

# THREE FUTURES FOR THE U.S. PHARMACEUTICAL INDUSTRY

**Alan Sager, Ph.D.**

**Director, Health Reform Program**

**Professor of Health Services**

**Boston University School of Public Health**

**asager@bu.edu**

**617 638 4664**

# Oxford Bioscience Partners' Biopharmaceutical Summit

**Chatham Bars Inn  
Chatham, Massachusetts**

**30 May 2003**

# Web posting

[www.healthreformprogram.org](http://www.healthreformprogram.org)

# Overview

- I. Three futures**
- II. Forces shaping the future**
- III. The easiest problem to fix in the U.S.**

# I. THREE FUTURES

1. **Business as usual**
2. **The angriest Congress in the history of the world**
3. **A durable prescription drug peace treaty**

# 1. Business as usual

- **Rx spending rises steadily**
- **Rx coverage declines**
- **Advocates and politicians flail in the general direction of containing cost and expanding coverage**
- **Average profits trend gradually downward owing to reduced coverage, public actions, and development of few breakthrough meds**

## 2. The angriest Congress

- **Soaring drug cost and plunging coverage panic and infuriate voters**
- **U.S. health care melts down generally as hospitals close, doctors drive cabs, and ambulances circle in the snow**
- **Economic crisis owing to trade deficit, falling dollar, budget deficit, political instability**
- **Political crisis as hard right is replaced by soft (or hard) left in wake of health meltdown and economic crisis**

### **3. Prescription drug peace treaty**

- **Winning affordable meds for all is the easiest problem to fix in U.S.**
- **Low marginal cost of most production**
- **Cut price and boost volume**
- **Guarantee return on equity**
- **And reward breakthroughs very richly**
- **Public evaluation of efficacy**
- **Publicly disseminated guides to use (end of marketing/advertising)**



# Comments on three futures

- **Middle grounds or combinations possible**
- **One future may prevail for a while, and then be supplanted**
- **What looks likely or desirable now may not look that way in 3-5-10 years**
- **Managing politics is current preference**
- **Contingency planning greatly lacking**

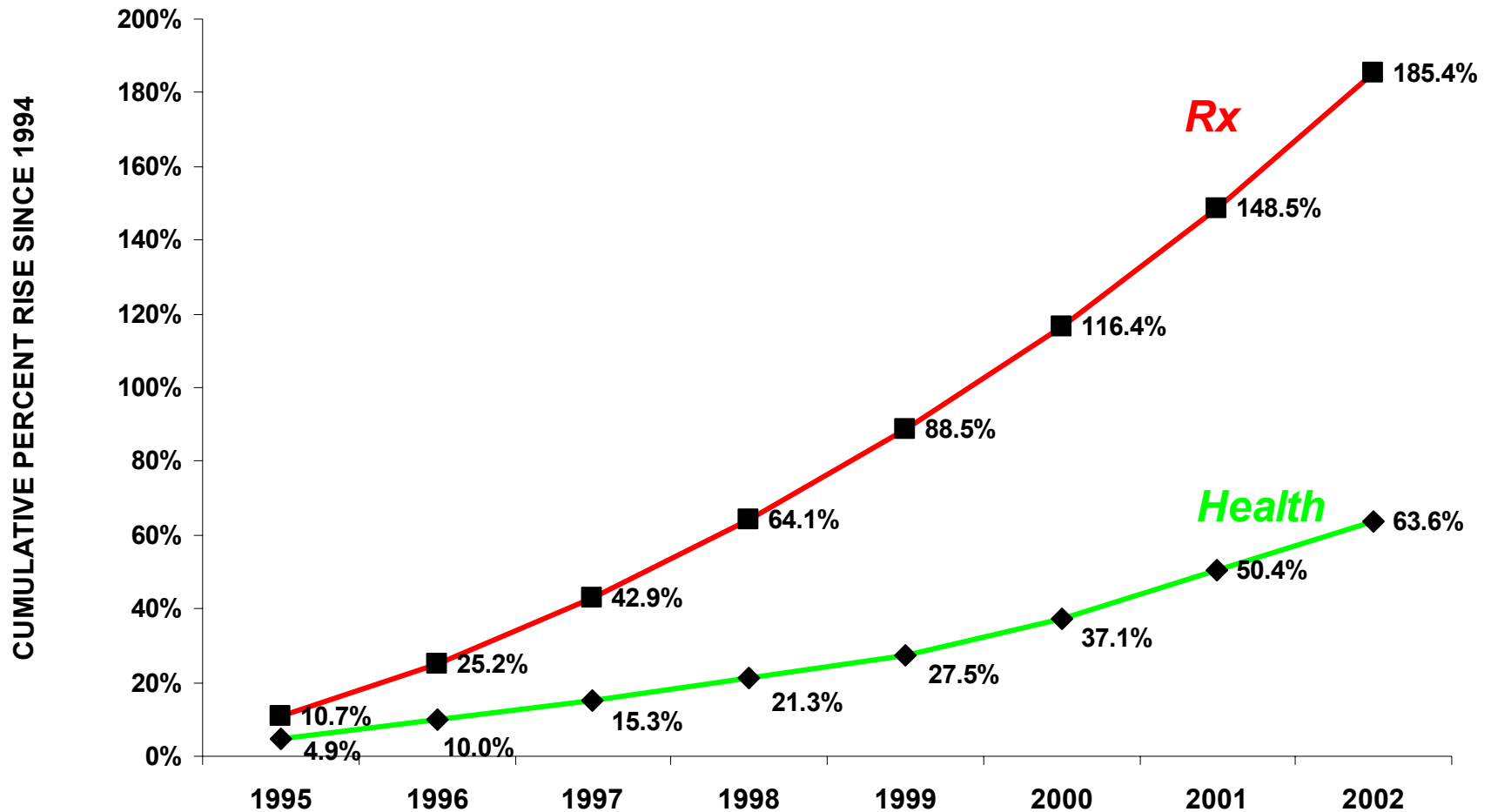
## **II. FORCES SHAPING THE FUTURE**

- a. Rx cost and coverage**
- b. Drug makers' dependence on U.S.**
- c. Health care generally**
- d. Economy**
- e. Politics, Rx and general**
- f. Design and testing of practical reform options**

## a. Rx cost and coverage

- **Spending trends**
- **Prices**
- **Uninsured or under-insured**

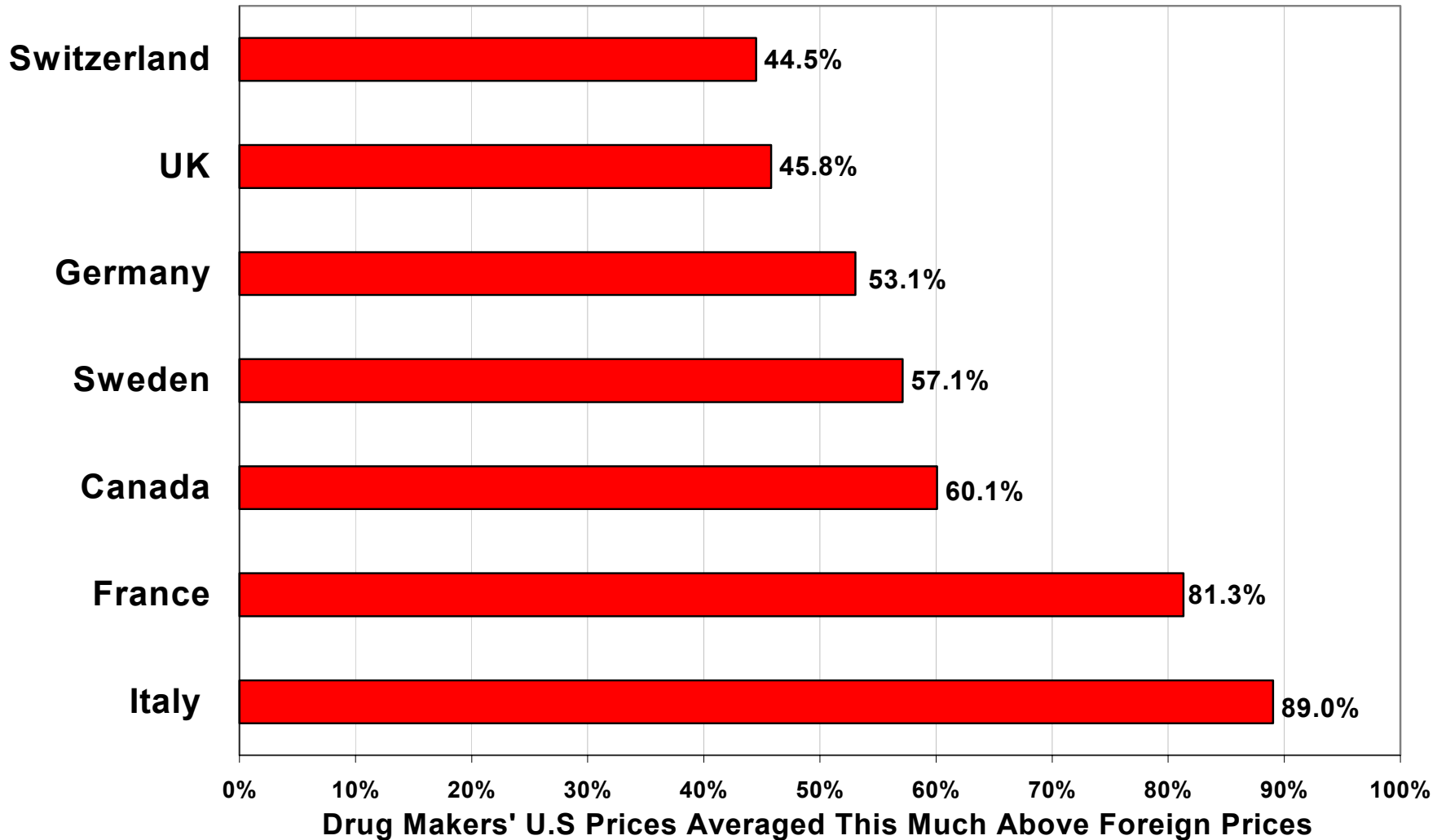
# Rx SPENDING RISES MUCH FASTER THAN TOTAL HEALTH SPENDING, 1994 - 2002



# U.S. drug prices

- **50 - 100 percent higher than prices in other wealthy nations, though Bayer parallel import EU decision may alter**
- **PhRMA long denied U.S. prices are higher**
- **Now, PhRMA says that high prices are good for us**
- **Few people believe this**

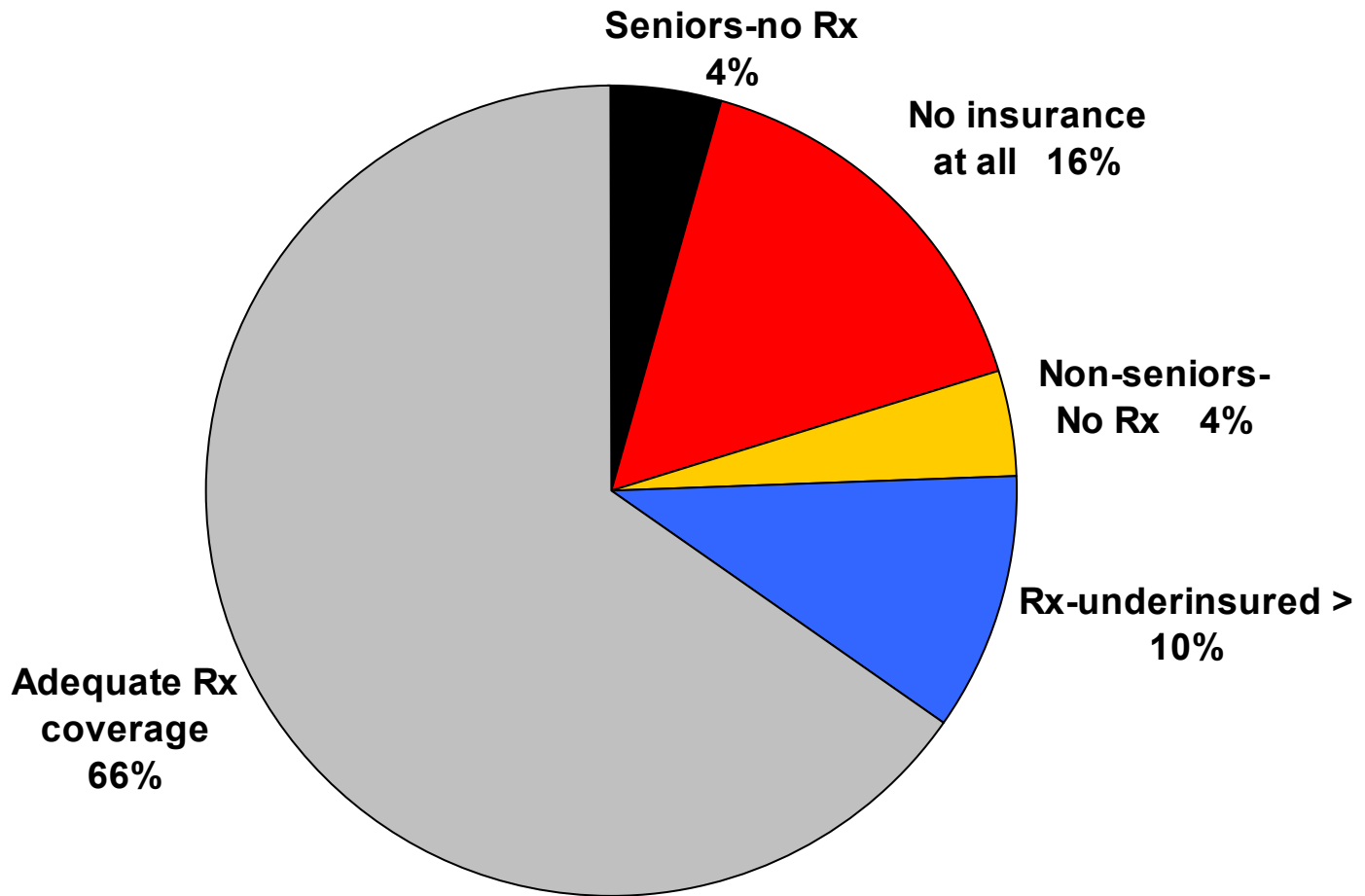
# U.S. EXCESS ABOVE 7 NATIONS' FACTORY DRUG PRICES, 2000



# Declining coverage

- **Number of completely uninsured rising**
  - Loss of jobs
  - Loss of jobs with insurance
  - Health insurance cost--\$10K for family
- **Loss of retiree health insurance, with soaring Rx costs prominently implicated**
- **Rising co-pays**
- **Formularies**
- **Falling annual dollar drug benefits**

# 98 MILLION LACKED PRESCRIPTION DRUG FINANCIAL SECURITY IN U.S. IN 2000



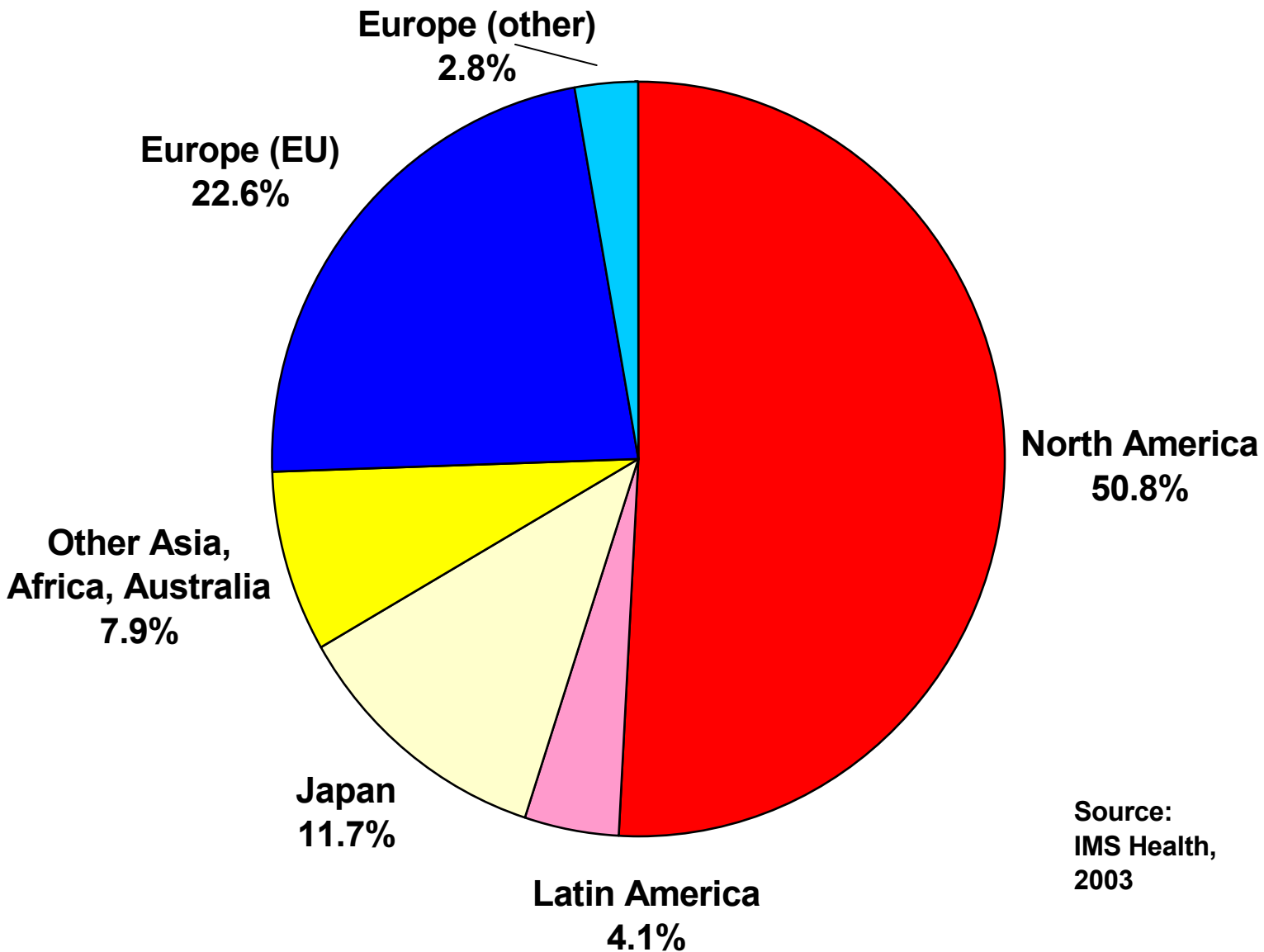


## **b. Drug makers' growing dependence on U.S. market**

- **U.S. now provides almost 1/2 of drug makers' worldwide revenue**
- **North American share rose from**
  - **34.7 % in 1996 to**
  - **41.5 % in 1998 to**
  - **50.8 % in 2002**
- **Market share gives great power, but also great obligation to use it carefully when we finally act**

**(U.S. is now ~ 95 % of North American; Source: IMS Health)**

# U.S. BUYS HALF OF WORLD'S DRUGS, 2002



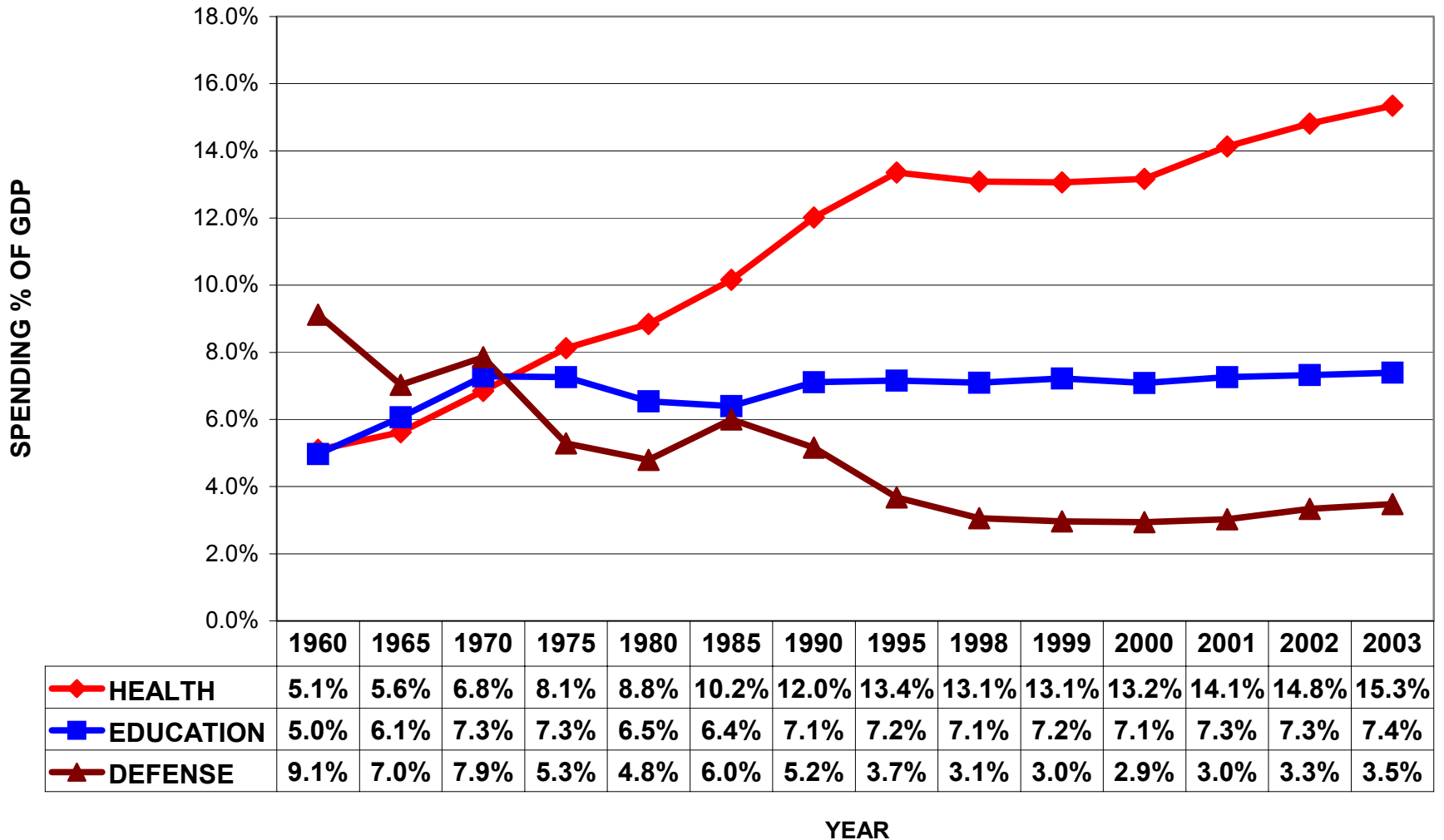
## c. Health care generally

- Spending ~ \$1.7 trillion in 2003
  - about 4X defense and >15% of GDP
  - Rx alone equals one-half defense
- Family premiums >\$10K yearly
  - Rising cost causes coverage to fall
- Caregiver fragility
  - Hospital closings + bed shortages even before SARS
  - ER gridlock with ambulances circling
  - Nursing home closings + bed shortages
  - Physician income worries

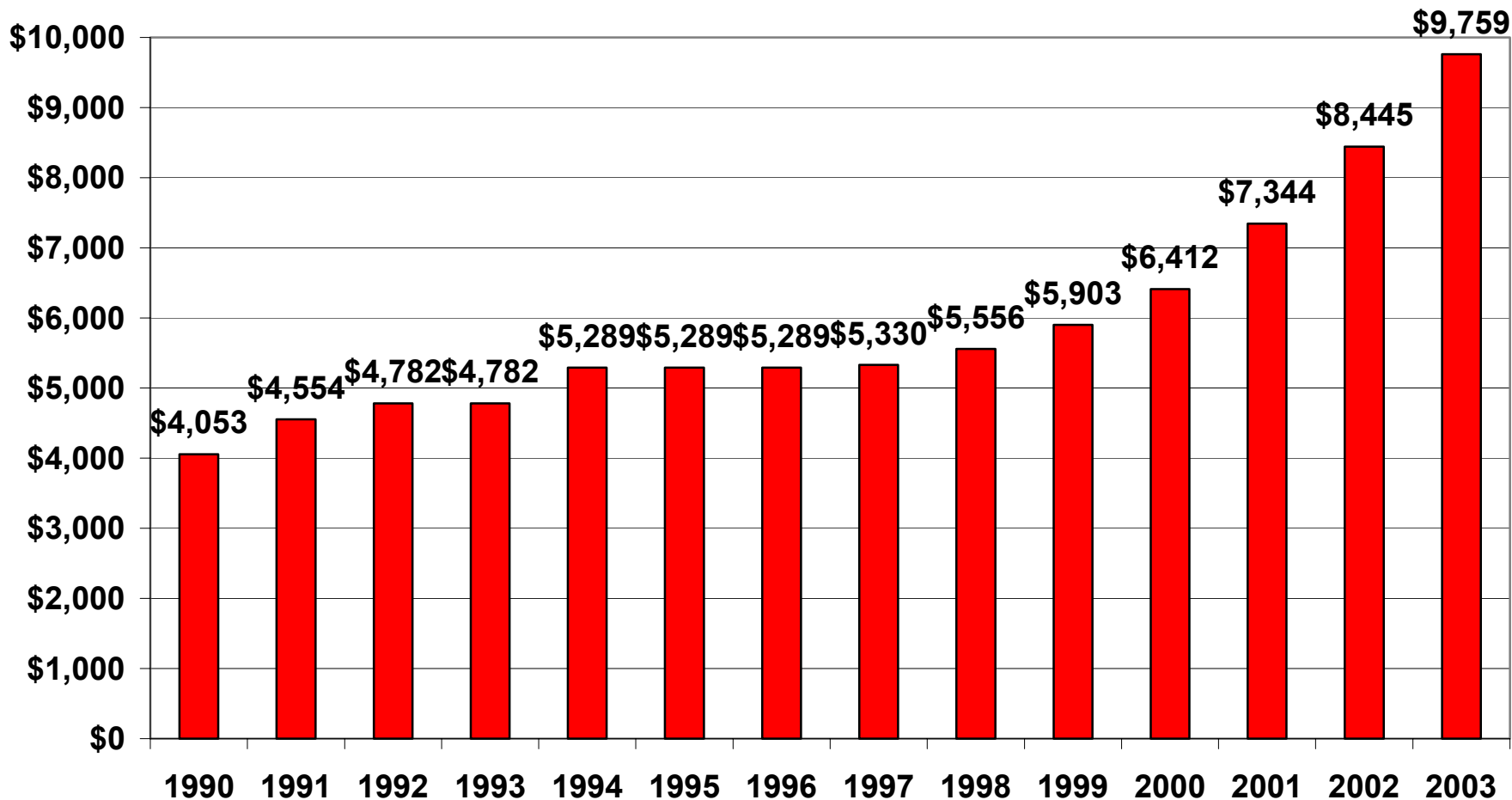
# c. Health care generally

- One-half of health dollar wasted
  - Theft, ineffective care, administration
  - After failure of price competition, no cost control ideas on warehouse shelf
  - Now no political push to squeeze waste
- Medical meltdown possible
  - Pressure for change would result
  - But no one would know what to do owing to lack of contingency planning
- Contingency planning vital
  - How to cover all people at affordable cost, organize and pay all needed caregivers

# HEALTH, EDUCATION, AND DEFENSE SPENDING, U.S., 1960 - 2003, AS PERCENT OF GDP



# FAMILY HEALTH INSURANCE ANNUAL PREMIUM, STEADY BENEFIT PACKAGE, BIG EMPLOYER, EASTERN MASSACHUSETTS, 1990-2003



## d. Economy

- **Fragile, brittle**
- **Trade deficit– living beyond our means**
  - Many U.S. exports vulnerable to pirating
- **Weaker dollar could spur inflation and foreign disinvestment**
- **Federal deficits– Keynes would laugh**
- **Growing income inequality means fewer paying customers**
- **Japanese-style quagmire possible**

## e. Politics, Rx and generally

- **Political paralysis**
- **PhRMA's fog of fear**
- **Futile skirmishing around the edges**
- **Dispersing the fog**
- **Rx politics merge with general politics**



# Political paralysis

- **What will pass won't work and what can work can't pass.**
- **Why?**
  - **Generally**
    - **mistrust of government, love of markets**
    - **Weak analysis: Politicians ask experts for new ideas but experts' answers are constrained by their own guesses about what politicians think is now politically possible**
  - **Rx**
    - **PhRMA's power**
    - **Wasting time coping with symptoms**

# PhRMA's Fog of Fear

- **Then: U.S. prices aren't higher**
- **Now: high prices are good for us**
  - **High prices mean high profits**
  - **High profits mean life-saving new drugs**
  - **Price controls mean: “The lights go out in the labs, and there is no R&D.”**  
**(Baroni)**
- **Always: a free market justifies high prices**

**Futile skirmishing is harmful, useless, or offers brief relief only**

- **PBMs**
  - **Fiduciary duties, failures to save**
- **Formularies**
  - **Inspire mistrust, savings doubtful**
- **Drug discount cards**
  - **Market segmentation: do drug makers really want to administer a welfare benefit?**
- **Greater use of generics**
  - **Other nations manage without them**

**Futile skirmishing is harmful, useless, or offers brief relief only**

- **Importing from Canada/Mexico**
  - Boilers explode without safety valves
- **Higher co-pays**
  - Deter use of the very drugs MD ordered
  - Regressive tax on sick people
- **Fragmented demands for big price discounts**
  - Spurred by financial need
  - Justified by international differences
  - Legal, political, administrative barriers

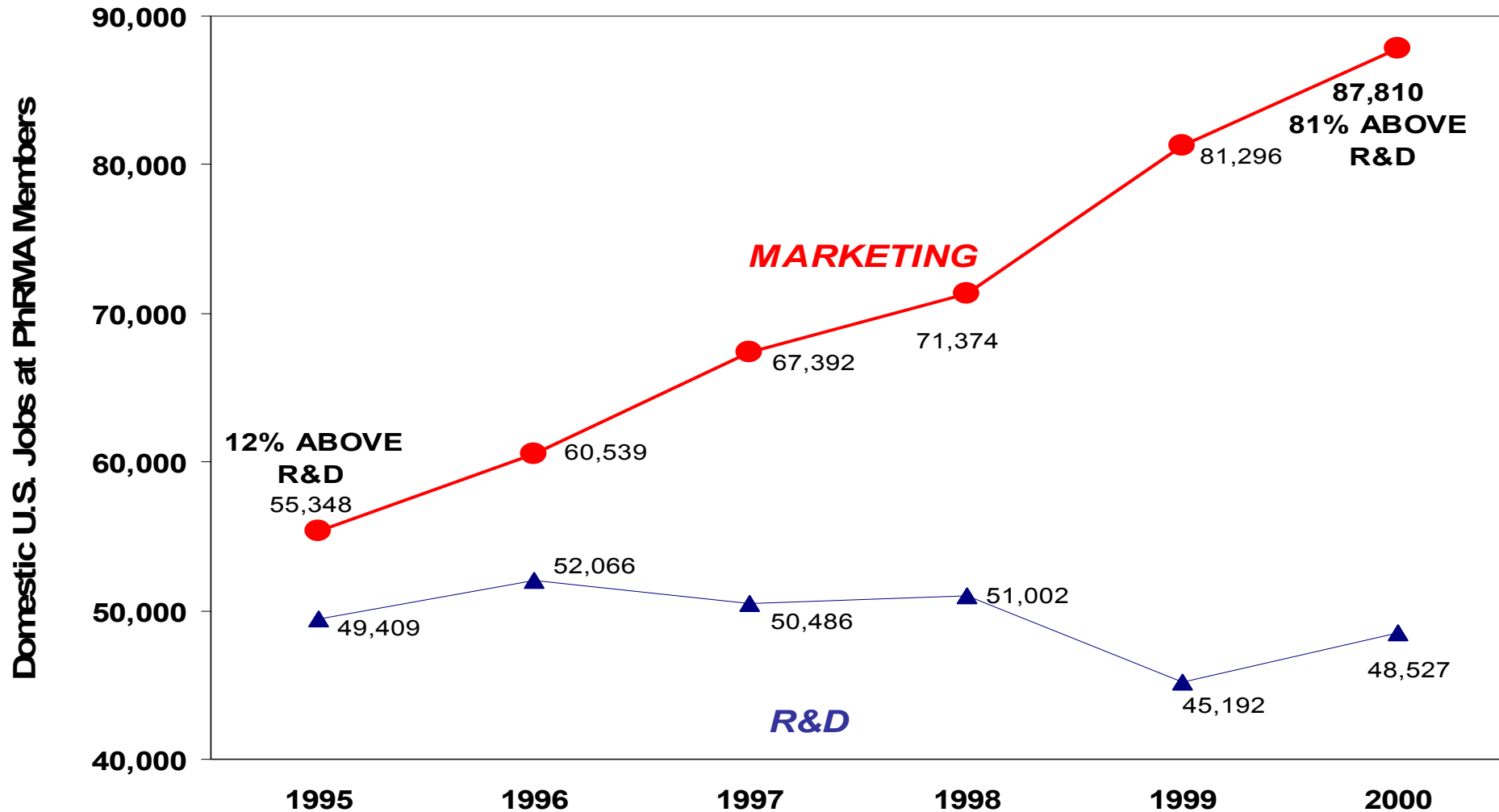
**Futile skirmishing is harmful, useless, or offers brief relief only**

- ***No coordination* between these attempted controls and patients' needs or drug makers' needs**
- **If drug makers neutralize or deflect these techniques, costs keep rising and anger grows**
- **If these techniques work, drug maker revenue suffers but current wasteful administrative, marketing, and political practices persist and multiply**
- **Either way, drug makers lose**

# Dispersing the fog

- **Higher prices + more marketing = a way for some drug makers to keep profits high even without finding good new drugs**

# MARKETING JOBS UP 60% BUT R&D FLAT, 1995 - 2000



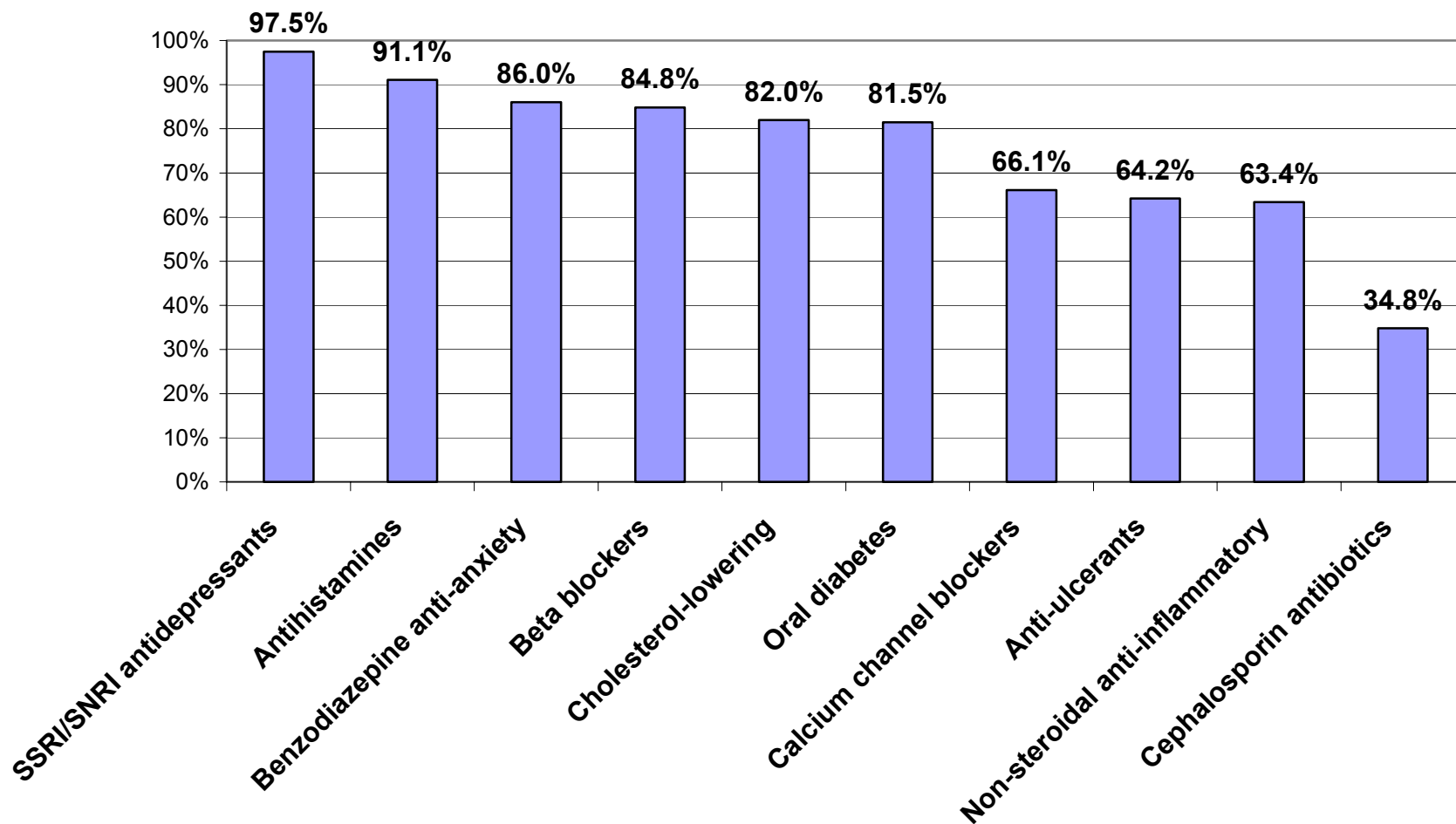
# Dispersing the fog

- **Higher prices + more marketing = a way for some drug makers to keep profits high even without finding good new drugs**
- **No free market legitimates high profits, industry-wide (no market + no government = anarchy)**



# MARKET CONCENTRATION IN THE TOP THERAPEUTIC CATEGORIES, 1998

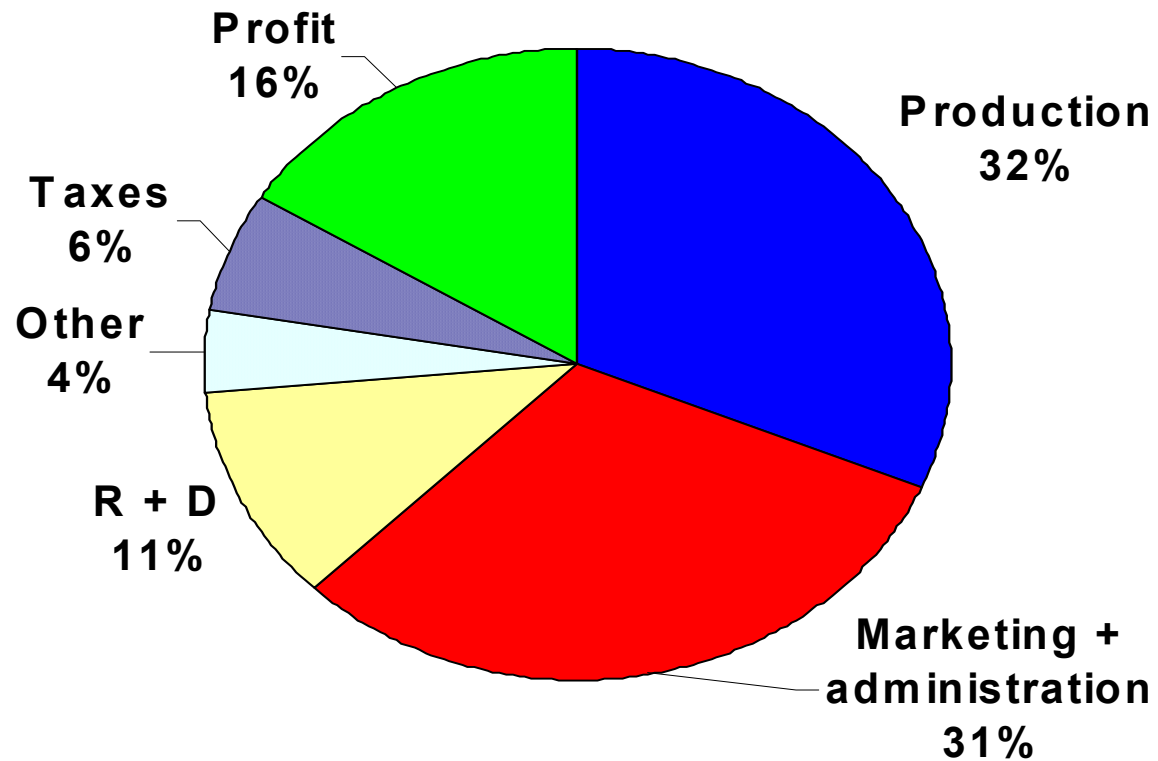
MARKET SHARE - TOP 4 FIRMS



# Dispersing the fog

- **Higher prices + more marketing = a way for some drug makers to keep profits high even without finding good new drugs**
- **No free market legitimates high profits, industry-wide (no market + no government = anarchy)**
- **High profits don't finance research—profits are what's left over after paying for everything else**

# HOW SIX DRUG MAKERS SPENT THEIR MONEY, 1999



# Dispersing the fog

- **Higher prices + more marketing = a way for some drug makers to keep profits high even without finding good new drugs**
- **No free market legitimates high profits, industry-wide (no market + no government = anarchy)**
- **High profits don't finance research—profits are what's left over after paying for everything else**
- **High prices: usually very toxic**

# High prices: drug makers' worst enemy, micro view

- **Once research is done and factory is built, incremental cost of making more pills is usually very low**
- **High prices not justified by market or production cost**
- **High prices spur efforts to restrict use, since that's only other way to cut cost**
- **But people suffer as a result**
- **And spending growth does not slow**

# High prices: drug makers' worst enemy, macro view

- **High prices and soaring Rx spending (despite efforts to restrict use) will help elect the world's angriest Congress, which could slash prices, gutting research**
- **This should be viewed as a serious contingency**
- **Unless something changes**

# Politics generally

- **Right-of-center dominance since 1968**
- **Drift farther to right + arrogance**
- **Governing well beyond mandate?**
- **Left-of-center has few ideas well-tested in states (very different from 1930s)**
- **If left-of-center wins political power in time of crisis or turmoil, demand for action will be great, but dollars and experience will be scarce**
- **Failure → anger + instability**
- **Needed: victories for competence and compassion**

## f. Design and testing of practical reform options

- **Three paths**
  - Death
  - Dollars
  - Discontinuity
- **Who are the most nervous people?**
- **Five opportunities**
  - High spending
  - Low marginal cost
  - Pre-empt political + financial disaster
  - *Drugs are a smart investment in better health*
  - Package deals possible



# Death, dollars, or discontinuity

- **Continued suffering** and dying for lack of needed drugs. *Intolerable.*
- **Paying much more** public and private money for needed drugs. *Unaffordable.*
- **Changing our ways,** to secure needed drugs at small additional costs while rewarding innovation. *Unavoidable.*

**“Drug makers are the most nervous very-well-dressed people in the U.S.A.”**

**“We know we are defying gravity.”**

- **Addicted to rapid revenue growth**
- **Prices unnaturally high**
- **Too few breakthrough drugs**
- **Too much marketing**
- **No fall-back position (none)**
- **Reliance on backroom politics and non-credible propaganda**

# Tomorrow: five opportunities

- Today's \$225+ billion for Rx is enough
- It usually costs little to make more pills once the research is done and the factories are built
- Political pre-emption—the sooner you compromise, the better your deal
- Imagine drugs for Alzheimer's, arthritis
- Needed: *A package deal* to lower prices and boost volume

# **III. THE EASIEST PROBLEM TO FIX IN THE U.S.**

**a. Not easy, just easier than all others**

**b. Two options**

- A very good Medicare Rx benefit**
- Rx peace treaty**
  - Short-term and long-term elements**

**a. Not easy,  
just easier than all others**

- **All other problems require much more money**
- **By all reasonable standards, we already spend enough on health care and, especially, on meds**
- **Barriers to addressing all parties' core needs are mainly matters of politics, trust, or lack of imagination, not lack of money or organizational capacity**

# What are core needs?

- **Patient—confidence my doctor will prescribe the right drugs and I can comfortably afford them**
- **Payers—reassurance that total drug spending will rise at manageable rates or that higher drug spending will actually be offset by lower hospital-doctor-other cost**
- **Drug makers—profits commensurate with value of product, adequate financing, clear and stable rules, freedom from constant attack, lower cost of running business**

## **b. Two options**

- **A very good Medicare prescription drug benefit**
- **A comprehensive prescription drug peace treaty**

# Option 1: Very good Medicare Rx

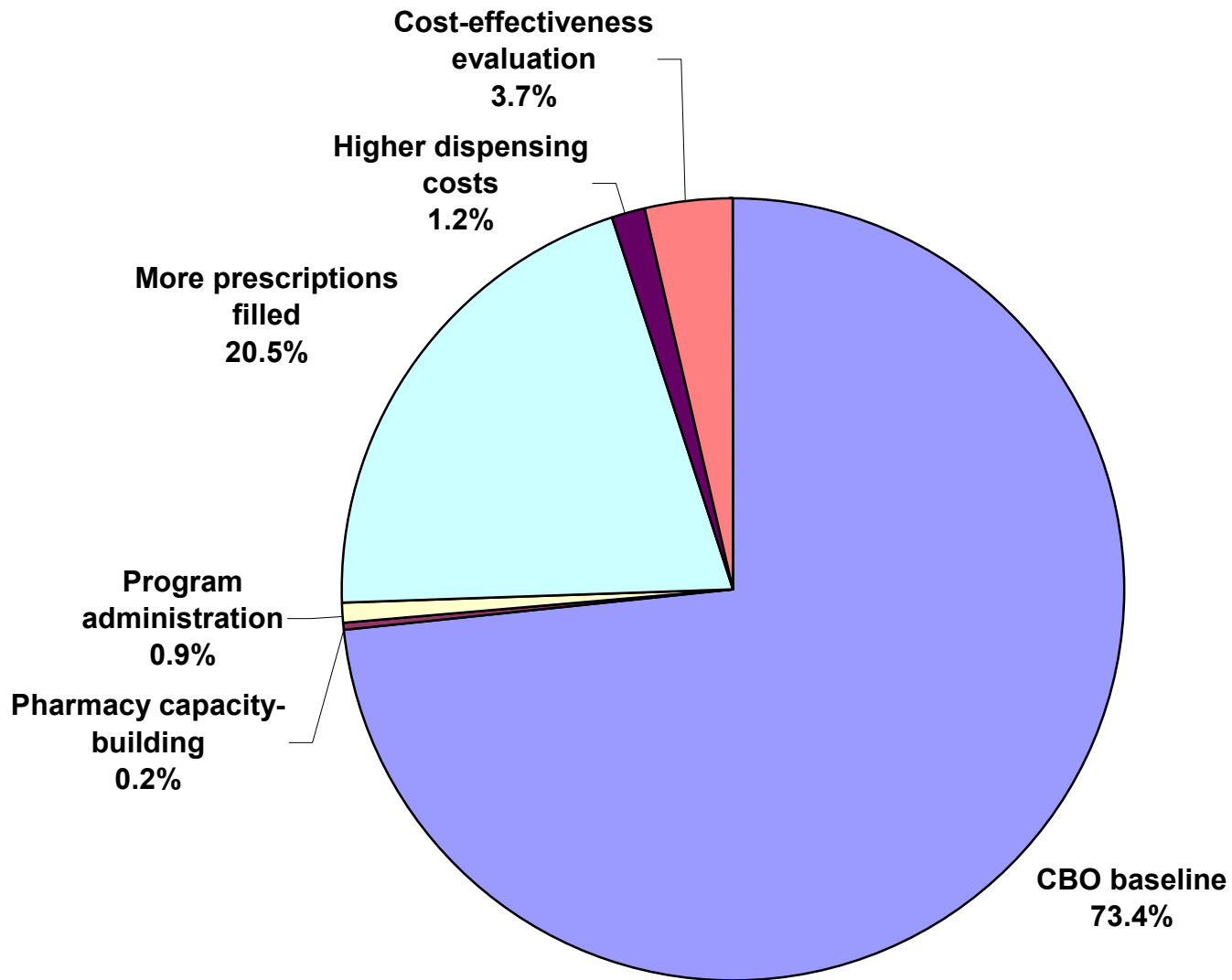
- **Total gross cost**—about \$2.2 trillion for 10 years, if we continue business as usual
- **Financing**
  1. **Very low premiums and co-pays—and no gaps**
  2. **Capture Rx marketing + advertising spending**
  3. **Slow spending increases—use drugs more carefully**
  4. **Pay for higher volume of prescriptions at actual manufacturing cost (no windfall profits)**
  5. **Capture today's public and employer dollars**
  6. **Net federal cost—\$40 billion yearly**



# Medicare's Part Rx – 10-year total gross cost, \$ billion

<b>CBO March 2002 baseline</b>	<b>\$1,580</b>
<b>Pharmacy capacity-building</b>	<b>\$5</b>
<b>Program administration</b>	<b>\$20</b>
<b>Higher Rx volume at retail</b>	<b>\$441</b>
<b>Additional dispensing costs</b>	<b>\$27</b>
<b>New cost-effectiveness evaluation</b>	<b>\$80</b>
<b>Total</b>	<b>\$2,153</b>

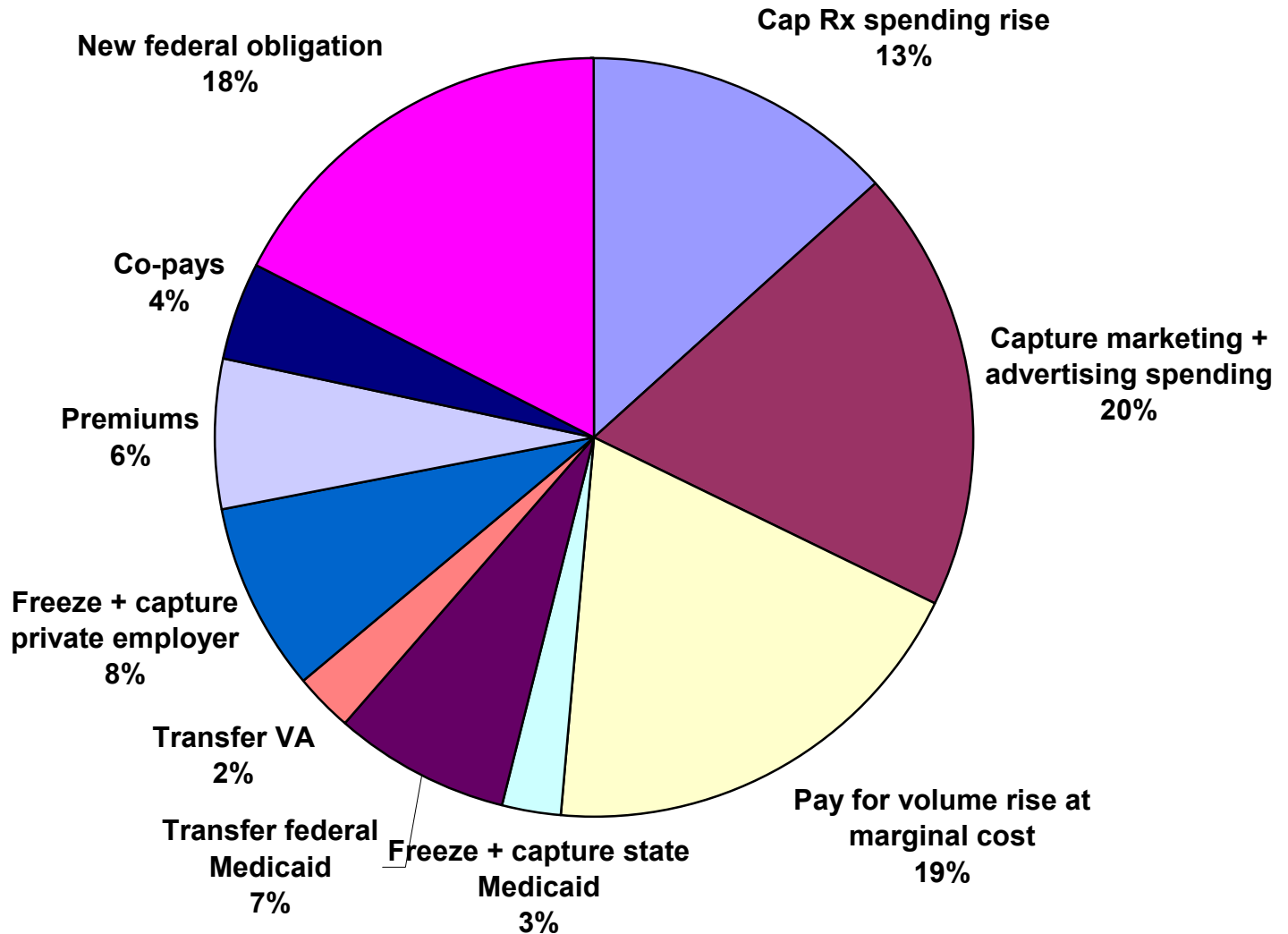
# COSTS OF MEDICARE'S NEW PART Rx, 2002 - 2011



# Medicare Part Rx – 10-year revenue, \$ billion

<b>Slow spending rise</b>	<b>\$286</b>
<b>Capture marketing + advertising</b>	<b>\$483</b>
<b>Pay volume rise at marginal cost</b>	<b>\$408</b>
<b>Freeze + capture state Medicaid</b>	<b>\$59</b>
<b>Transfer VA</b>	<b>\$54</b>
<b>Freeze + capture private employer</b>	<b>\$174</b>
<b>Premiums</b>	<b>\$160</b>
<b>Co-payments</b>	<b>\$87</b>
<b>New federal obligation</b>	<b>\$378</b>
<b>Total</b>	<b>\$2,153</b>

# Financing Medicare's New Part Rx, 2002-2011



# Option 2: Rx peace treaty

- 1. Legislate deep cuts in drug makers' U.S. prices. Revenue falls.**
- 2. Most lost revenue replaced through higher private Rx use, in response to price cut**
- 3. Replace the rest of lost revenue with public subsidies for people not able to afford even the lower prices**
- 4. Pay drug makers' actual cost of making the extra pills**

# Peace treaty provisions, short-run

1. **Legislate Canadian-level factory prices for brand-name drugs, cutting manufacturers' U.S. revenues by ~ \$45 B in 2003**  
**-- if do nothing else**
2. **Replace much or most of lost revenue through higher private market volume responding to lower prices (extent depends on price-elasticity of demand)**

# Peace treaty provisions, short-run

- 3. Provide the rest of the revenue needed to maintain pre-reform return on equity, for each drug maker, via publicly-subsidized purchases for people who can't afford even the newly-discounted private prices.**

# Peace treaty provisions, short-run

4. To maintain return on equity, publicly subsidized prices would be set to replace that share of the \$45 B in lost revenue not recouped privately (in step 2), plus marginal cost of new volume. The upper limit on revenue replacement would be that required to maintain return on equity, allowing for reasonable cost rises.



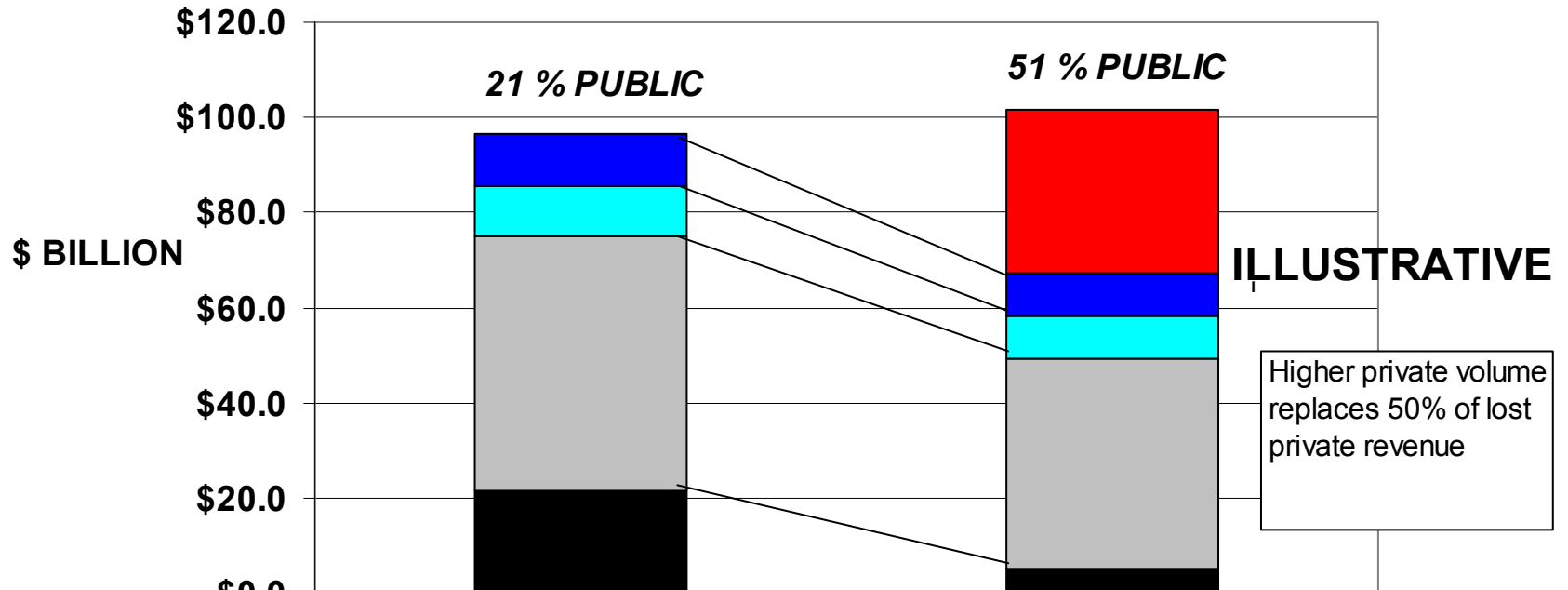
# Strengths of short-run elements

- **All prescriptions needed by Americans are filled, a rise of perhaps 1 billion above today's 3 billion Rx's**
- **Incremental cost of manufacturing + dispensing = only about \$ 9 billion**
- **Each manufacturer is financially whole: returns on equity would be maintained at pre-reform levels for (say) 5 years**

# Complications and problems, short-run (1)

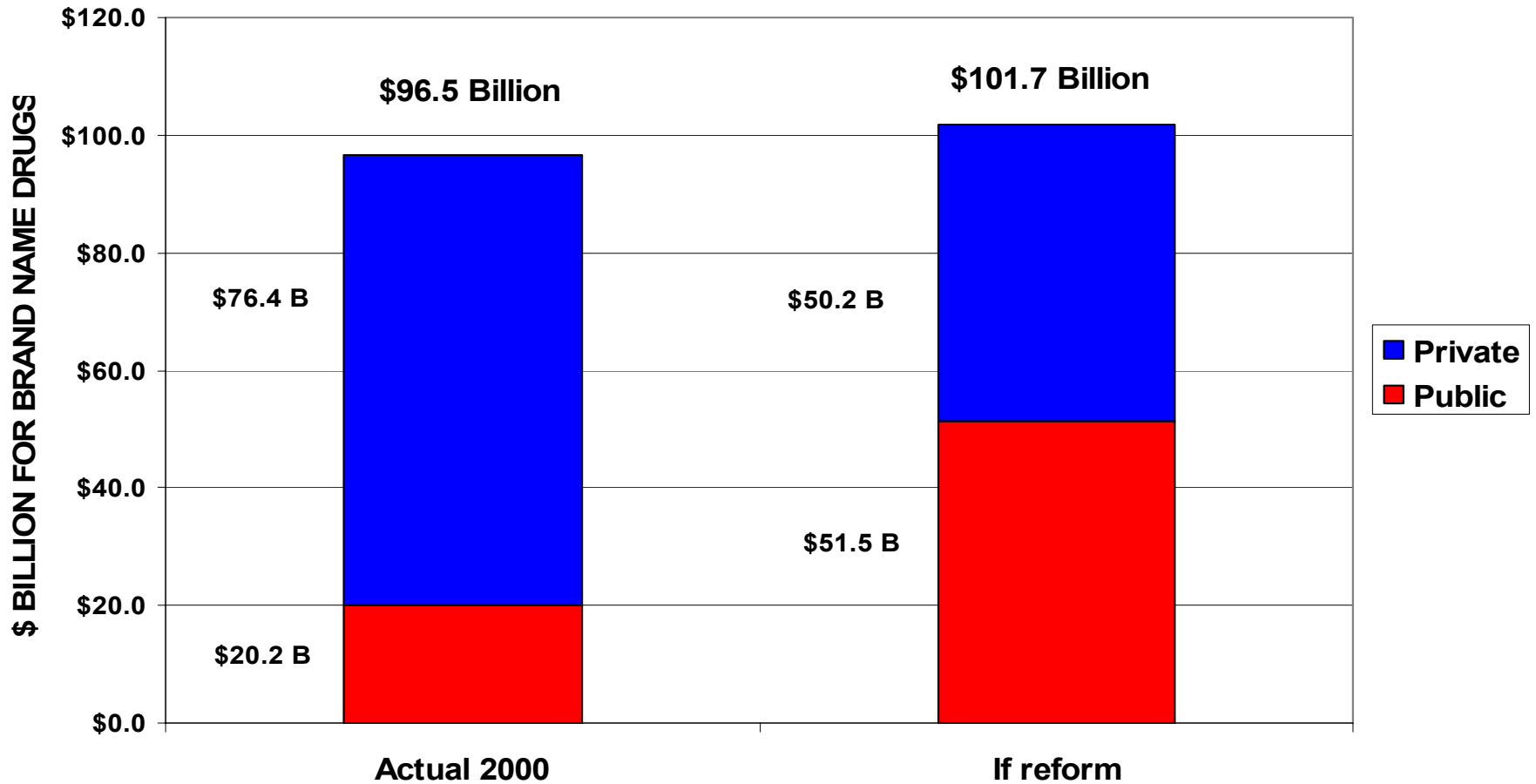
- **Public share of Rx cost rises visibly and private share falls somewhat less**
- **Asymmetry between pain and gain: private parties who pay less may be less vocal than taxpayers who pay more—unless enough people buy in to the package deal**

# BRAND NAME Rx PAYMENT BY SOURCE, 2000 AND POST-REFORM, AT FACTORY PRICES



	Total actual 2000	Total if reform
■ new public prog	\$0.0	\$34.6
■ hosp+NH	\$11.0	\$9.0
■ Medicaid	\$10.3	\$8.8
■ private ins.	\$53.8	\$44.3
■ cash	\$21.3	\$5.0

# ILLUSTRATIVE PUBLIC AND PRIVATE Rx PAYMENTS, BEFORE AND AFTER REFORM, FACTORY PRICES, 2000



# Complications and problems, short-run (2)

- How to measure revenue each manufacturer needs to sustain return on equity?
- How to set public payor's price for each drug at level needed to sustain company-wide return on equity, and cover each drug's marginal cost of manufacturing?
- Burden on pharmacies/pharmacists
- Risk to research and innovation

# Dealing with Complications

## short-run

- **We can learn from other nations' regulatory experience, such as U.K.'s profit regulations**
- **Researchers will find gainful employment measuring marginal costs and needed revenue**
- **Building a trusting private-public partnership is key to peace treaty**

# Dealing with complications short-run

- **Competition and regulation are allies, not antagonists.**
  - **Competition and adequate financing will spur innovation.**
  - **Regulation to lower price and achieve universal coverage will sustain political and financial support.**
- **We could make one lump-sum payment to each manufacturer in exchange for filling all prescriptions for their drugs**

# Inevitable limitations of short-run peace treaty

- **While short-term elements make today's meds affordable for all,**
  - They do little to slow rise in drug spending
  - They do little to squeeze out waste
  - Alone, they may sustain today's level of innovation but don't spur greater innovation



# Peace treaty provisions long-run elements

1. Raising the money
2. Paying for medications
3. Identifying and rewarding good innovation
4. Financing research
5. Protecting competition
6. Ending marketing waste
7. identifying and promoting affordable drugs

# 1. Raising the money

- **The public share of the Rx dollar will rise from about 20% to 50%.**
- **Why not go whole hog and consider complete public financing?**
  - + Would simplify administration**
  - Drug makers would see threat of constricted revenues if must compete in budget against other priorities**

## 2. Paying for medications

- **In a free market, we all pay the same price for the same thing**
- **Why should different payors pay different prices for drugs?**
- **So why not set a single price at which all public and private payors pay for the same drug?**

# 3. Identifying and rewarding good innovation

- After 5 years of short-term profit protection, future profits would depend on value of new drugs developed.
- Set prices on valuable innovative drugs to yield very generous but fair profits on investment
  - What is “very generous but fair”?
  - Enough to sustain desired level of investment
  - (What level of investment is desired?)

# **3. Identifying and rewarding good innovation**

- Drug makers claim that high profits are needed to finance risky research**
- But drug makers have not been willing to identify a profit floor below which research would suffer, or a profit ceiling above which no further useful research would be elicited**

# 3. Identifying and rewarding good innovation

- **Reward copy-cat research only in proportion to its benefits**
  - **If 40 % of research is copy-cat, ending it would liberate some \$9-10 B annually**
  - **Copy-cats no longer needed to engender competition to moderate prices, since regulation does that**

# 4. Financing research

- **Continued NIH budget growth means more public money to finance the riskiest research**
- **Politically, the public will increasingly demand a fair return on its growing investment, in the form of affordable medications**
- **How to ensure that innovation is not stifled by bean-counters or study sections?**

# 5. Protecting competition

- **Mergers mean less competition**
- **High marketing costs can spur mergers**
- **So can high research and development costs**
- **Competition requires competitors**
- **Removing dollar burden of marketing and sharing research costs with the public will spur competition, especially when innovation and value are rewarded**



# 6. Ending marketing waste

- **Drug makers boast about research spending**
- **But don't even estimate their own marketing costs**
- **Marketing cost estimates appear inaccurate and incomplete**
- **They are huge and growing**

# 6. Ending marketing waste

- **Marketing = wrong way to give doctors information on need, efficacy, or cost**
  - 1 of 4 MDs prescribes recommended antibiotic for urinary tract infection
  - Right Rx prescribed 49 % in 1990 but 24 % in 1998 (14 Jan 02 *Annals of Internal Medicine*)
- **Aggressive marketing of high-price drugs spurs payors to erect barriers to use**
- **Negotiate end to marketing as a peace treaty provision**

# 7. Identifying effective and affordable drugs and promoting their use

- **Well-insulated public or independent organization collates available evidence and collects additional**
- **Disseminate results to all physicians**
- **Recycle a fraction of the saved marketing dollars to finance this work, and use the rest of the savings to finance another \$10 B for research**

# Winning Durably Affordable Medications for All

- **A drug peace treaty will be difficult to negotiate and implement.**
- **But, since more money for business as usual is bad and unsustainable, we have no choice but to change.**
- **If we are smart and careful, winning affordable medications for all can be the easiest problem to solve in the U.S.A.**

