fewer markets to make profits



Synthesis to 1st in Humans
  1st in Humans to NDA
  U.S. Approval Phase