

PROTECTING CONSUMERS  
COMPLETELY AND REWARDING  
DRUG MAKERS FAIRLY:  
A prescription drug peace treaty  
for the U.S.A.

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# Trans-Atlantic Consumer Dialogue

## The Impact of Intellectual Property Rules on Consumers of Health Care Services

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# Acknowledgement

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conducted with my colleague,  
Deborah Socolar

# Web posting

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

# Overview

- I. Spending, prices, and unprotected people
- II. Three choices: death, dollars, discontinuity
- III. Paralysis
- IV. Action is vital
- V. Peace treaty

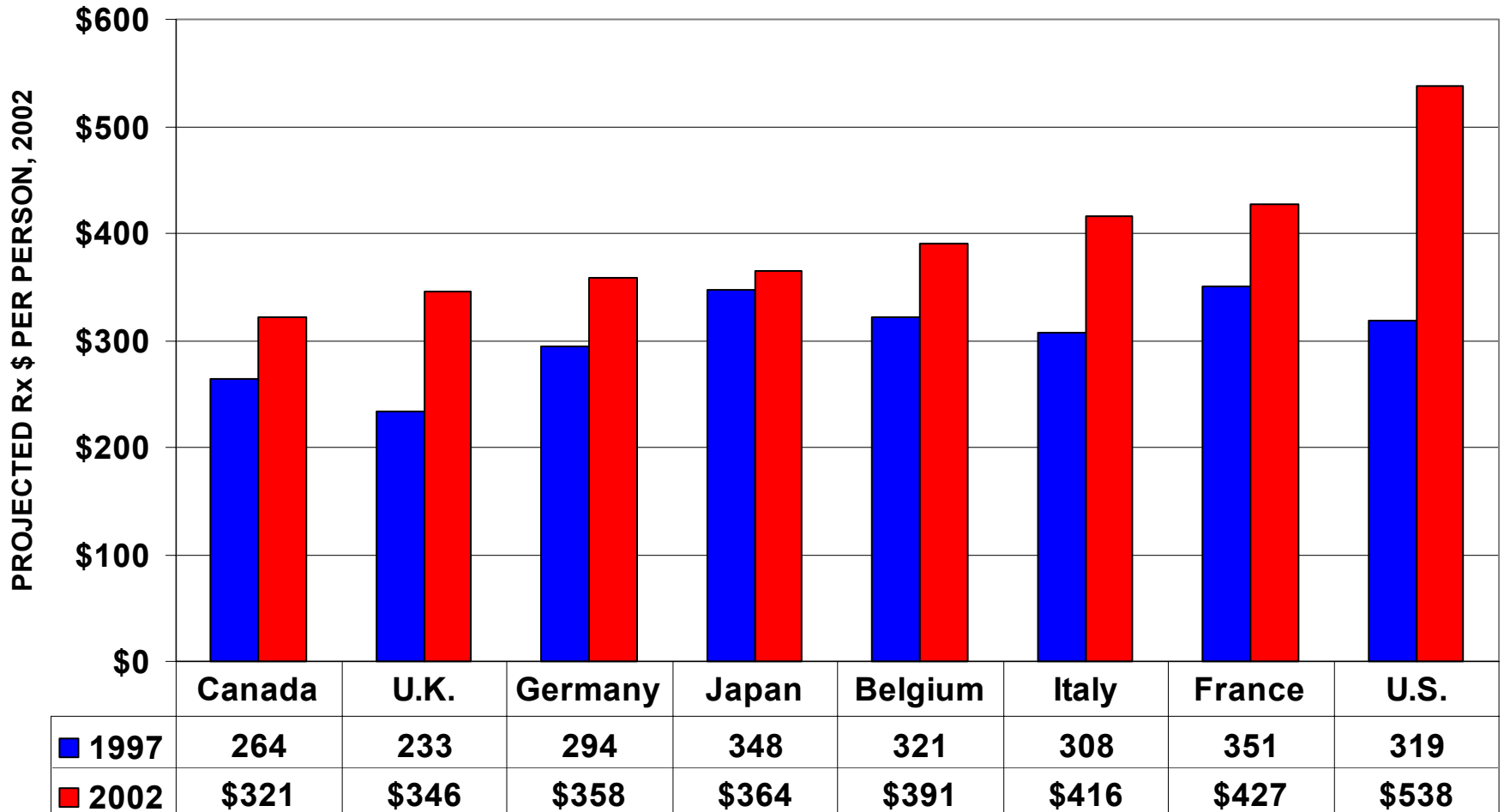
# I. Problems

A. Spending

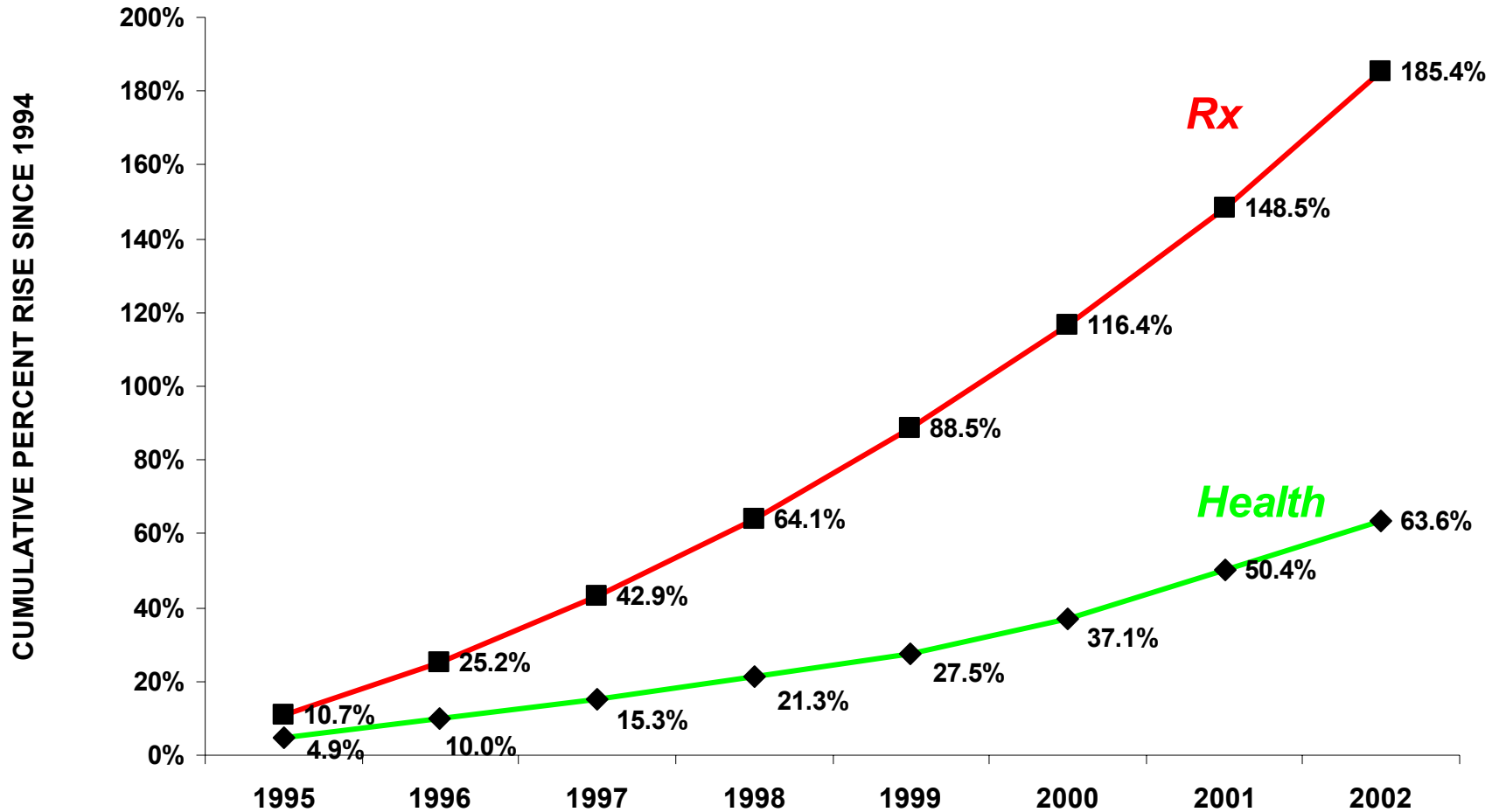
B. Prices

C. Unprotected people

# PRESCRIPTION DRUG SPENDING PER PERSON, 1997 + 2002 (projected)

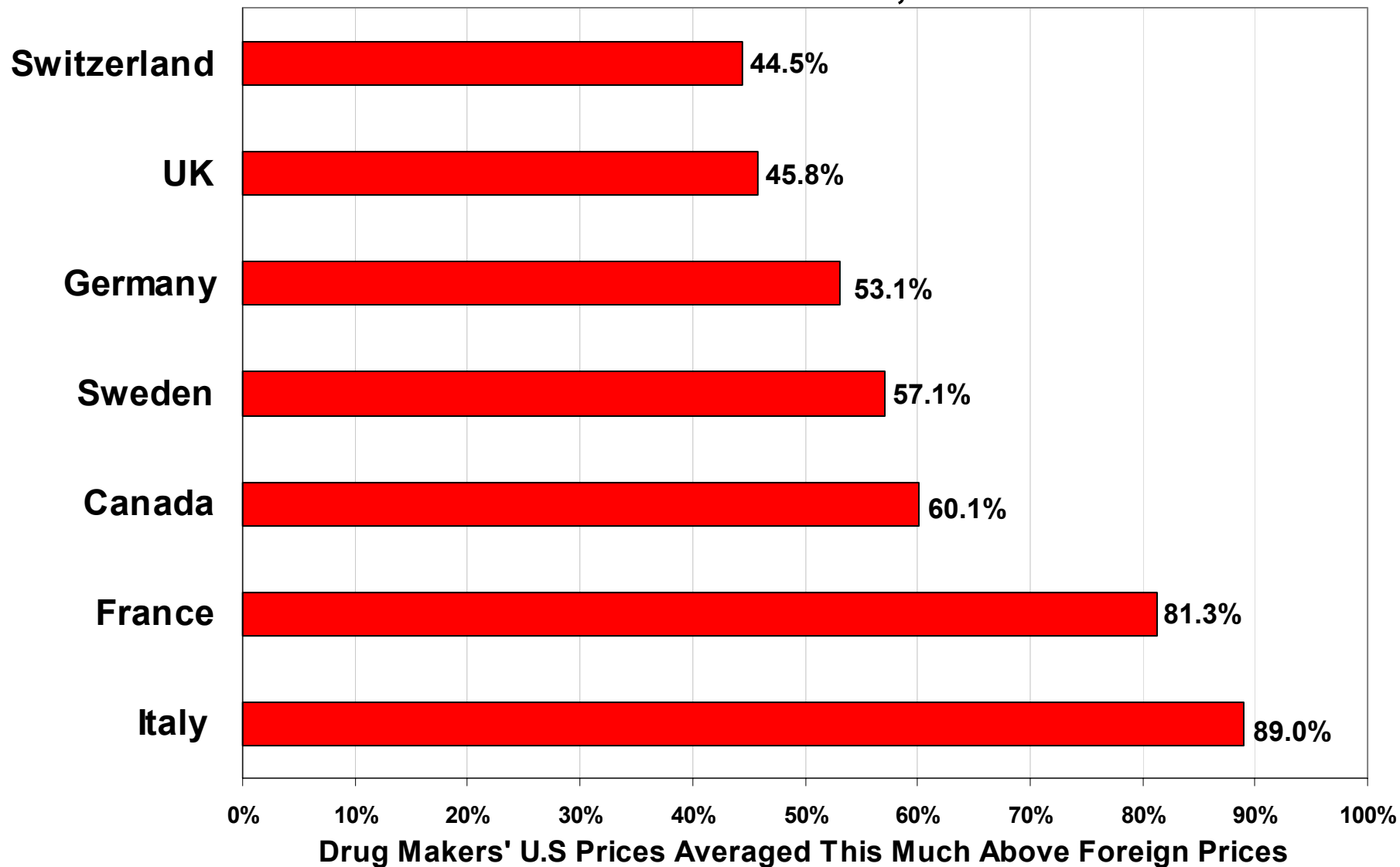


# CUMULATIVE RISE IN RETAIL Rx + TOTAL HEALTH SPENDING, 1994 - 2002

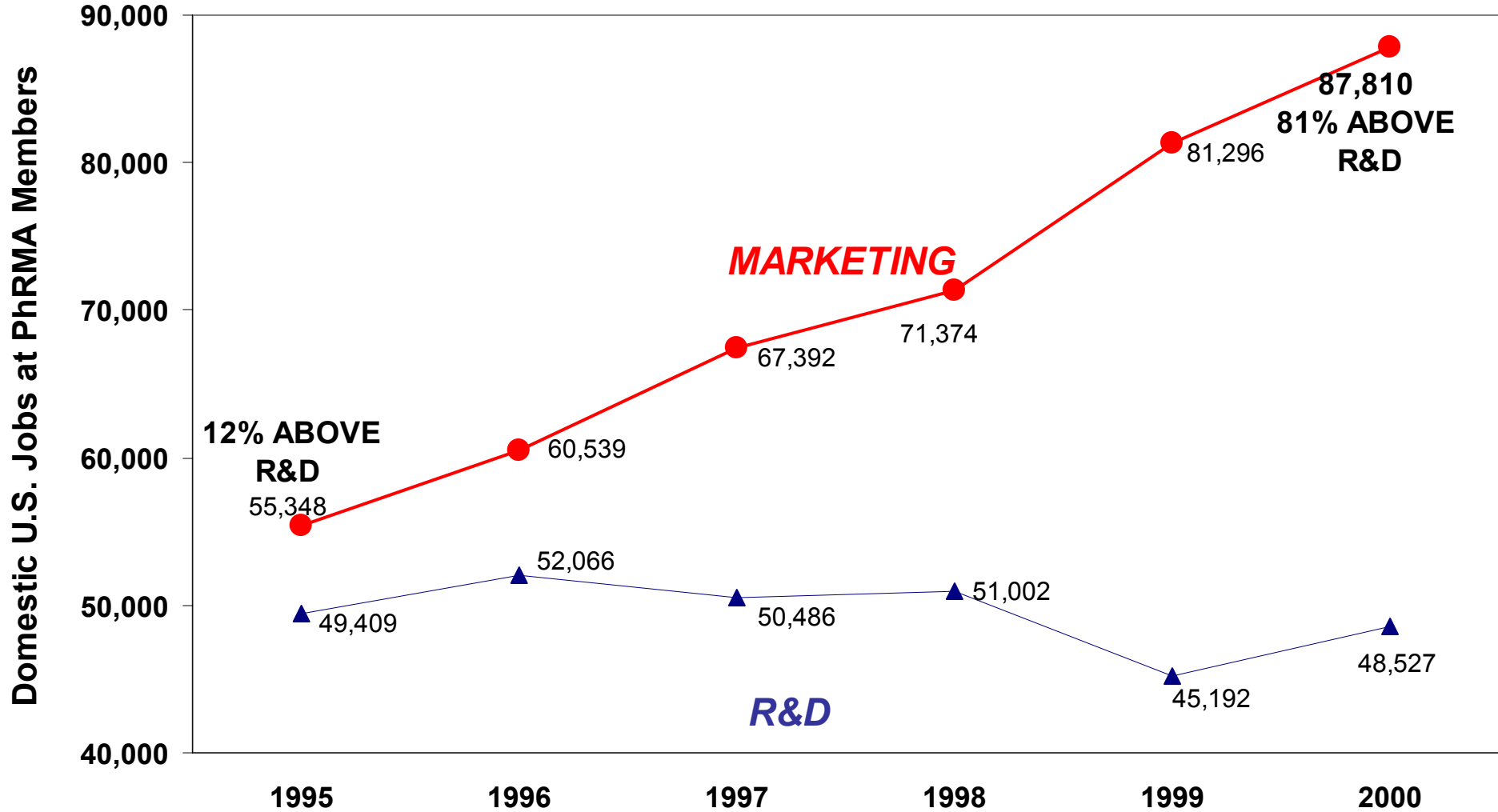




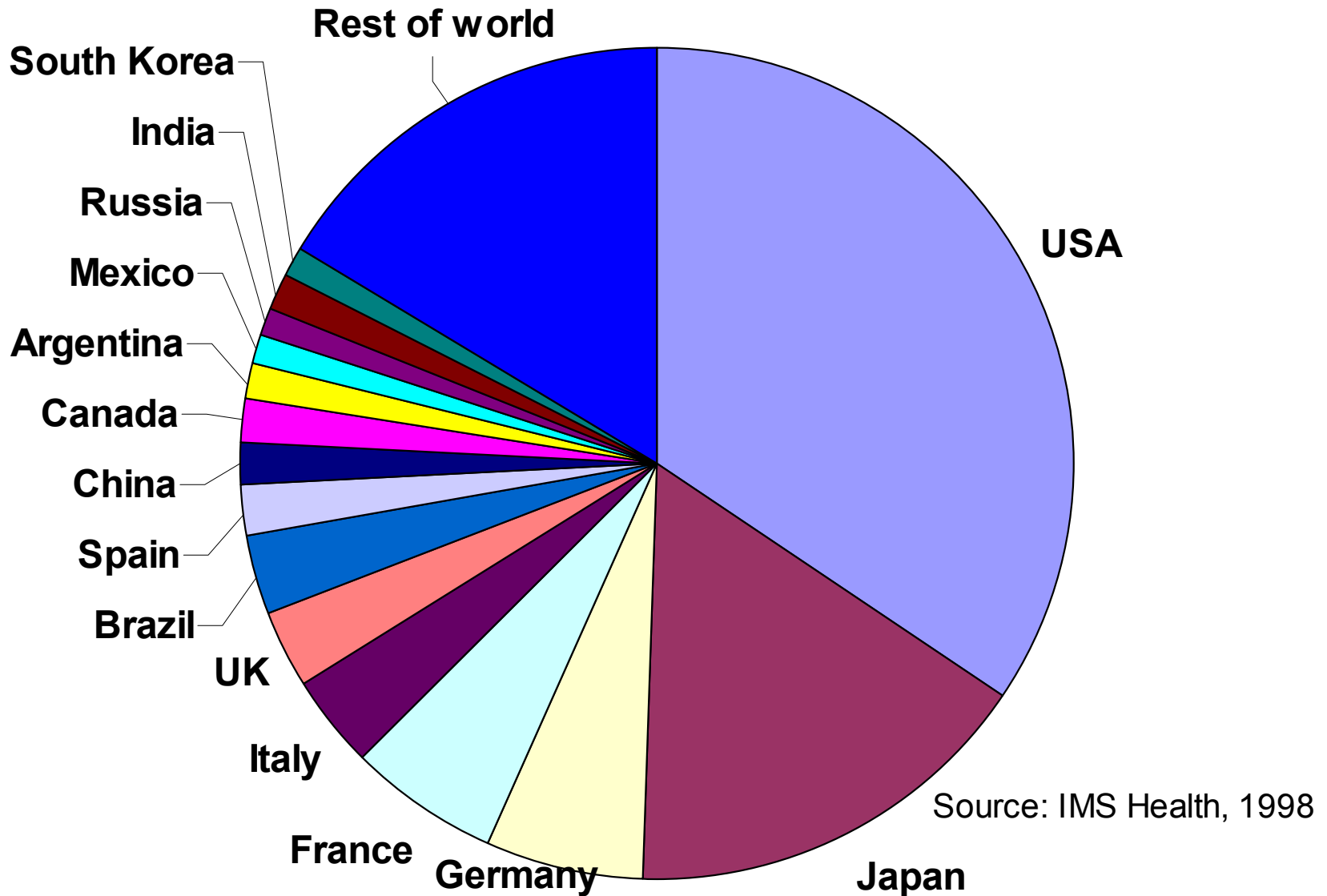
# U.S. EXCESS ABOVE 7 NATIONS' FACTORY DRUG PRICES, 2000



# BRAND NAME DRUG MAKERS' MARKETING AND R&D JOBS, 1995 - 2000

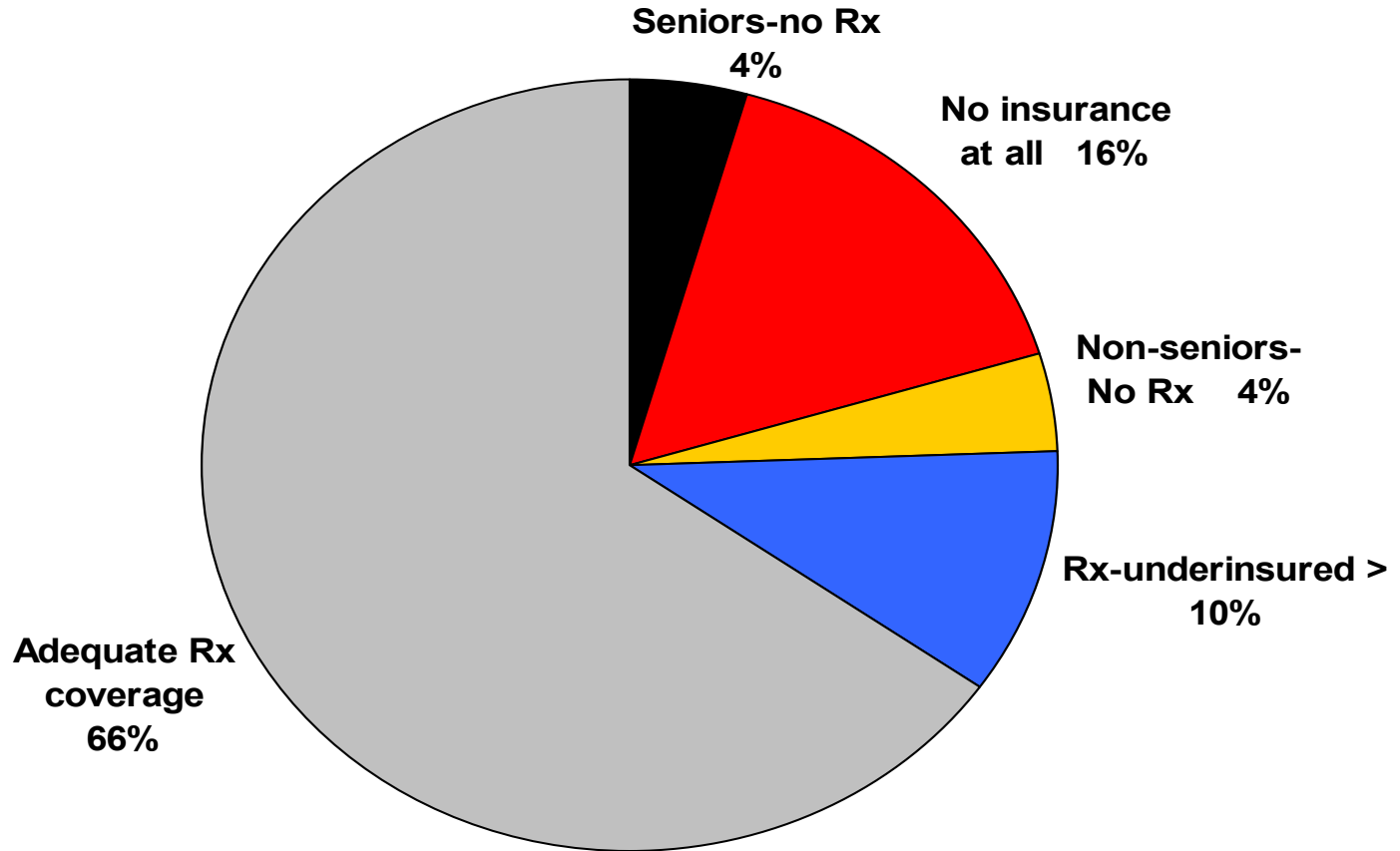


# SHARES OF WORLD DRUG MARKET, 1997



Source: IMS Health, 1998

# 98 MILLION LACKED PRESCRIPTION DRUG FINANCIAL SECURITY IN 2000



# Suffering is growing

- Employers cut retiree Rx coverage
- HMOs cut Rx benefits
- Rising Rx prices

## II. Three choices

## II. Three choices: death, dollars, 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.*

To-date, suffering, hand-wringing, and higher payments have been much more common than reasonable change and reform. New ideas are scarce. Americans tinker and innovate.



# In the face of growing suffering,

Congress has examined Medicare Rx benefit

States have sought to cope with rising costs

- More money
  - Senior pharmacy programs
  - Rx insurance
- Price control efforts
  - Maine Rx price limits
  - Extend Medicaid rebates to more people

# III. Paralysis

# III. Paralysis

Why has progress been slow?

- PhRMA's power + weak analysis = diversion of effort,
- wasting time coping with symptoms

# Solutions that have enjoyed good political currency

A. To lower prices or spending

B. To expand coverage

# To lower prices or spending

- PBMs
- formularies
- counter-detailing
- drug discount cards
- greater use of generics
- importing from Canada/Mexico
- de-insure patients--make them pay more
- fragmented public and private demands for discounts

# All are badly flawed

- Delaying actions and diversions, not solutions
- Probably won't be very effective in making drugs affordable
- ***No coordination*** between these controls and patients' needs or drug makers' needs
- If these controls do cut use and therefore spending, they may well cut dollars drug makers say are needed to finance research

# To expand coverage

- “Reform Medicare,” enroll elders in competing HMOs, and let those HMOs worry about Rx coverage
- legislate Medicare Rx benefit without substantial price controls
- Neither likely to be enacted
- Neither likely to work if enacted

# Why?

- Saving Medicare HMOs will be costly
- Medicare Rx without lower prices = high premiums and subsidies but low benefits
- Industry hopes for windfall profit on new volume
- Ten-year federal cost of modest plan
  - ❑ \$118 B - June 1999 and
  - ❑ \$318 B - June 2001
  - ❑ \$500 B - June 2002



# Underlying causes of paralysis

- PhRMA's power
- weak analysis
- failure of imagination

# Origins of PhRMA's power

- PhRMA's fog of fear
- PhRMA's desperate pursuit of strategies (fear + high prices + marketing) that cannot work in the long run
- Public worry that costs are rising so rapidly already--how will we be able to buy enough drugs to help even more people? Stunted empathy.

# PhRMA's Fog of Fear

- Years of denial that U.S. prices *were* high
- Then, high prices are good for us
  - High prices mean high profits, and high profits mean innovation
  - Price controls deter investment. “The lights go out in the labs, and there is no R&D.” (Baroni)
- And high prices result from market forces

# Dispersing the fog

- Recently soaring prices don't result from much breakthrough research
- Raising prices on existing drugs + more marketing = *substitute* for breakthroughs, not means to innovation
- No free market legitimates drug profits.

# Double anxiety

- Drug makers are the most nervous very-well-dressed people in the U.S.A.
  - High prices depress use, arouse political anger
  - Dearth of new breakthrough drugs
  - Over-reliance on high prices and marketing
  - Lack of fall-back position
- Their fear for future profits presses them to frighten us and to seek political protection.

# PhRMA's high prices: Enemy of research

- Claims that high prices and profits are essential to breakthrough drugs are thrown into question by May 02 NIH/CM report
- Soaring Rx spending will elect world's angriest Congress, which could slash prices, gutting research dollars. Not whether but when: 2004? 2006? 2008?

# Weak analysis

- Very low marginal, incremental cost of higher volume
- High prices deter use; low prices hike use
- Need for deal that protects all stakeholders
- Package deal means thinking in different ways--ways that depart from the tradition of opportunistic incrementalism
- Build on state efforts to provide more public money and to control price

# Stronger analysis

- ~ \$200 B for Rx in 2002 should be enough
- Pre-empt devastating price cuts
- Higher factory prices spur cuts in use
- Lower factory prices permit all needed use
- Total revenue = price \* quantity (!)
- Need *package deal* to align lower prices with higher volume, to protect total revenue, profits, and research



# IV. Public action is vital

Federal  
State

# Federal Action

- *Caution: With the U.S. buying over 1/3 of world's drugs, we must act cautiously, in ways that don't destabilize arrangements in other nations, rich or (especially) poor.*

## Advantages

- Power and scope to address drug makers
- Pre-empt possible Commerce Clause, ERISA, Medicaid, or other challenges
- Easier to eliminate/minimize reform by-products that could hurt other nations
- Medicare is logical starting point

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

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

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

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

# State Action

- Congress unlikely to move in time to protect public or drug makers
  - Lack real-world experience with solutions (recall the Clintons' 1993-94 effort)
  - Republicans seek Medicare reform via HMOs, but HMOs lack Rx solutions
  - Sticker shock of most Medicare Rx plans
  - Some states willing/able to tinker, innovate
  - Stakes are lower
  - More chances to talk with drug makers

# State Rx action: two choices

- Continued attention to Medicaid, state \$
  - Prior approval or Florida-style formularies. These offer one-time relief at best
  - Extend Medicaid price umbrella, as Vermont
  - Illinois-style rigid cap on federal Medicaid dollars for elderly in exchange for flexibility to extend Rx benefit to more seniors. Risky.
- Combine two traditional state approaches-- more state money + cost controls-- to win affordable Rx for all citizens

# Seeking affordable medications for all citizens

- State establishes itself as unique wholesaler
  - Buys on behalf of all residents
  - Takes legal title, not physical title, allowing drugs to be distributed as today
  - Why should different payors pay different prices for drugs? In a free market, we'd all pay the same price for the same thing.
  - So why not set a single price, which all public and private payors pay for the same drug?

# Seeking affordable medications for all citizens

- State establishes itself as unique buyer/  
single payor for prescription drugs, carving  
out Rx from all existing health plans. This  
facilitates covering everyone but means  
higher taxes.
  - State pays prescription by prescription
  - Or state contracts for unlimited volume using  
flexible budget (paying for higher volume at  
marginal or incremental cost)



# V. Peace Treaty

# Peace treaty **aims**

- **Short-run:** To finance and deliver all existing medications to all Americans who need them, at the lowest possible spending increase consonant with protecting research and manufacturers
- **Long-run:** To increase financing of breakthrough research, cut waste, get right medications to the patients who need them

# Peace treaty provisions, short-run

1. Legislate Canadian-level factory prices for brand-name drugs, cutting manufacturers' U.S. revenues by ~ \$40 B in 2002  
-- 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 \$40 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.

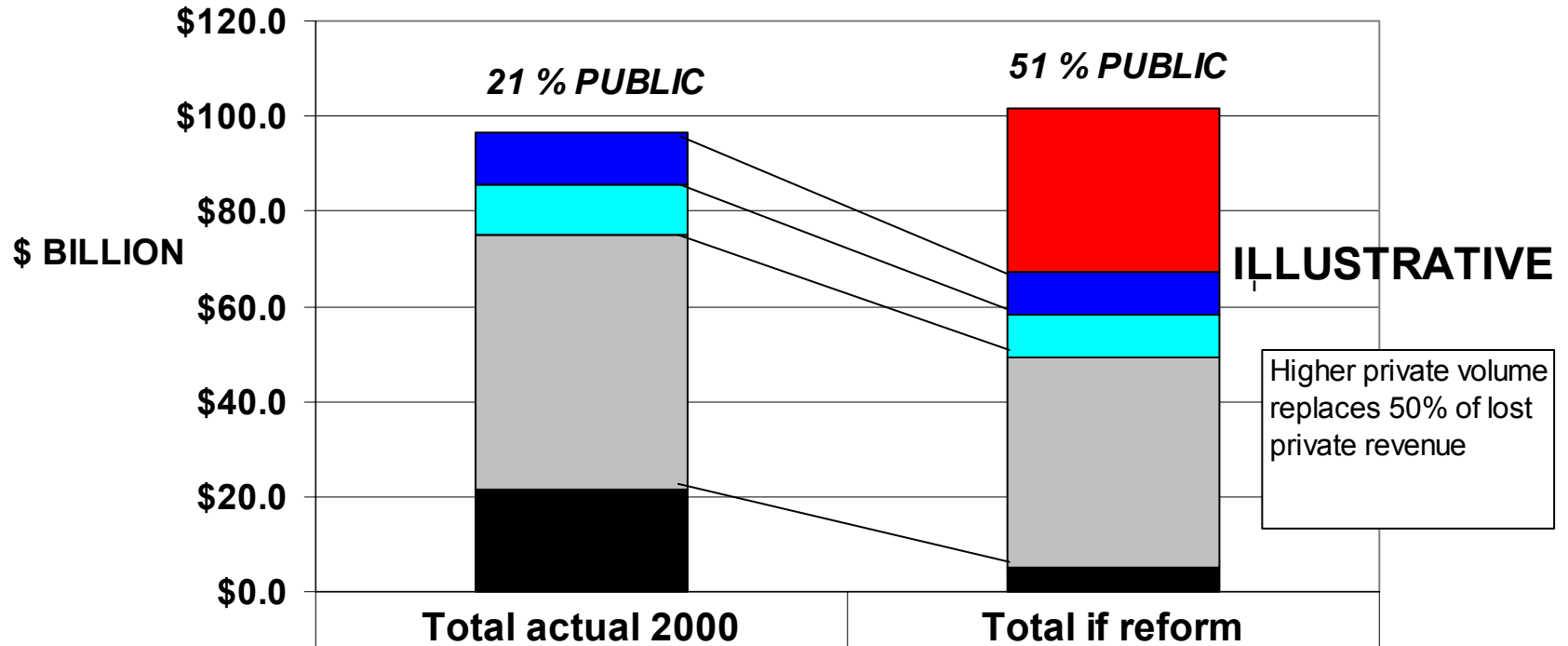
# Strengths of short-run elements

- All prescriptions needed by Americans are filled, a rise of perhaps 1 billion more than today's 3 billion
- Incremental cost = 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

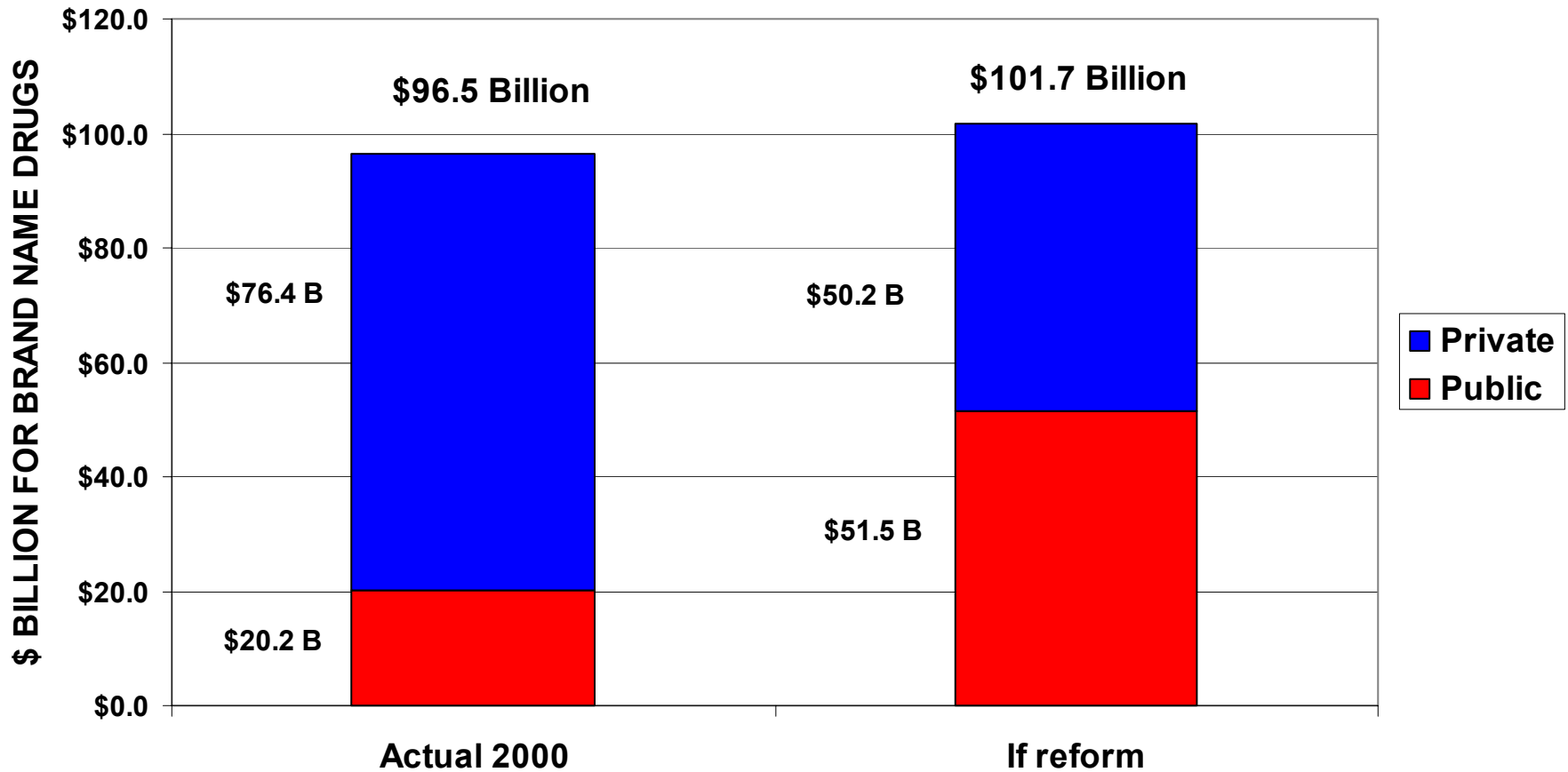
# BRAND NAME Rx PAYMENT BY SOURCE, 2000 AND POST-REFORM, AT FACTORY PRICES



	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



# 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.

# Inevitable limitations of short-run elements

- 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.
- Cease rewarding copy-cat research unless it offers demonstrably big benefits
  - It's no longer needed to engender competition to hold down prices, since regulation does that

### 3. Identifying and rewarding good innovation

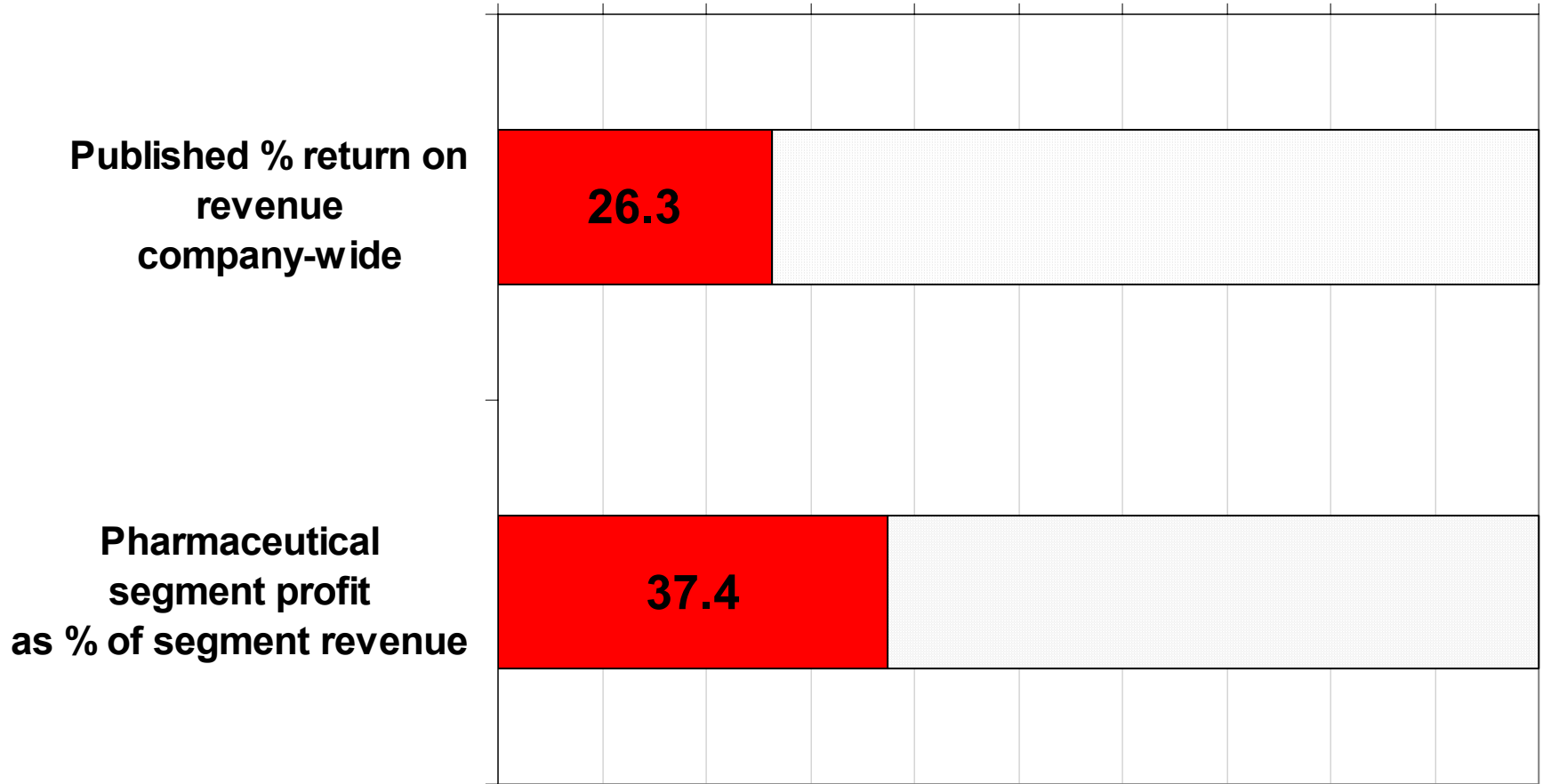
- If 40 % of research is copy-cat, ending it would liberate some \$9-10 B annually
- Set prices on valuable innovative drugs to yield generous but fair profits on investment
- What is “generous but fair”? Enough to sustain desired level of investment
- (What level of investment is desired?)

### 3. Identifying and rewarding good innovation

- To begin to set a benchmark, we need to know current profits *on making drugs*
- Merck, for example, reported company-wide return on revenue of 26.3 % in 1999
- How much did it make on prescription drugs, after teasing out its low-return-on-revenue Medco business?

# Merck Firm-Wide and Pharmaceutical Segment Return on Revenue, 1999

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%



### 3. Identifying and rewarding good innovation

- A 37.4 % return seems high
- Drug makers claim that high profits are needed to finance risky research. But each year's profits are residue after financing research, and have been high for decades
- And they have not been willing to identify a profit floor below which research would suffer, or a profit ceiling above which no further research would be elicited

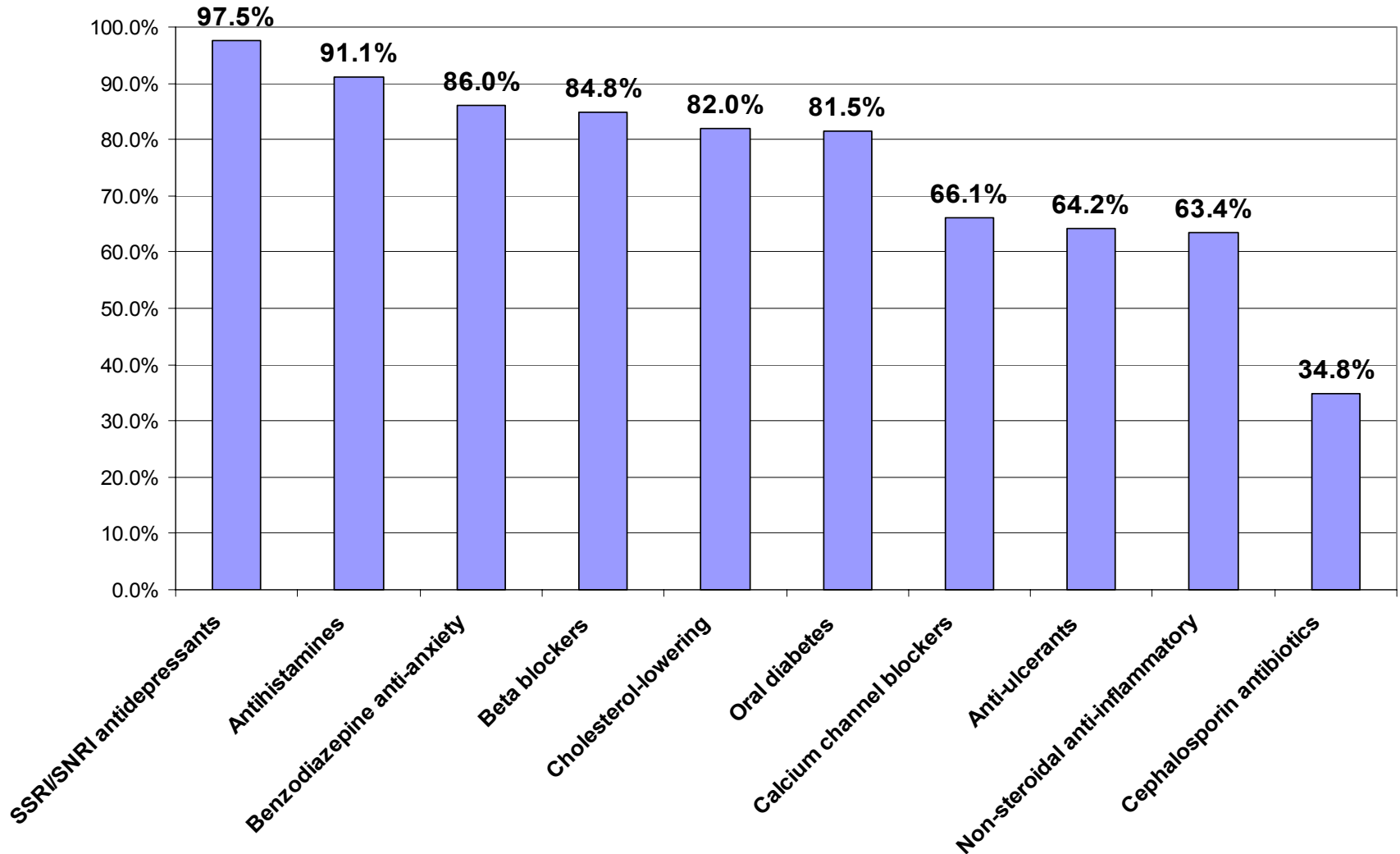
## 4. Financing research

- 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
- Eliminating marketing costs and sharing research costs with the public will spur competition, especially when innovation and value are rewarded

# MARKET CONCENTRATION IN THE TOP THERAPEUTIC CATEGORIES, 1998





## 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 *Ann Int Med*)
- 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

- Insisting on more money for business as usual will raise private barriers to use, spur radical public action to slash prices, or both
- Better to combine the two initial and more recent threads of state governments' efforts
  - to finance care for uninsured people and
  - to cut prices

And combine them in one peace treaty

# Winning Durably Affordable Medications for All

- A peace treaty will be difficult to negotiate and implement
- But if more money for business as usual is unaffordable and unsustainable, what is the alternative?