

# Prescription Drug Expenditures: What Do We Really Know?

**Assembly, California Legislature**  
*Committee on Health*

**March 11, 2003**  
**Sacramento, California**



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**Professor and Director**

***PRIME* Institute, University of Minnesota**

# Overview

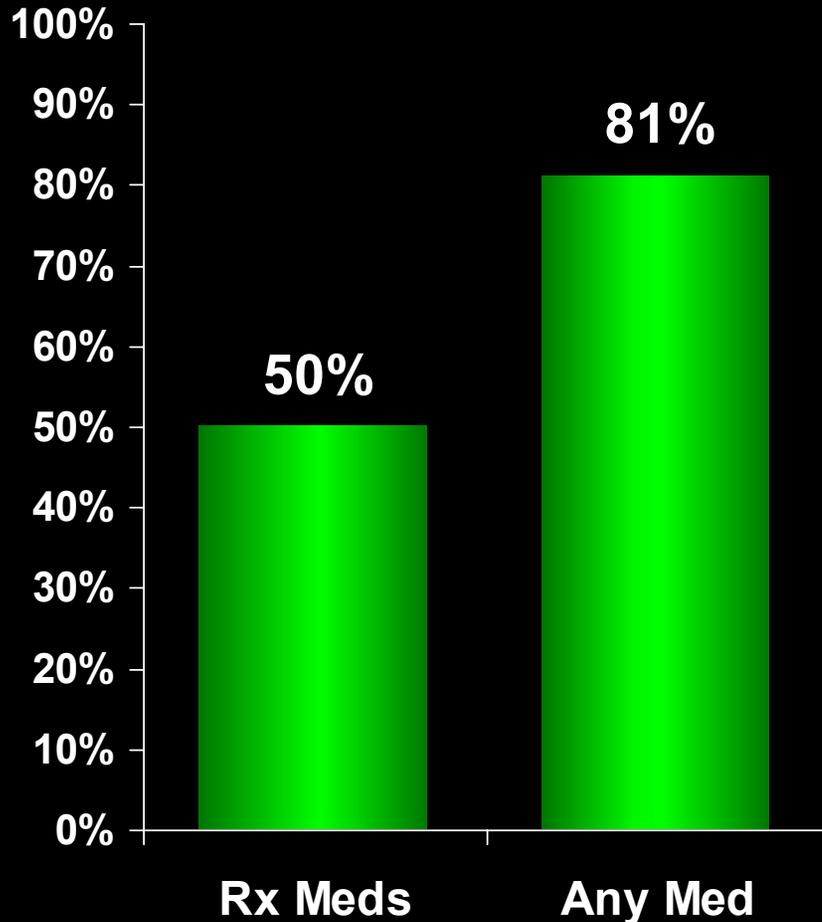
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## *What are the issues?*

- **Need for Medication**
- **Need to Question Obvious Assumptions**
- **Pharmaceutical Pricing Issues**
- **Does the Pharmaceutical Market Work?**
- **What Are Potential Roles for the State?**

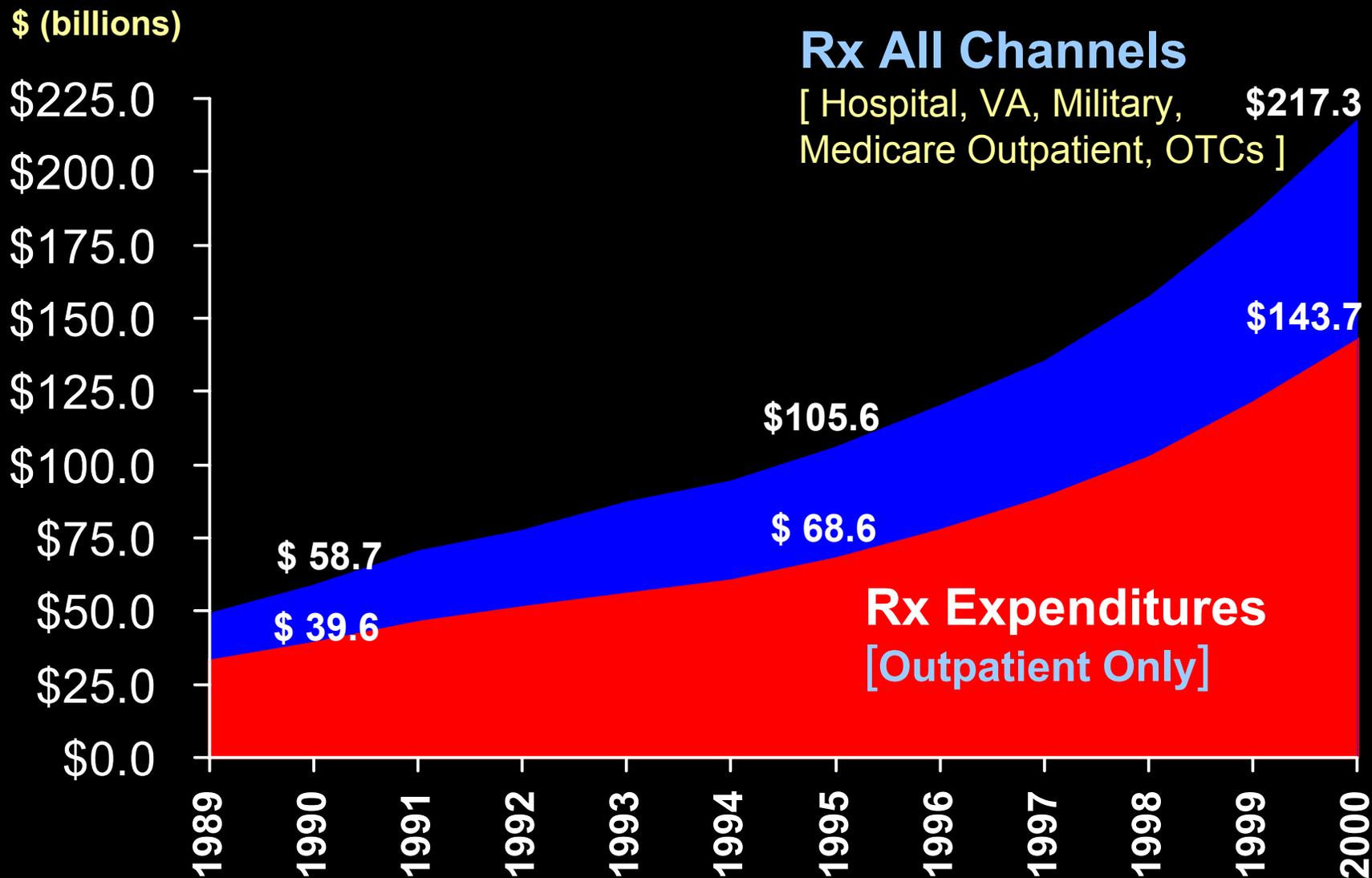
# **% of Adults Using Medication in Previous Week**

**% Using Meds  
In Previous Week**



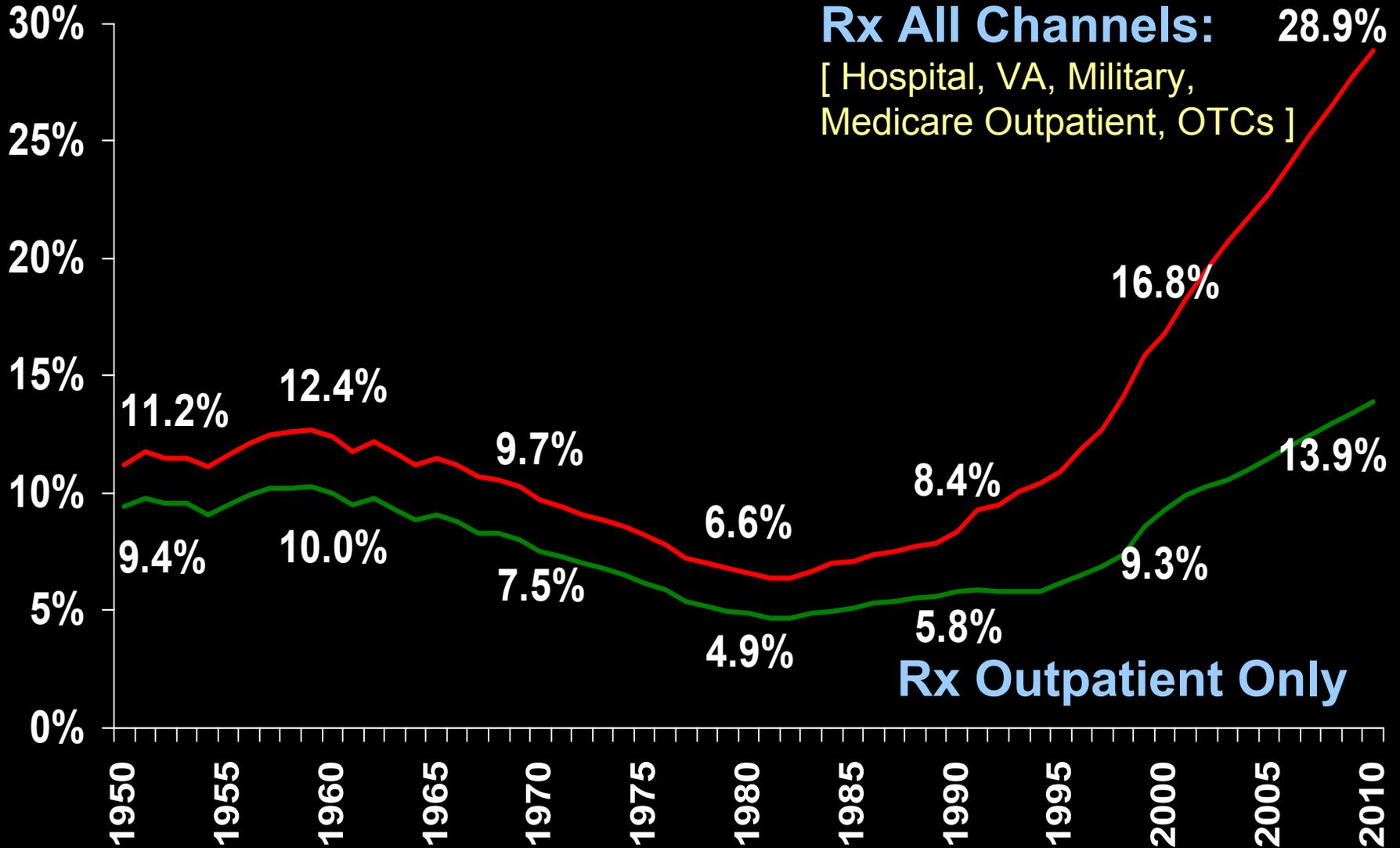
- **Virtually everyone in society needs, or will use Rx drugs**
- **Lack of access can mean life & death to a person**
- **Medications are an essential societal resource**

# U.S. Rx Expenditures: 1989 to 2000



# U.S. Rx Expenditures as a % of NHE: 1950-2010\* (est. 2001-2010)

% of NHE



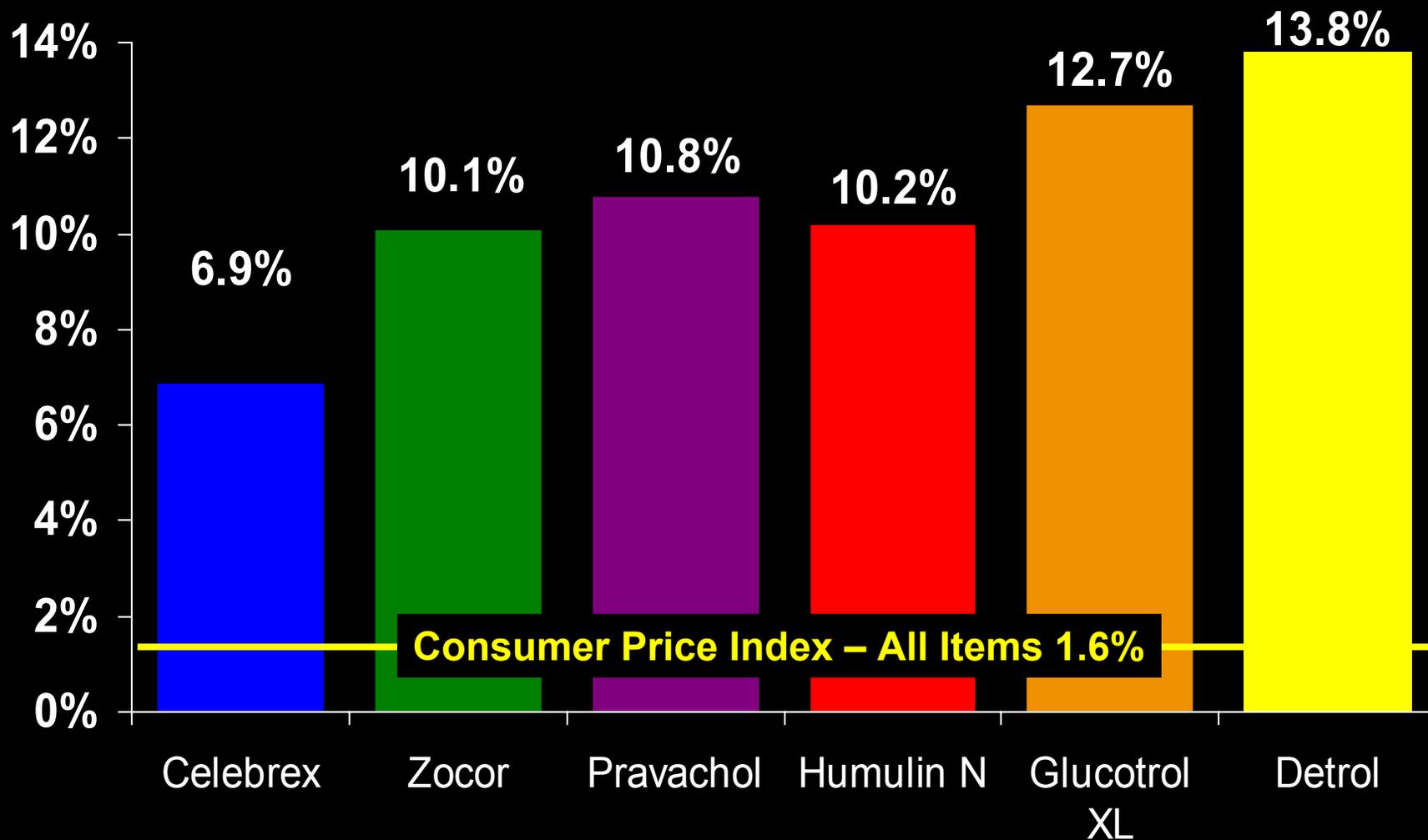
**We Spend More on  
Rx Drugs Than We  
Usually Admit**

**Are Drug Prices &  
Price Increases  
an Issue?**

# Recent Drug Price Increases: Jan 1, 2002 vs Jan 15, 2003

% Change in Price  
2003 v 2002

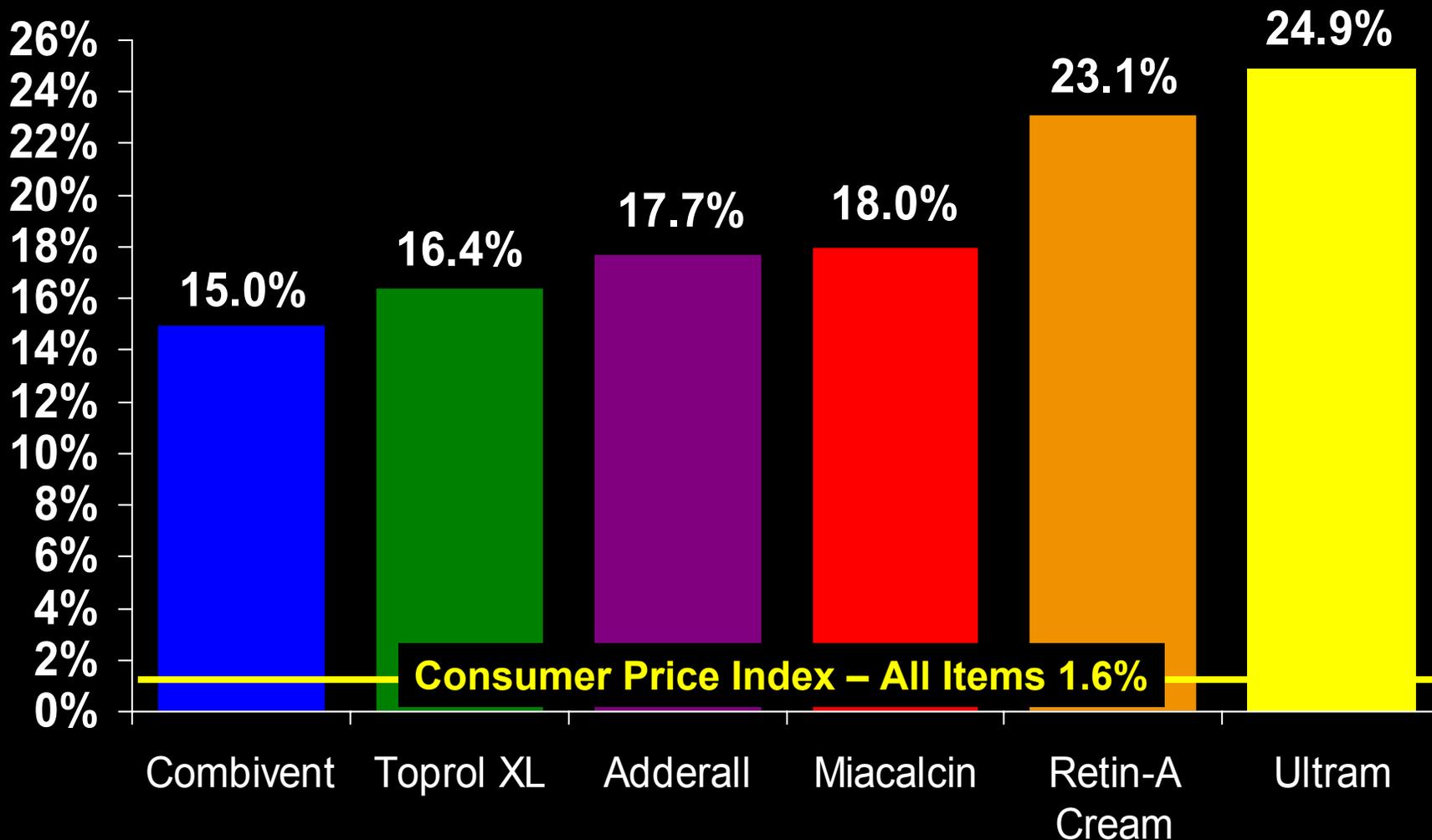
(Average Wholesale Price)



# Recent Drug Price Increases: Jan 1, 2002 vs Jan 15, 2003

% Change in Price  
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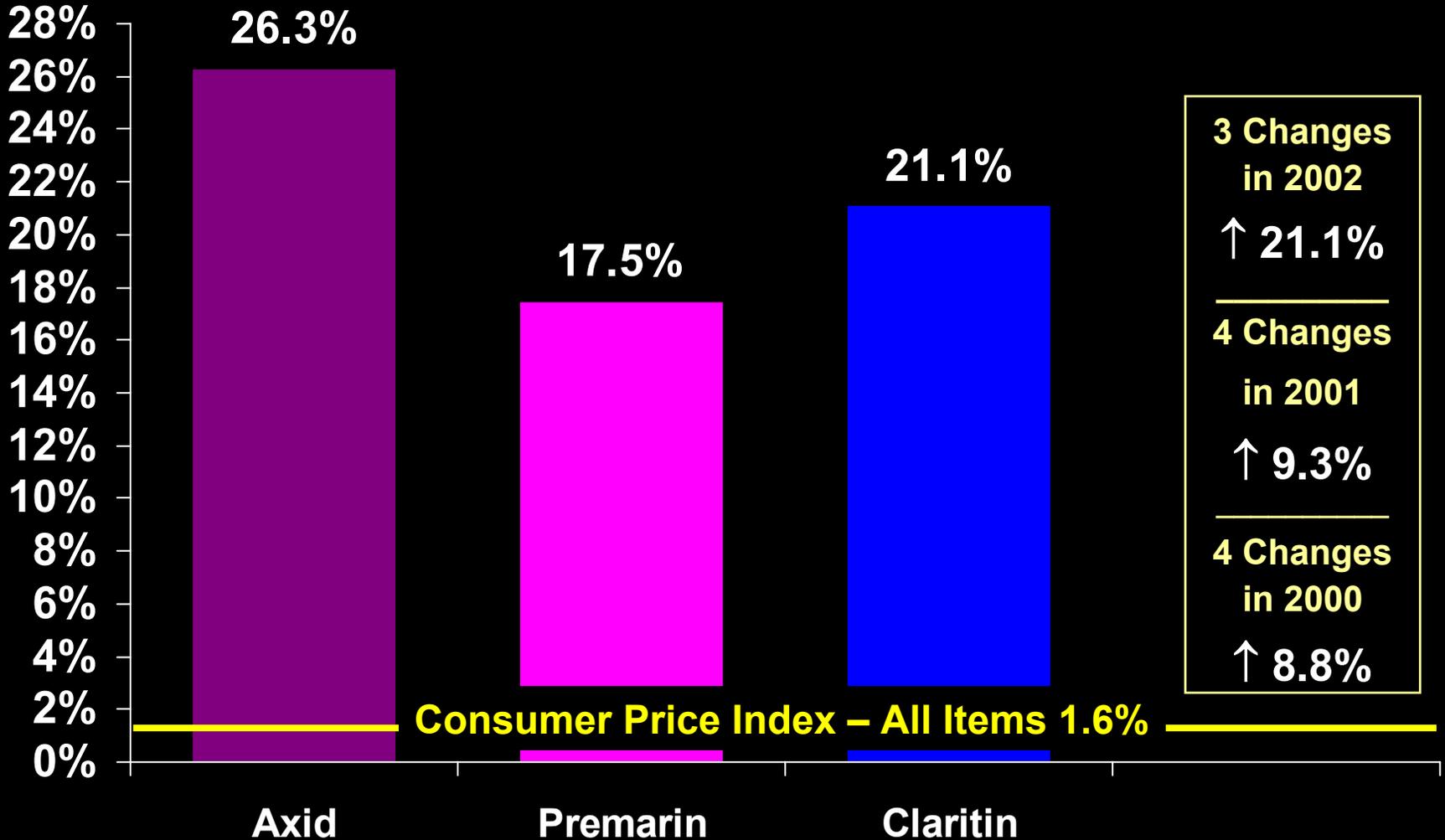
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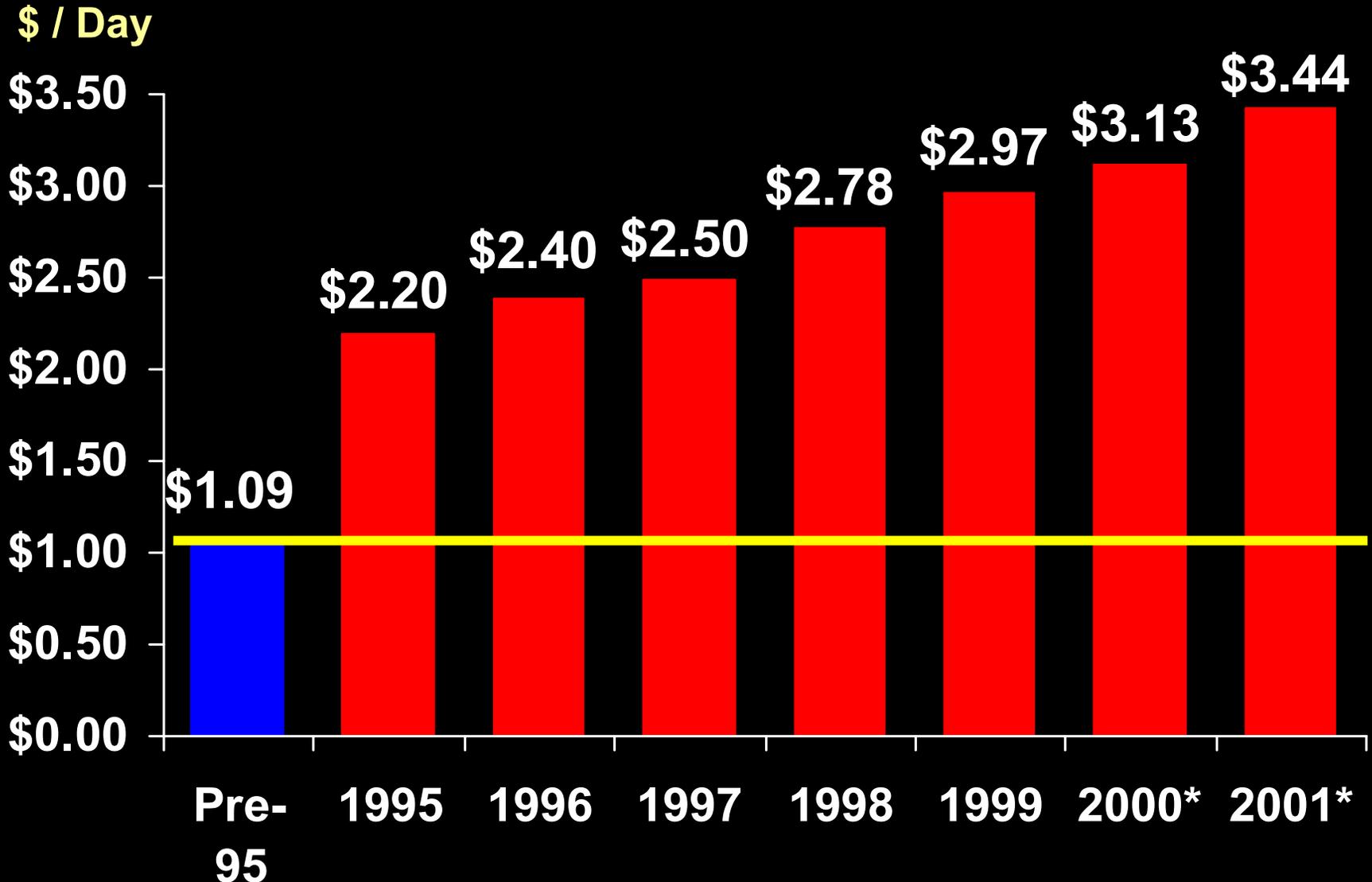
# Recent Drug Price Increases: Jan. 1, 2002 vs Jan. 15, 2003

(Average Wholesale Price)

% Change in Price  
2003 v 2002



# Average Cost per Day of Therapy New vs. Old Drugs: Pre-1995 to 2001



Source: National Institute for Health Care Management and “\*” estimates by the PRIME Institute, University of Minnesota.

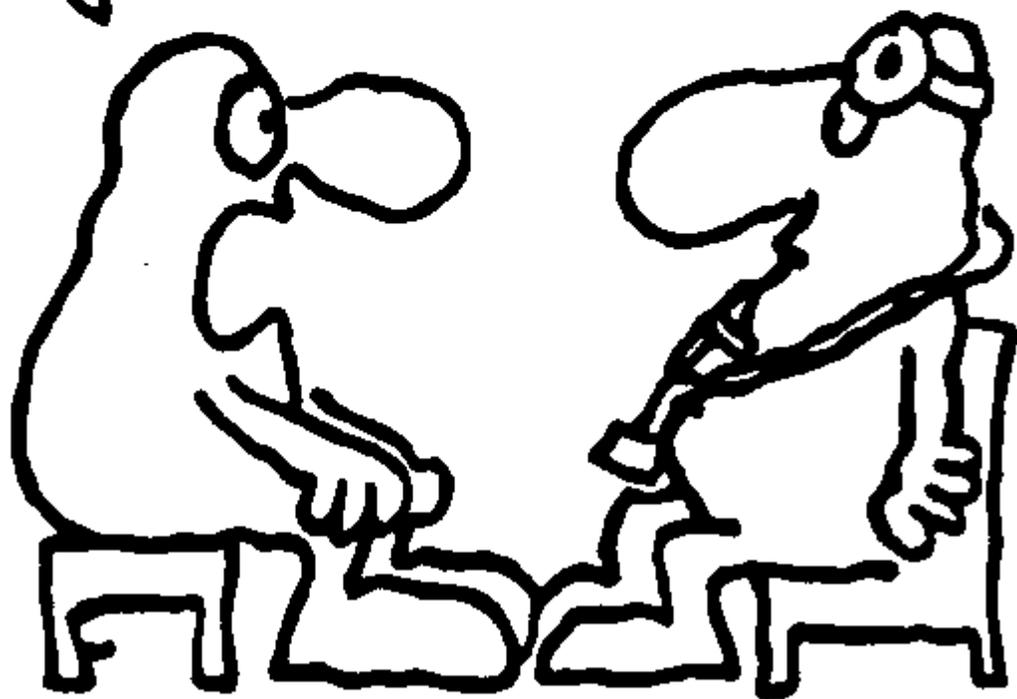
# Rx Price Impact

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*Does AWP price increase matter?*

- ◆ **AWP**  **Will Result in:**
  -  **Medicaid Payments**
  -  **Employer Payments**
  -  **Cash Payer Payment**

DOCTOR, HOW SICK  
AM I - IN DOLLARS  
AND CENTS?



# Consumer Perspective on Safety, Effectiveness & Cost

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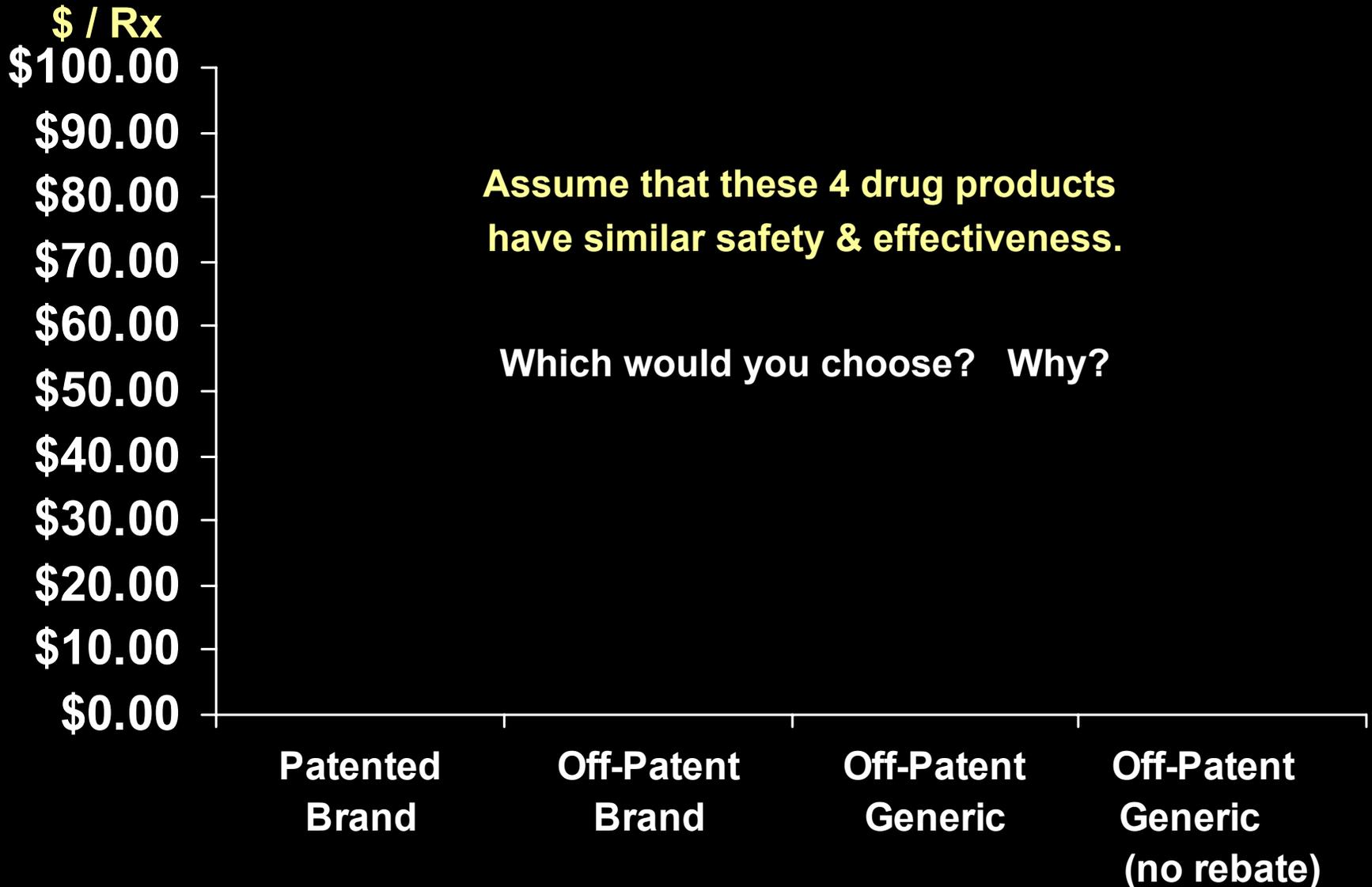
**“A drug that  
one can not afford is  
neither safe nor effective.”**

*-- Stephen W. Schondelmeyer  
PRIME Institute, 1996*

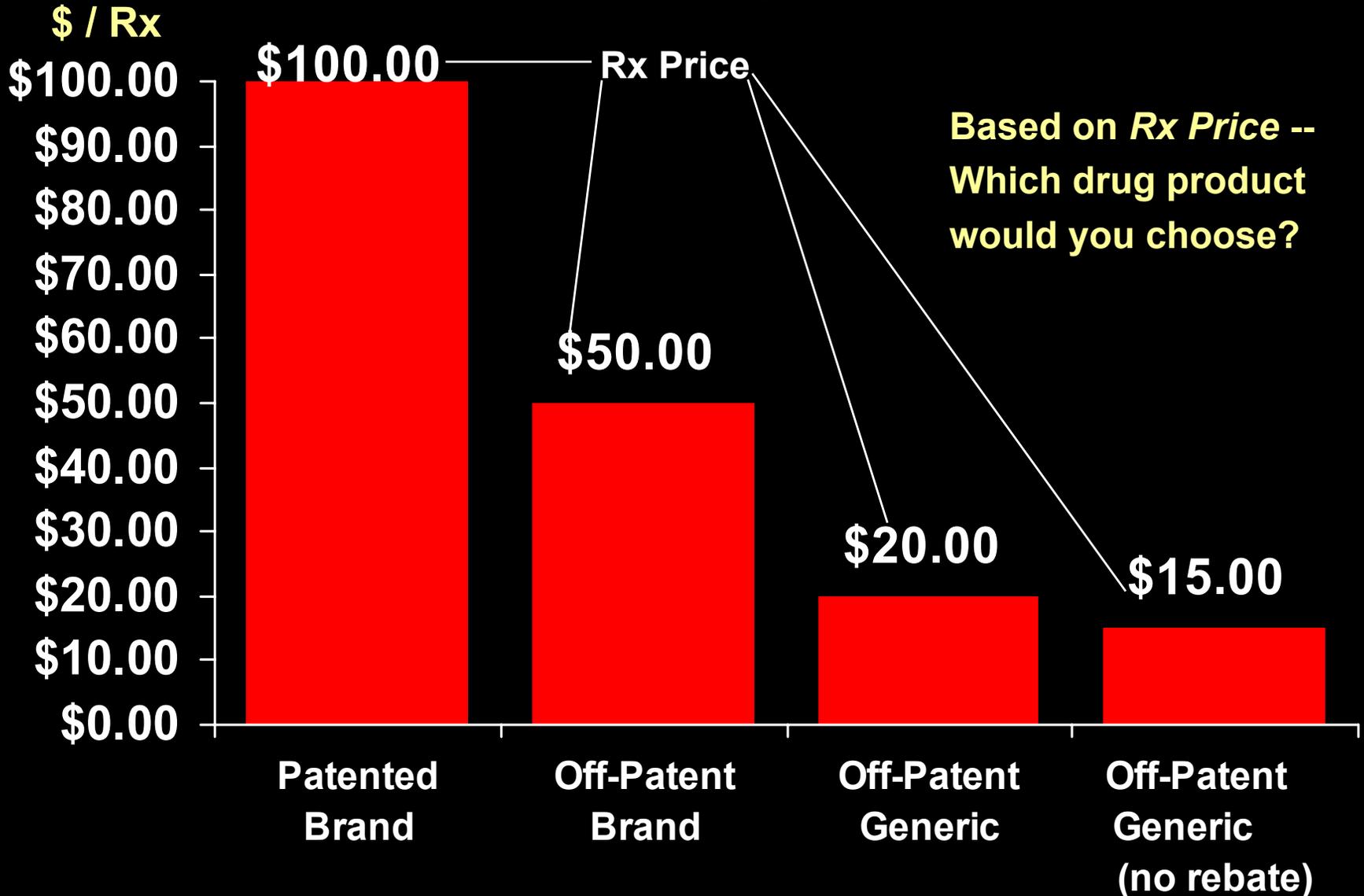
**Drug Price Increases  
Are a Major Part of the  
Current  
Drug Spending  
Situation**

**Do More Rebates  
Assure  
Lower Net Price?**

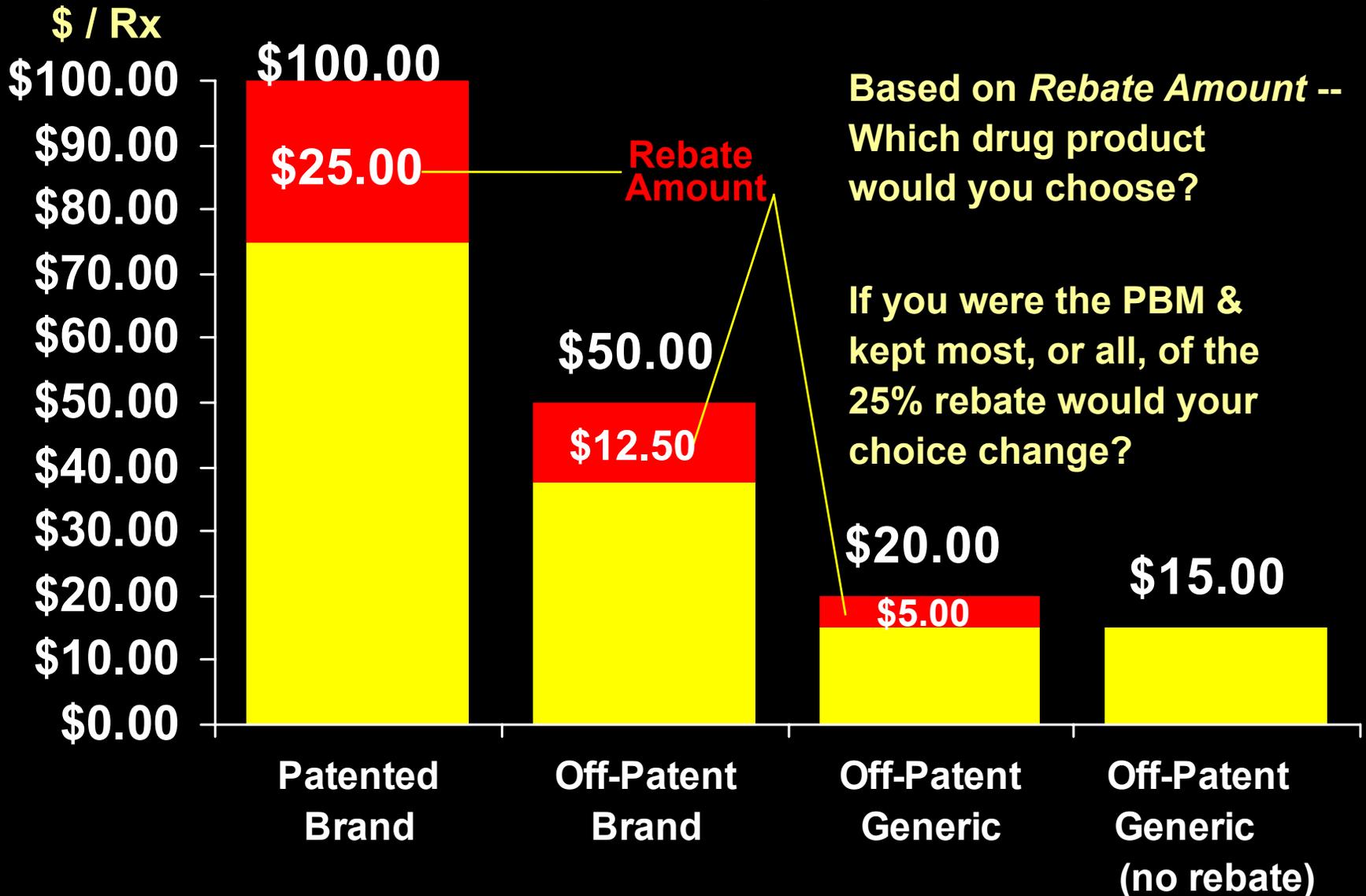
# Prescription Prices, Rebates & Net Cost to Payer & Patient



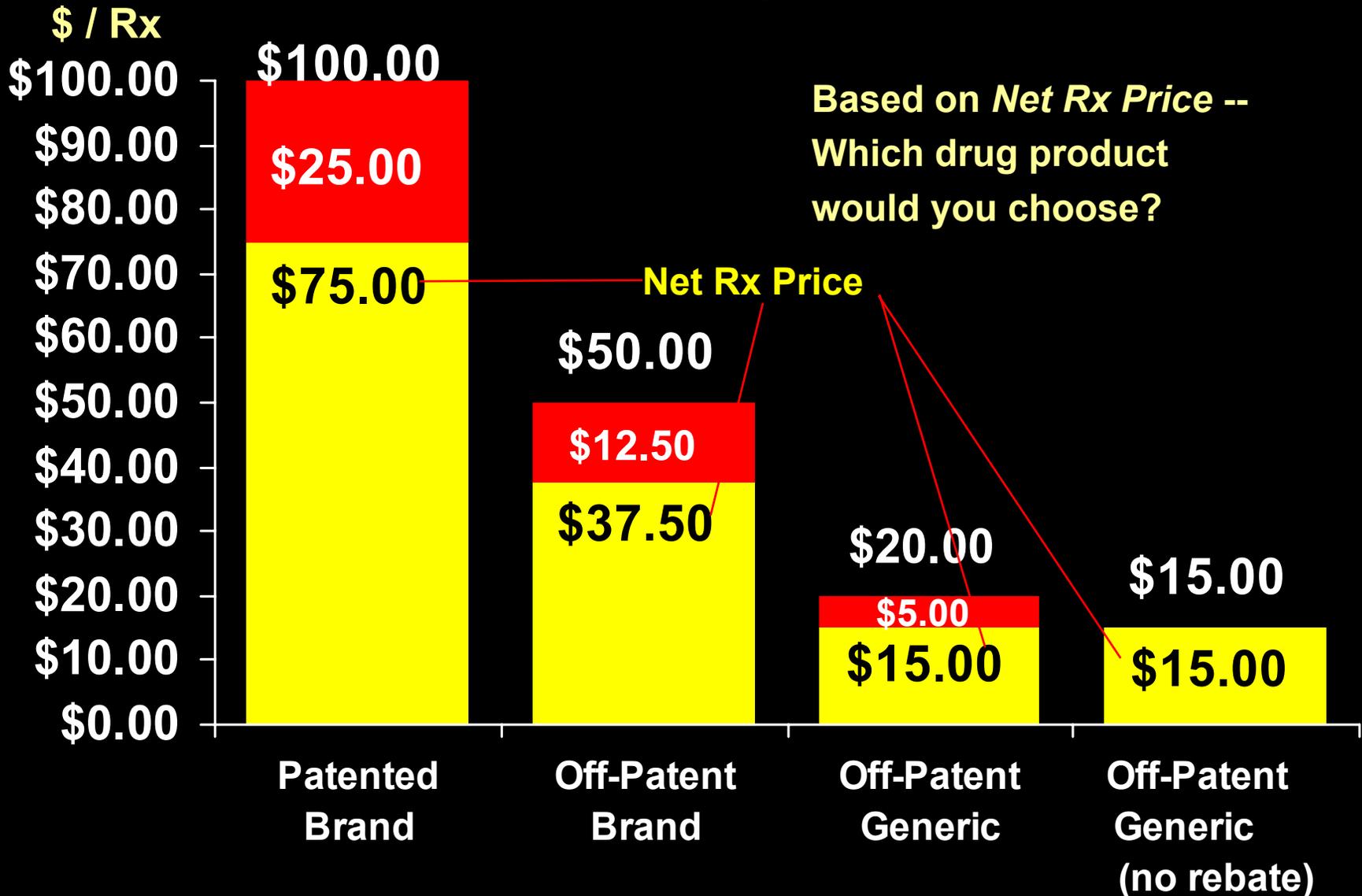
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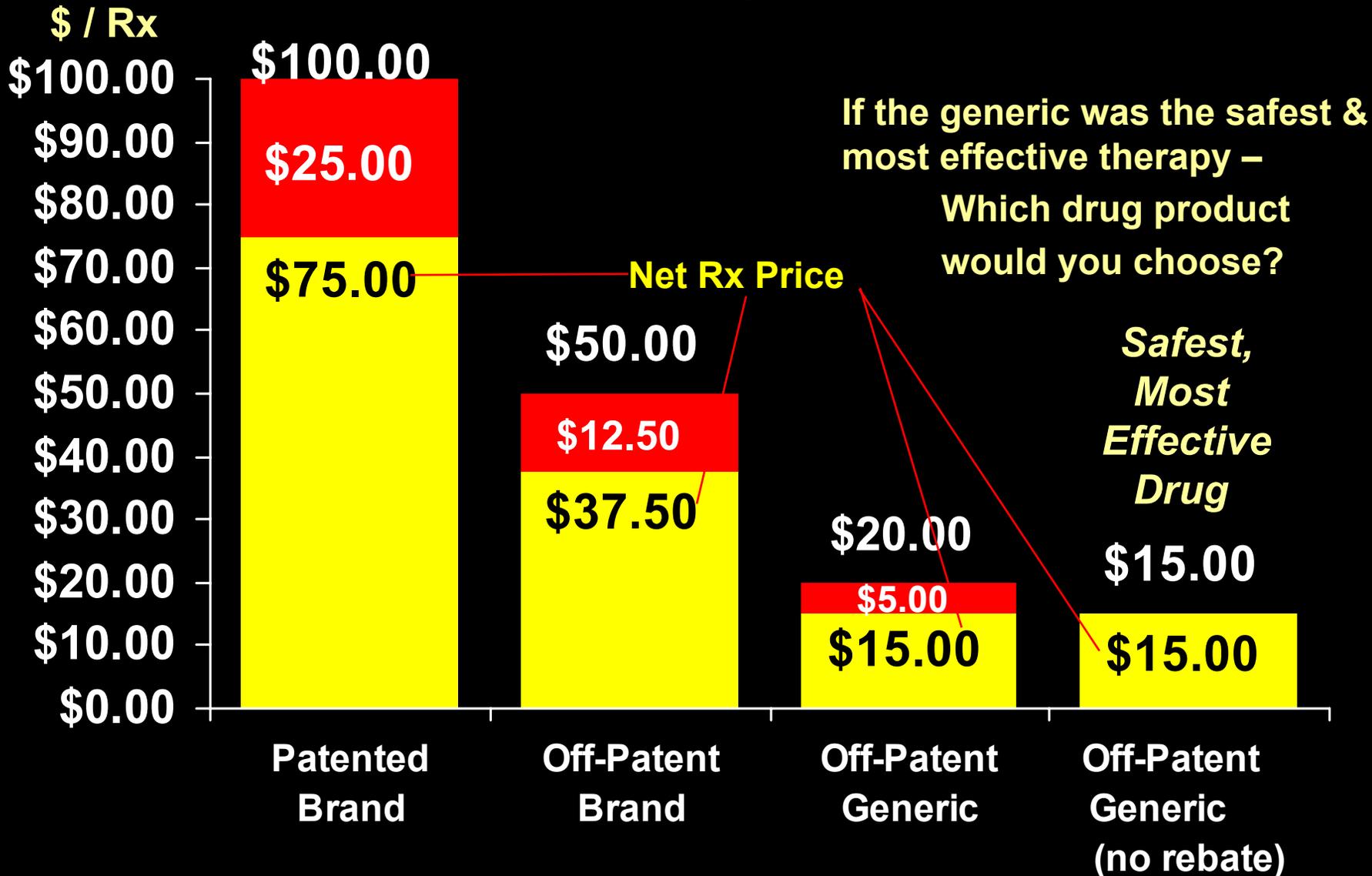
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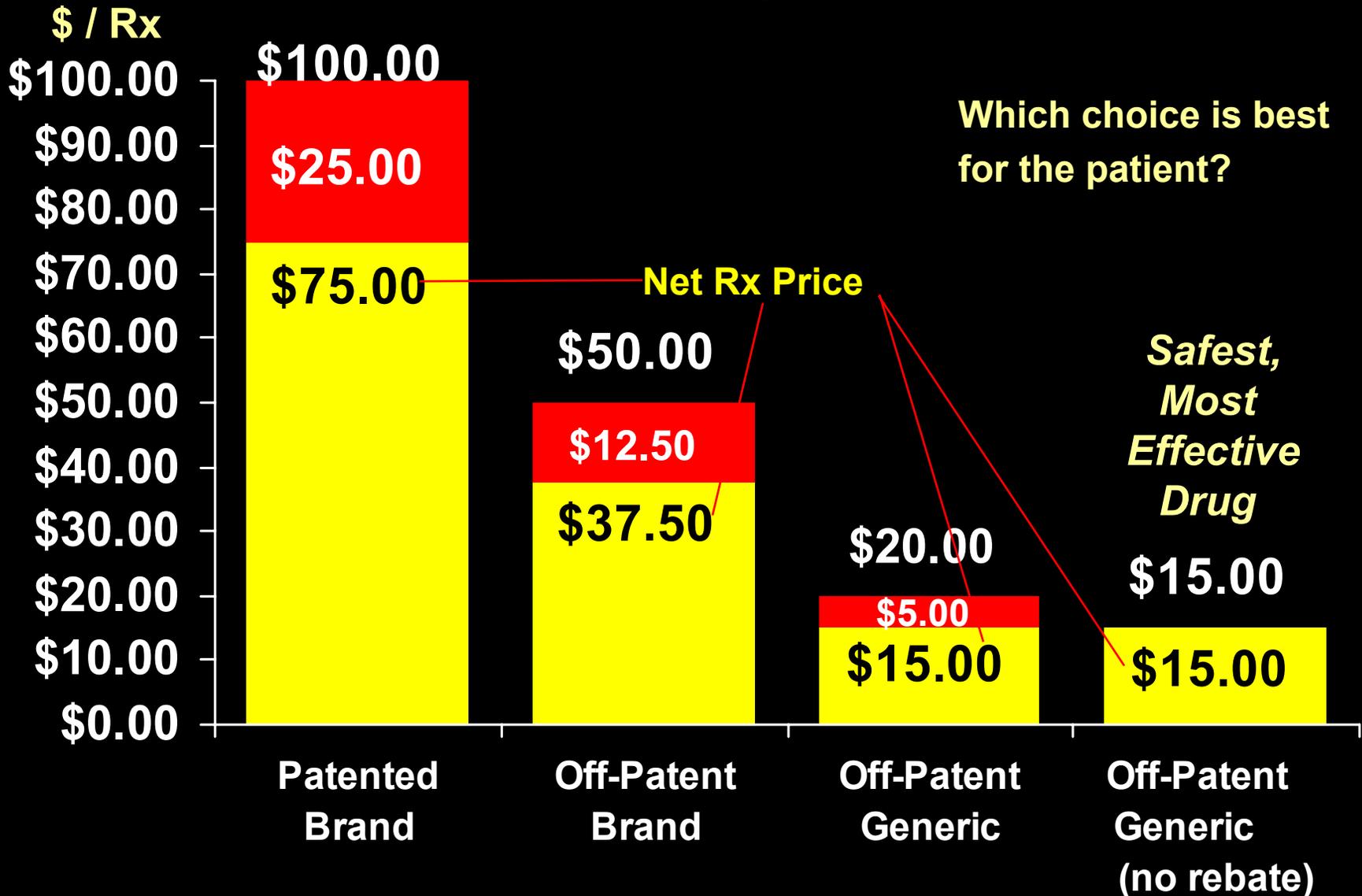
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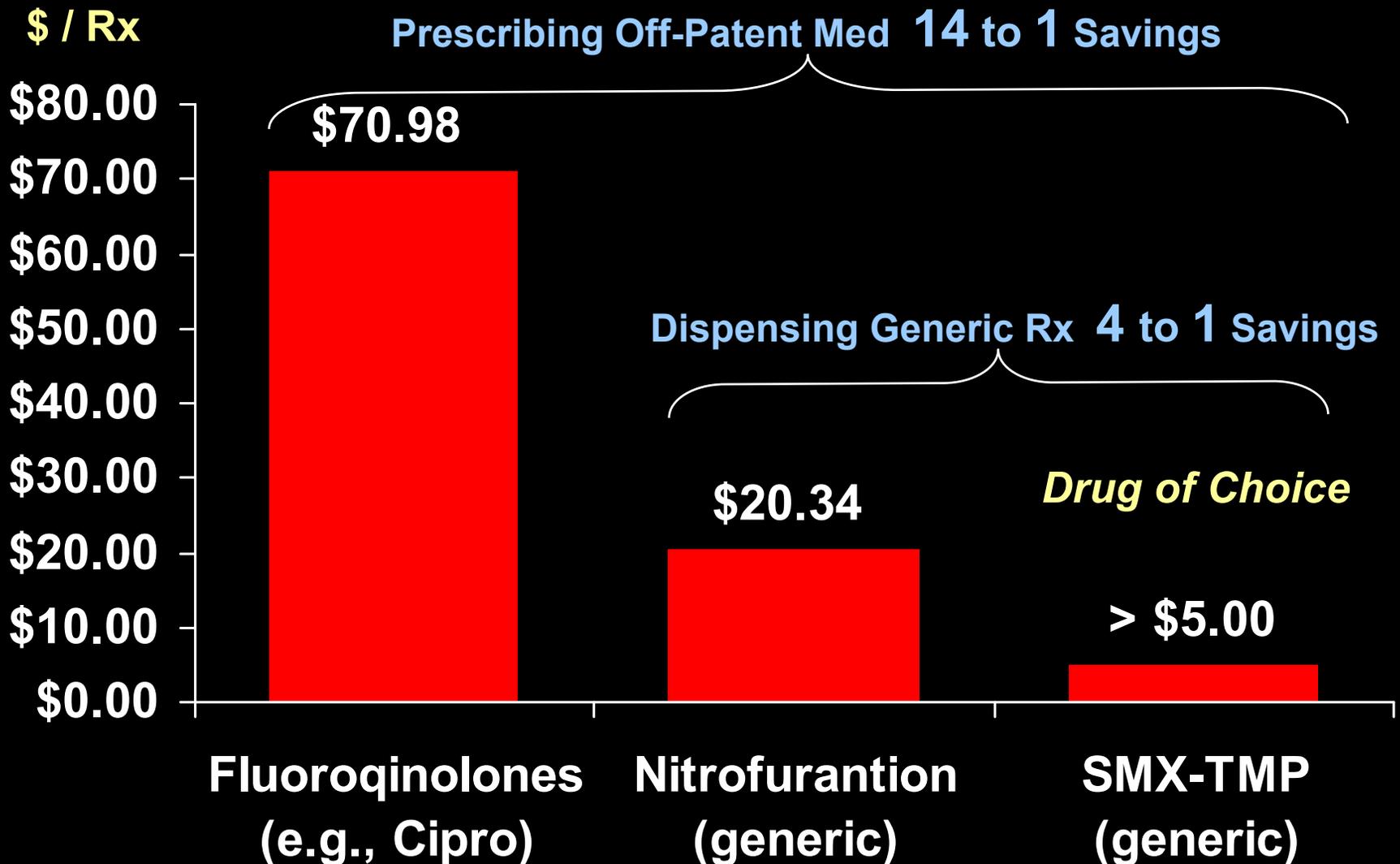
# Prescription Prices, Rebates & Net Cost to Payer & Patient



**Did More Rebates  
Result in  
Lowest Net Price?**

**NO !**

# Relative Price (1999 \$) of Prescriptions for Urinary Tract Infection



**Are Newer Drugs  
Always Better?**

**NO !**

# Can Older Drugs Be Better?

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*Several recent examples of evidence-based medicine showing older drugs to be the best drugs --*

- ◆ **Hypertension: NIH ALLHAT Study (JAMA 2002)**
  - Old drugs safer & more effective, yet lower cost
  - Thiazides are better than alternatives such as:
    - ACE Inhibitors, Ca Channel Blockers, Beta Blockers
    - Safer & More Effective than newer, higher priced drugs
- ◆ **Urinary Tract Infections**
  - Generic versions of sulfa combination (~\$10/Rx)
  - Drug of Choice for UTI
  - Most prescribed drugs are fluorquinolones (e.g., Cipro, ~\$100/Rx)
- ◆ **Arthritis**
  - COX-2 Inhibitors (e.g., Celebrex) incomplete data published
  - Older Non-steroidal anti-inflammatory drugs are first line of therapy

**Are PBMs Needed?**

**Yes !**

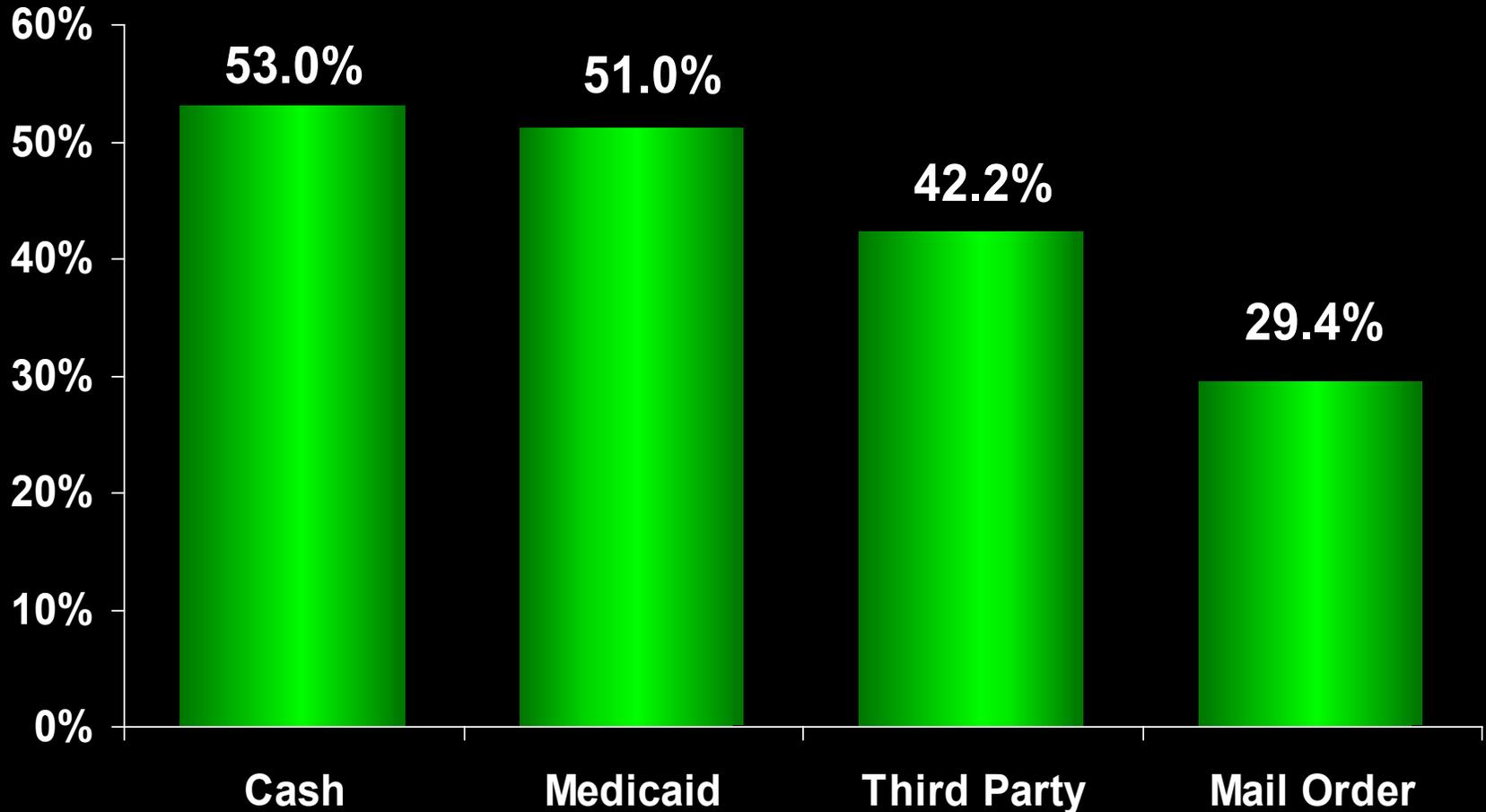
**Can PBM  
Conflicts of Interest  
Be Ignored?**

**NO !**

**Does Mail Order  
Increase Generic Use  
& Lower Price?**

# Generic Dispensing Rate By Source of Payment

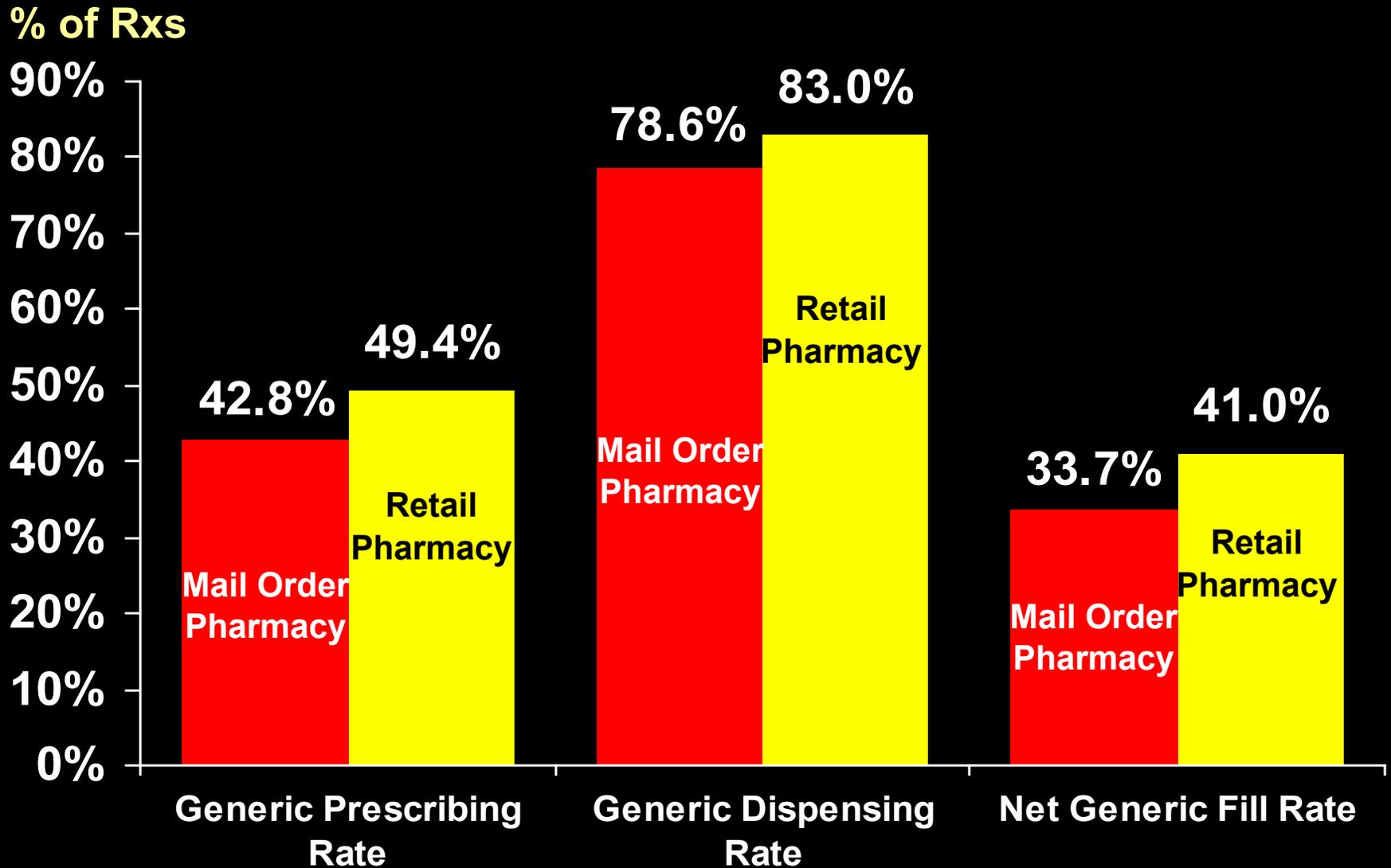
*% of All Rx's  
as Generic*



Source: Compiled by PRIME Institute, University of Minnesota from information found in Drug Store News, Aug 30, 2001, p.38 and based on IMS Health data; also Medicaid data from Medicaid State Drug Utilization files with analysis and estimates by the PRIME Institute.

# Various Generic Rates for Los Angeles, CA

## Mail Order vs Retail: 2002



Source: Compiled by PRIME Institute, University of Minnesota from data provided by CVS Pharmacy based on IMS Health data for same mix of drugs drawn from 10 most frequently dispensed therapeutic categories of drugs in mail order pharmacy from August 2001 to July 2002.

# Do Larger AWP Discounts Assure Lower Net Price from Mail Order vs Retail Networks?

Which contract terms offer the “best deal”?

## Retail Rx

AWP – 10%  
+ \$3 Disp. Fee

## Mail Order Rx (Re-Labeler Rx)

AWP – 25%  
+ \$0 Disp. Fee

# Net Rx Price for Retail & Mail Order (Re-Labeler) Celebrex 100 mg Cap (#60)

Net \$ /Rx

\$200

\$180

\$160

\$140

\$120

\$100

\$80

\$60

\$40

\$20

\$0

How can the *greatest AWP discount* give the *highest Rx price*?  
By assigning an inflated AWP  
to a re-labeled originator drug product.

How can this happen?

\$139.60

\$97.80

**Retail Rx**

AWP – 10%

+ \$3 Disp. Fee

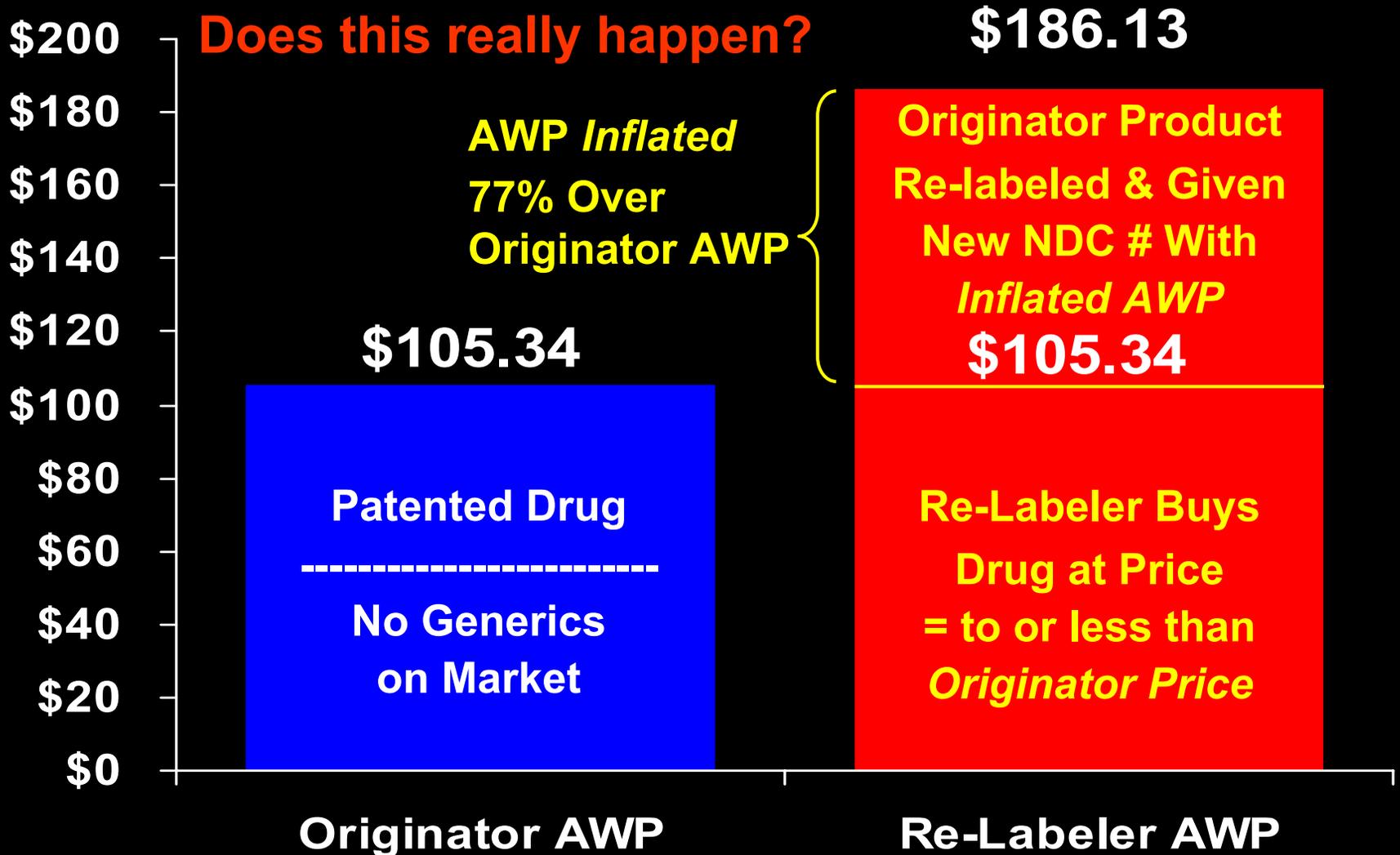
**Mail Order Rx  
(Re-Labeler Rx)**

AWP – 25%

+ \$0 Disp. Fee

# AWP Originator & Mail Order (Re-Labeler) Celebrex 100 mg Cap (#60)

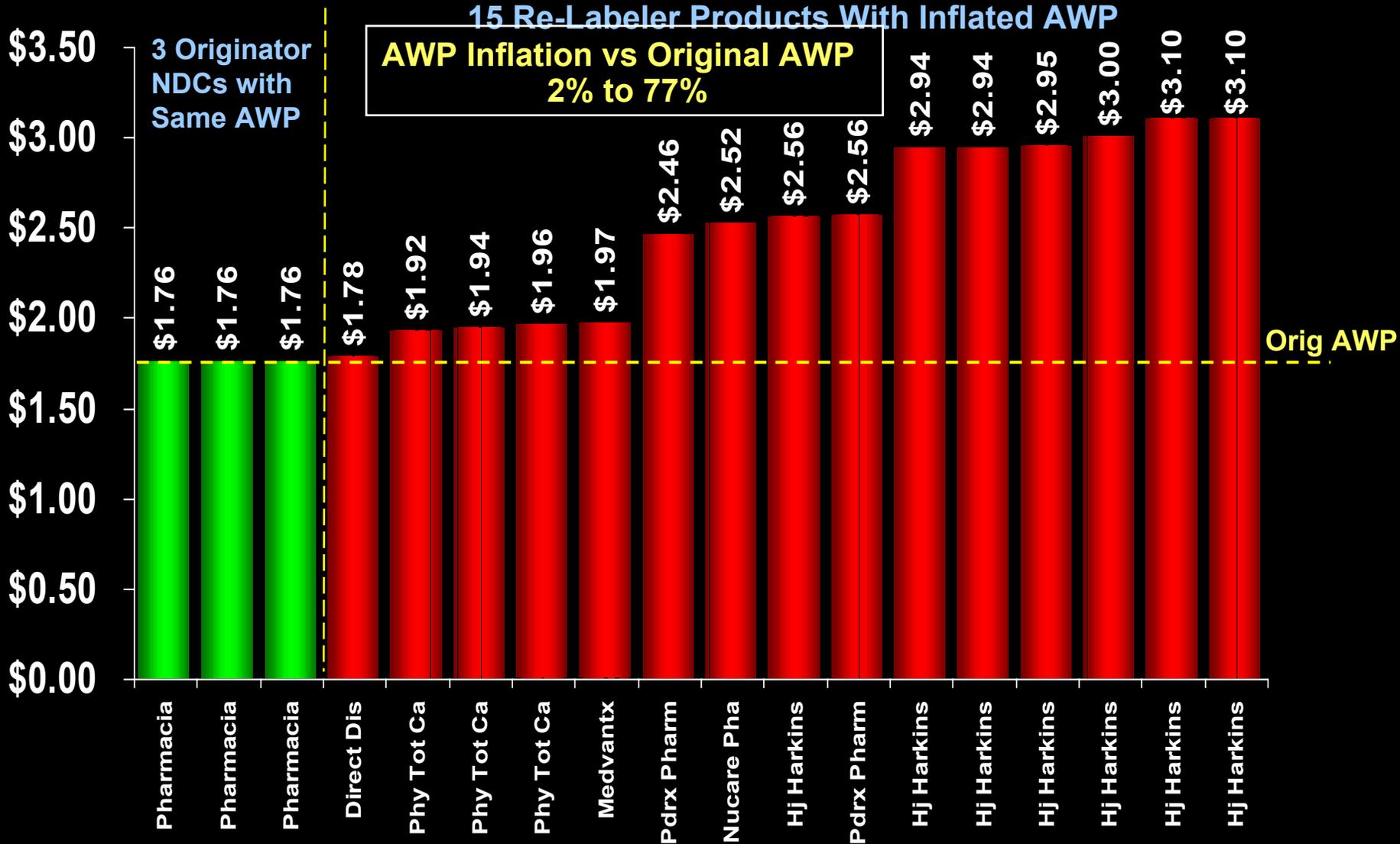
\$ AWP/Rx



# Actual AWP's Listed in Price Database

## Celebrex Cap 100 mg (Jan 1, 2003)

\$/Unit



# Net Rx Price for Retail & Mail Order (Re-Labeler) Celebrex 100 mg Cap (#60)

\$ AWP/Rx

\$200

\$180

\$160

\$140

\$120

\$100

\$80

\$60

\$40

\$20

\$0

Even with the *larger discount*,  
the *Re-Labeler Net Price is still*  
*higher than the Retail Net Price.*

**In this case . . .**

**47% More than Retail**

**\$139.60**

**\$97.80**

**A Larger Discount  
May Cost You More !!!**

**Retail Rx**

**AWP – 10%**

**+ \$3 Disp. Fee**

**Re-Labeler Rx**

**AWP – 25%**

**+ \$0 Disp. Fee**

**Originator AWP**

**Re-Labeler AWP**

# Bigger Discounts

## Don't Always Mean Lower Prices

*Contrary to the common sense notion, a bigger discount may not deliver a lower price because --*

### ◆ **Re-Labeled Drugs May Have Inflated AWP**s

- Many Re-Labeled Drugs Are Single Source Brand Names
- A New NDC # is Assigned with a Higher AWP (↑as much as 500%)
- More Than  $\frac{3}{4}$  of All Brand Name Drugs Have Re-Labeled Versions

### ◆ **Who Are the Re-Labelers?**

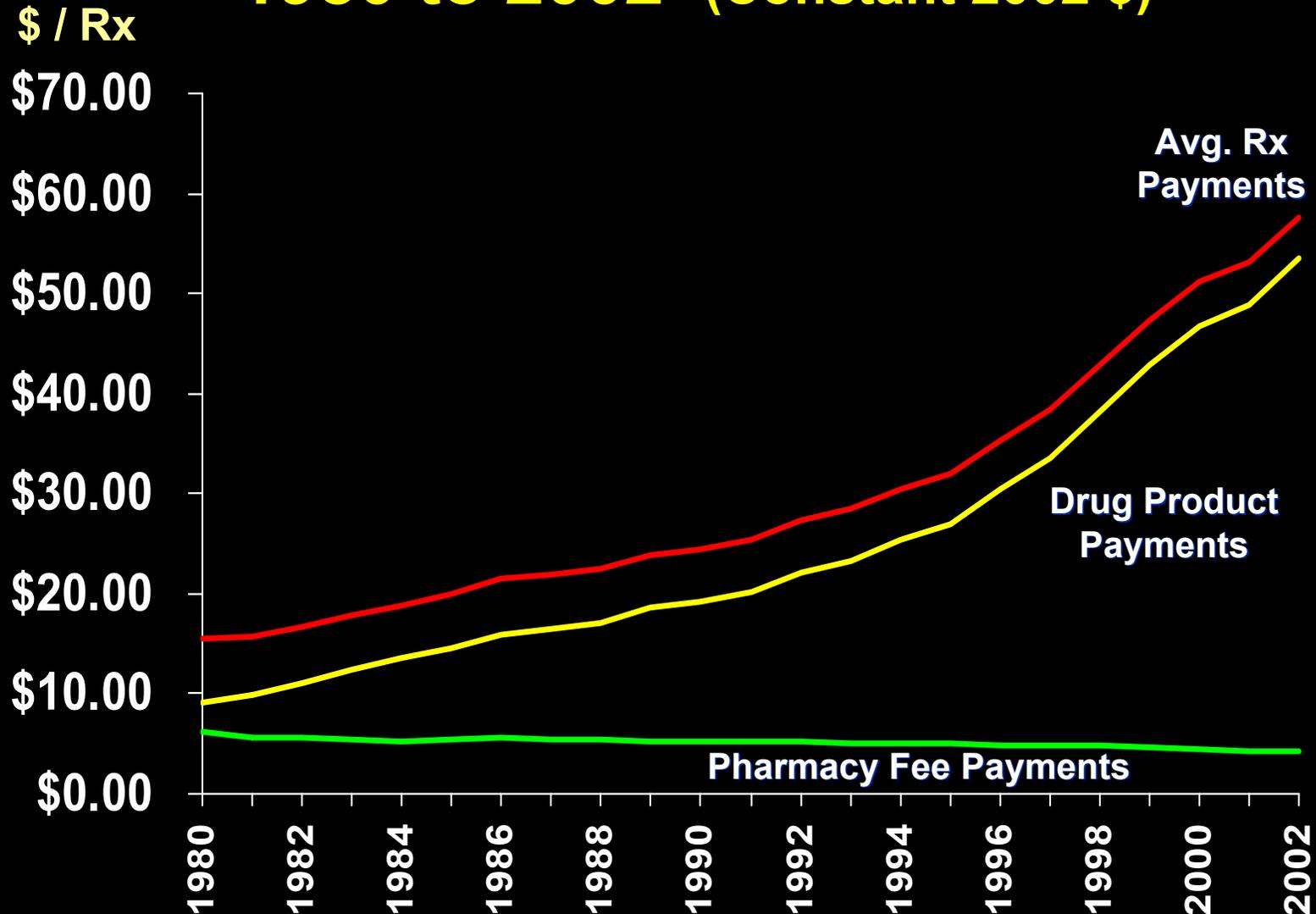
- Drug Marketing Firms That Buy Their Product from the Originator
- Re-Labelers Sell Only to a Limited Class of Clientele
- Re-Labeler Firms Usually Will Not Sell to Retail Pharmacies

### ◆ **Who Takes Advantage of These Inflated AWP**s?

- Mail Order Pharmacies & PBMs
- Physician Dispensers & Clinics
- Some Closed System Pharmacies (e.g., Long Term Care or Hospitals)

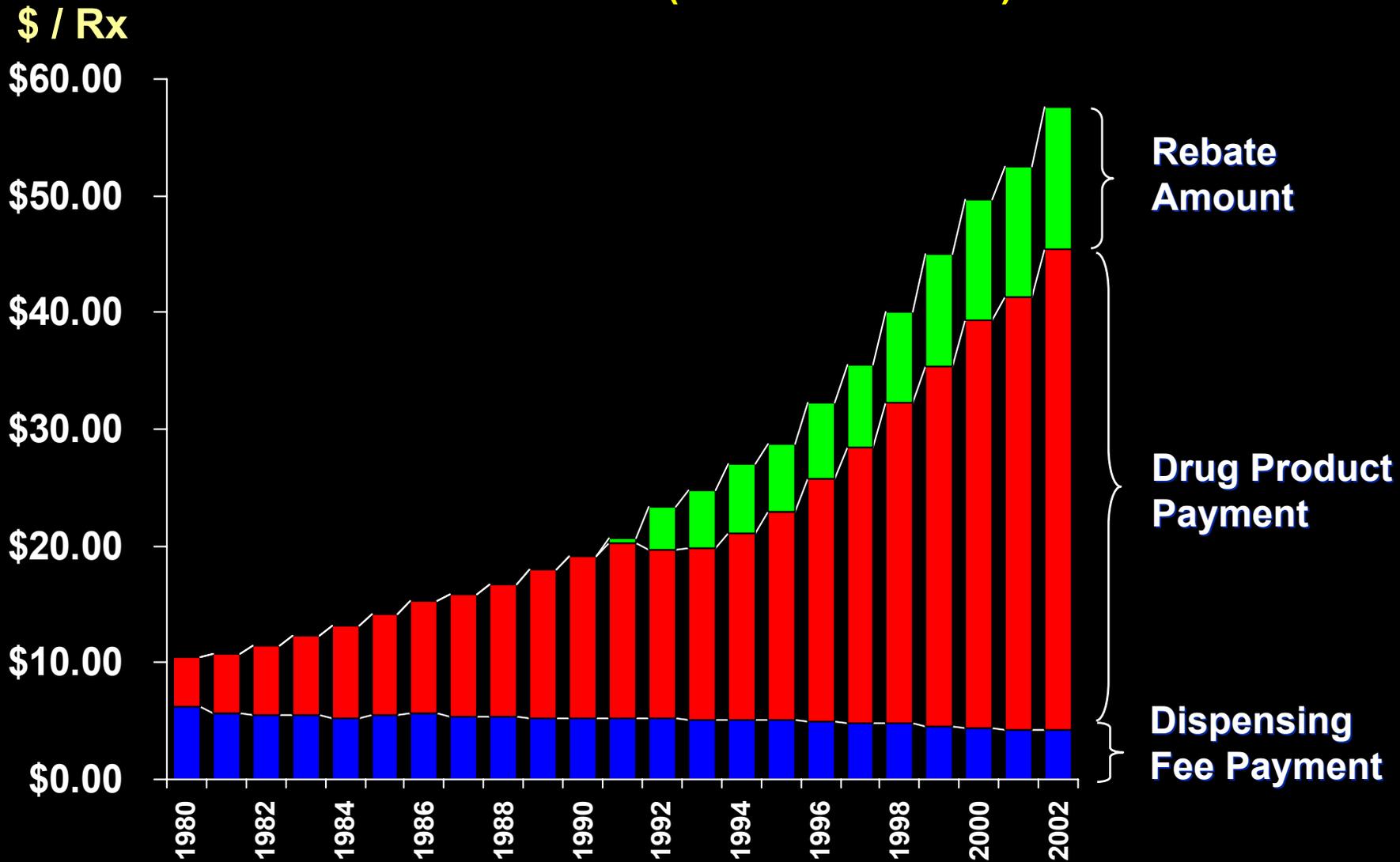
**Major Sources  
of Growth in  
Medicaid  
Drug Expenditures**

# Sources Driving Rx Payment Growth: 1980 to 2002 (Constant 2002 \$)



Source: Compiled by the PRIME Institute, University of Minnesota from data found in *Pharmaceutical Benefits Under Medical Assistance Programs*, National Pharmaceutical Council, 1975 to 2002

# Medicaid Rx Payment Components: 1980 to 2002 (Constant 2002 \$)

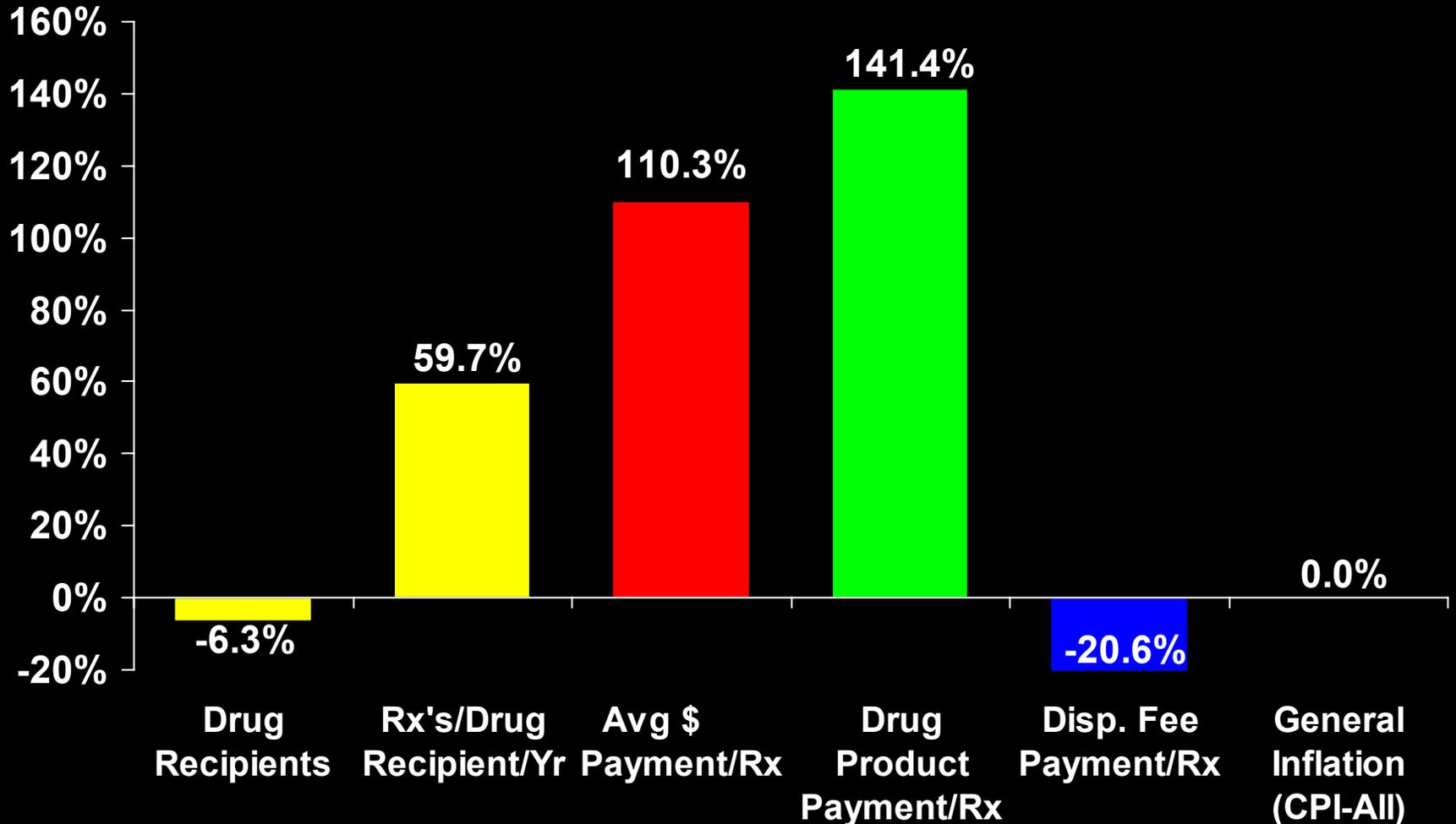


SOURCE: Compiled by the PRIME Institute, University of Minnesota from data found in Pharmaceutical Benefits Under State Medical Assistance Programs, National Pharmaceutical Council, 1976 to 1998.

# Factors Contributing to Change in Medicaid Drug Expenditures:

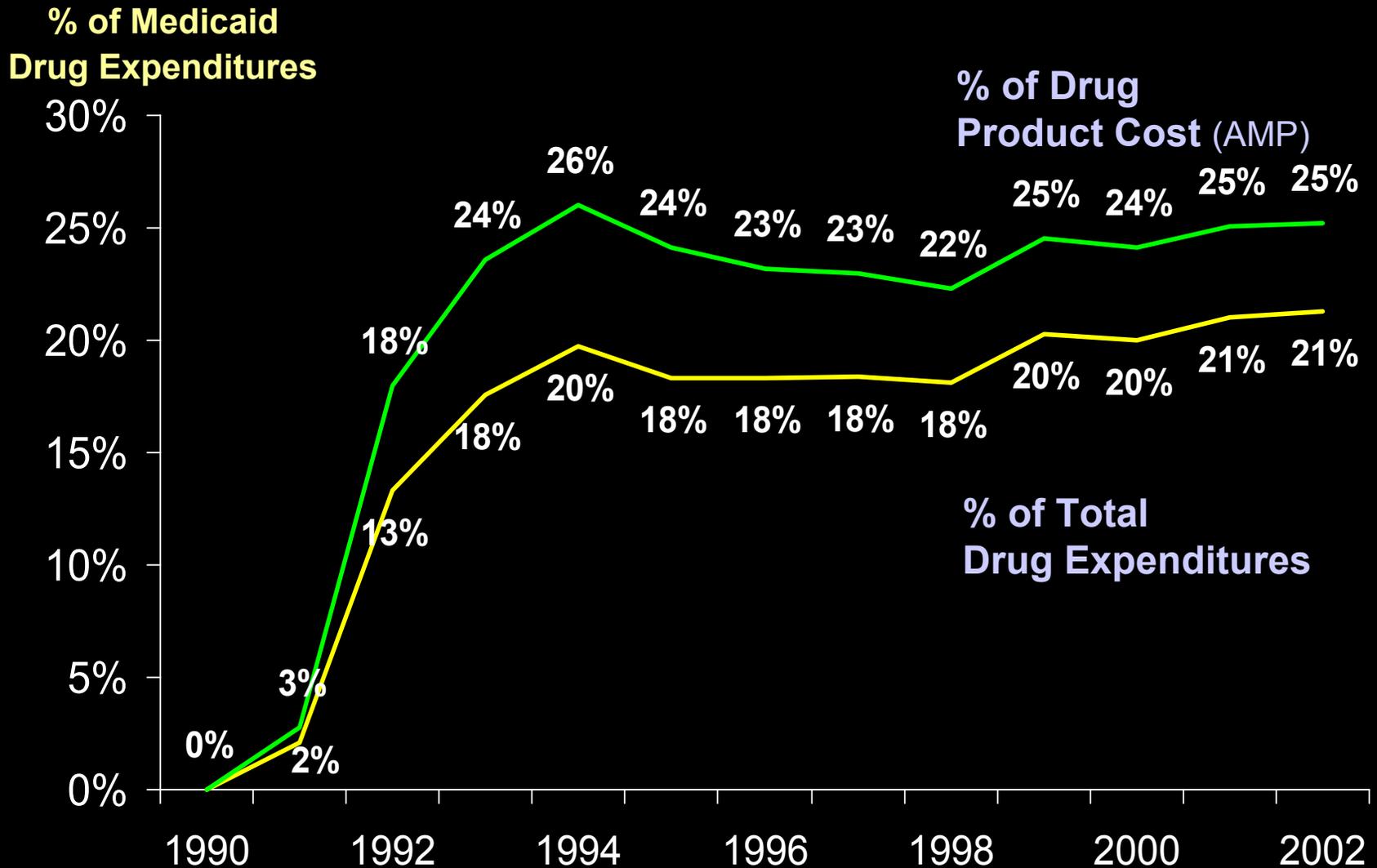
## 1992 to 2002 (Constant \$)

10-year  
% Change



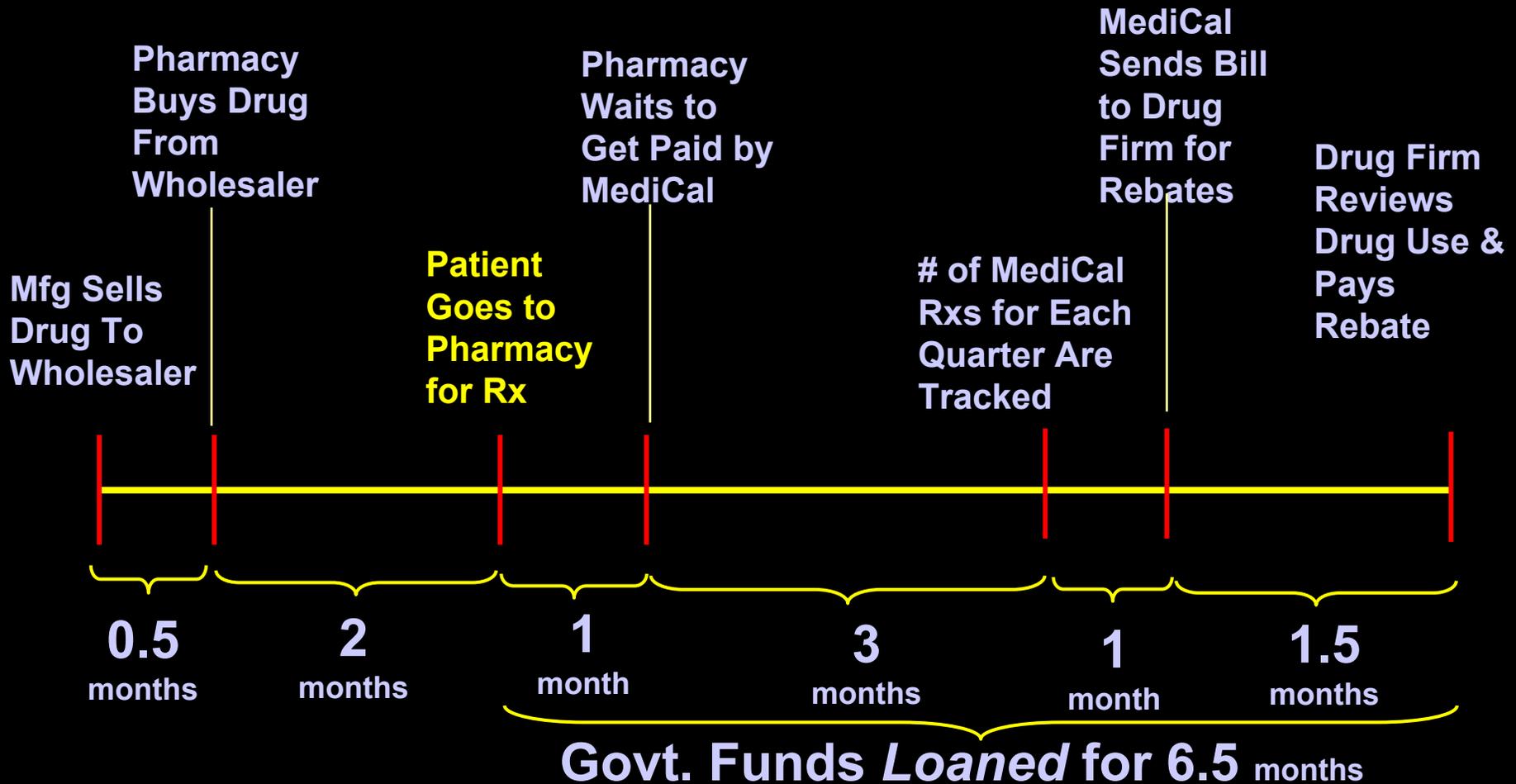
Source: Compiled by the PRIME Institute, University of Minnesota from data found in *Pharmaceutical Benefits Under Medical Assistance Programs*. National Pharmaceutical Council. 1975 to 1998

# Drug Rebates as a % of Total Drug Expenditures



Source: Compiled by the PRIME Institute, University of Minnesota from data found in *Pharmaceutical Benefits Under Medical Assistance Programs*, National Pharmaceutical Council, 1975 to 1998 and in HCFA Form 64.

# Steps in Drug Rebate Programs



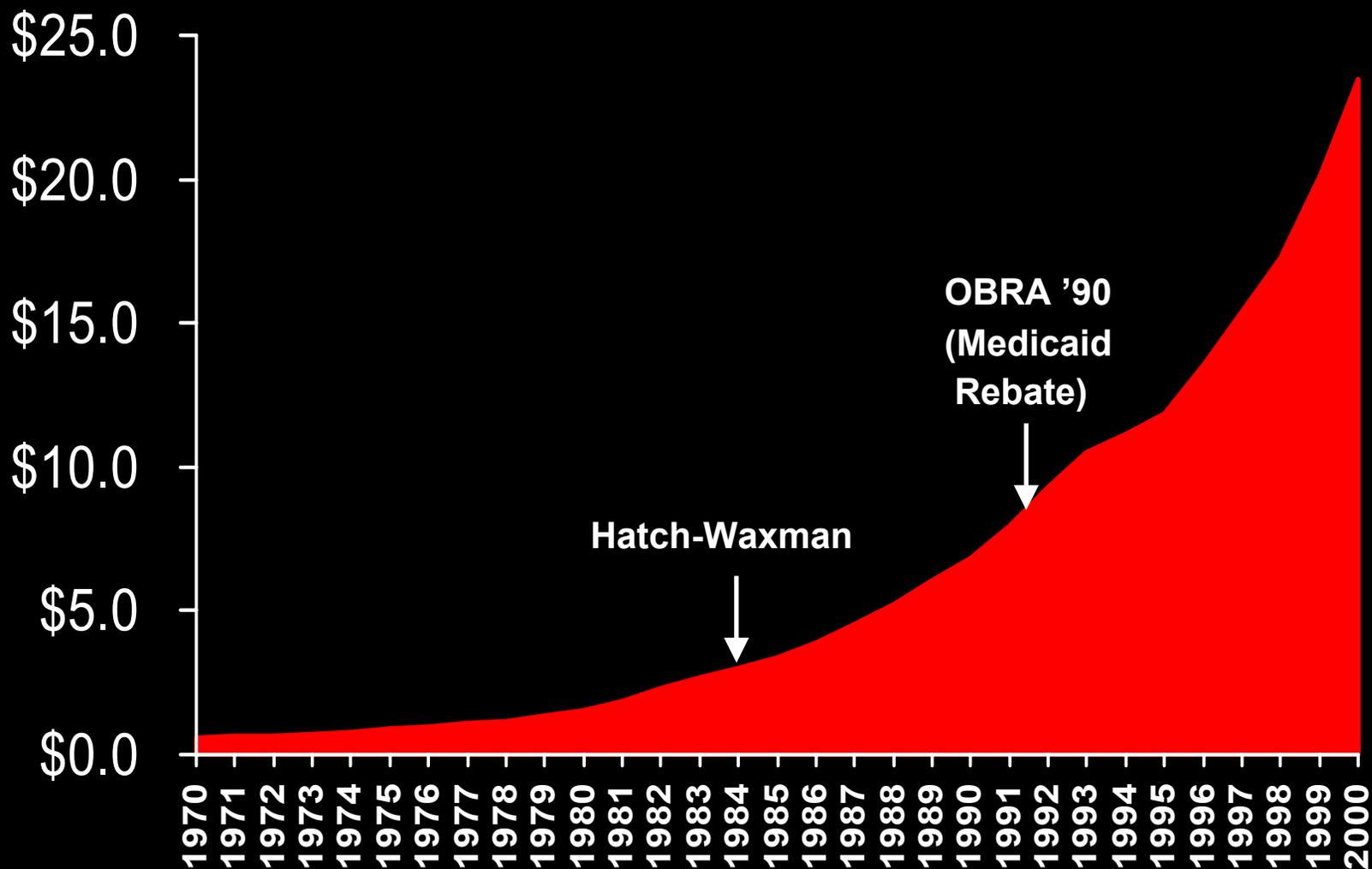
**\* Rebates Provide a 6.5 Month Govt. Loan to Drug Firms**

**\* California Rebates in 2003 Will Be \$1 Billion**

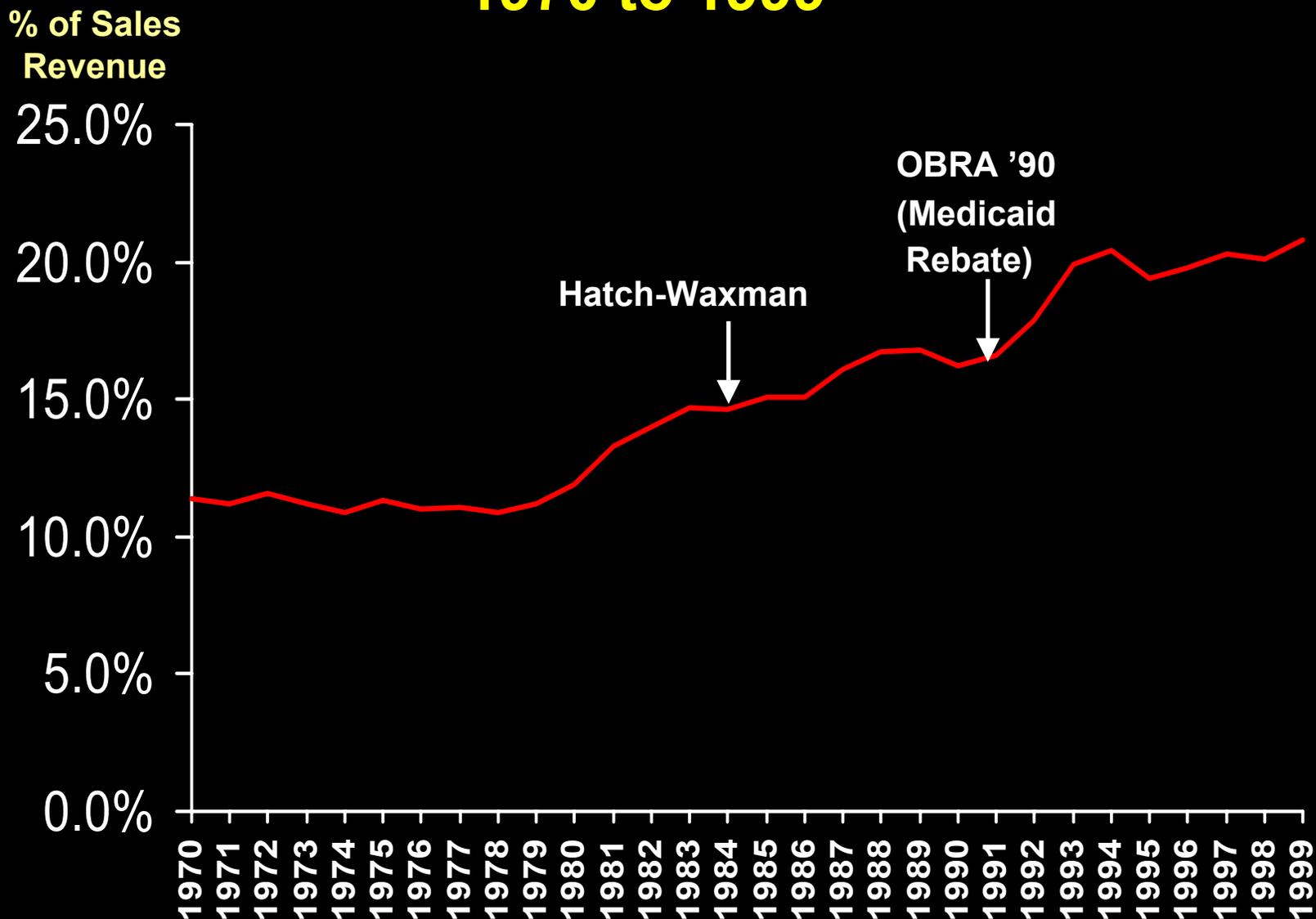
**Has Past Regulation  
Adversely Impacted  
Drug Firm R&D?**

# Drug Firm R & D Expenditures 1970 to 2000

\$ (billions)



# Drug Firm R & D as % of Sales 1970 to 1999

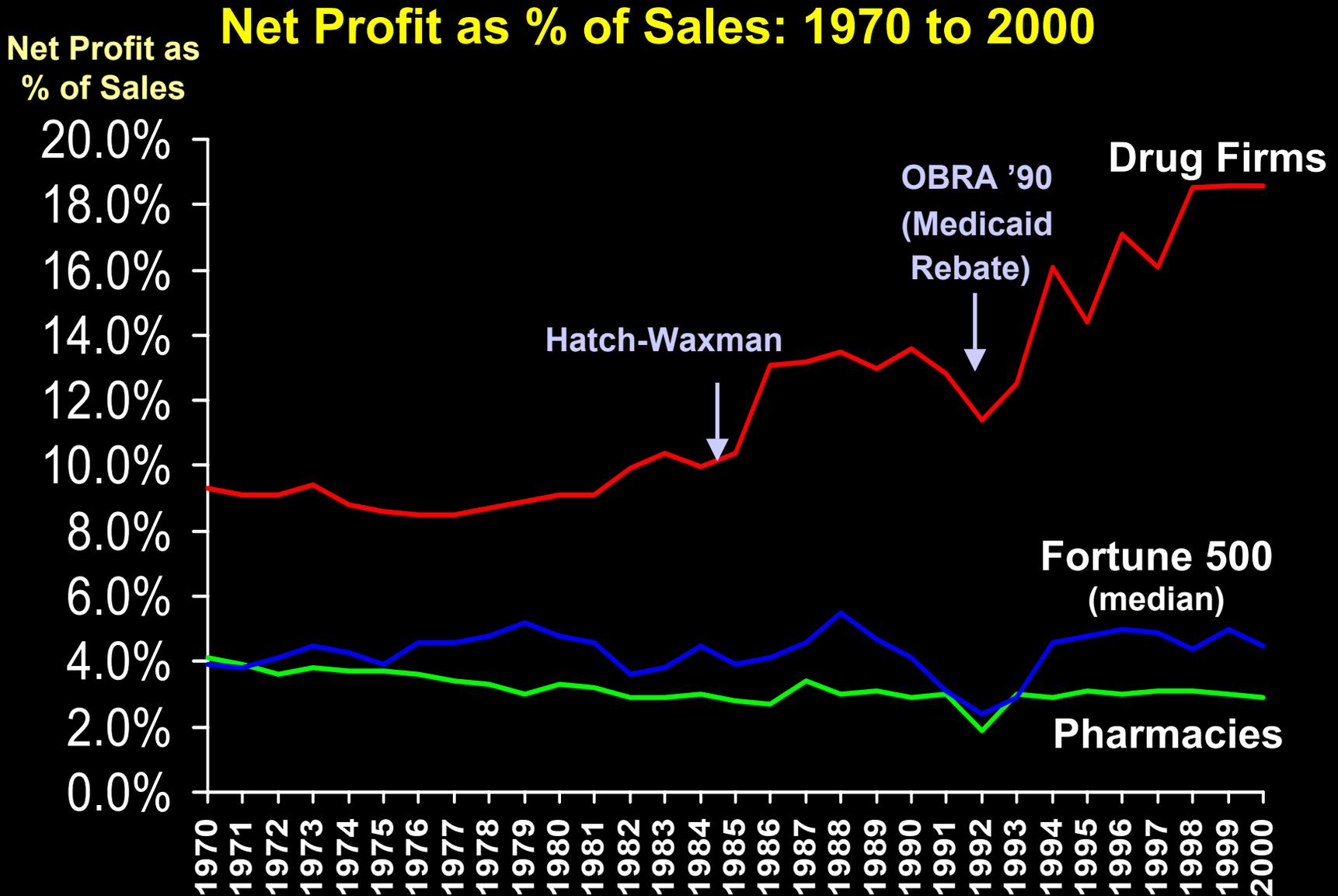


# **The Value of Innovation**

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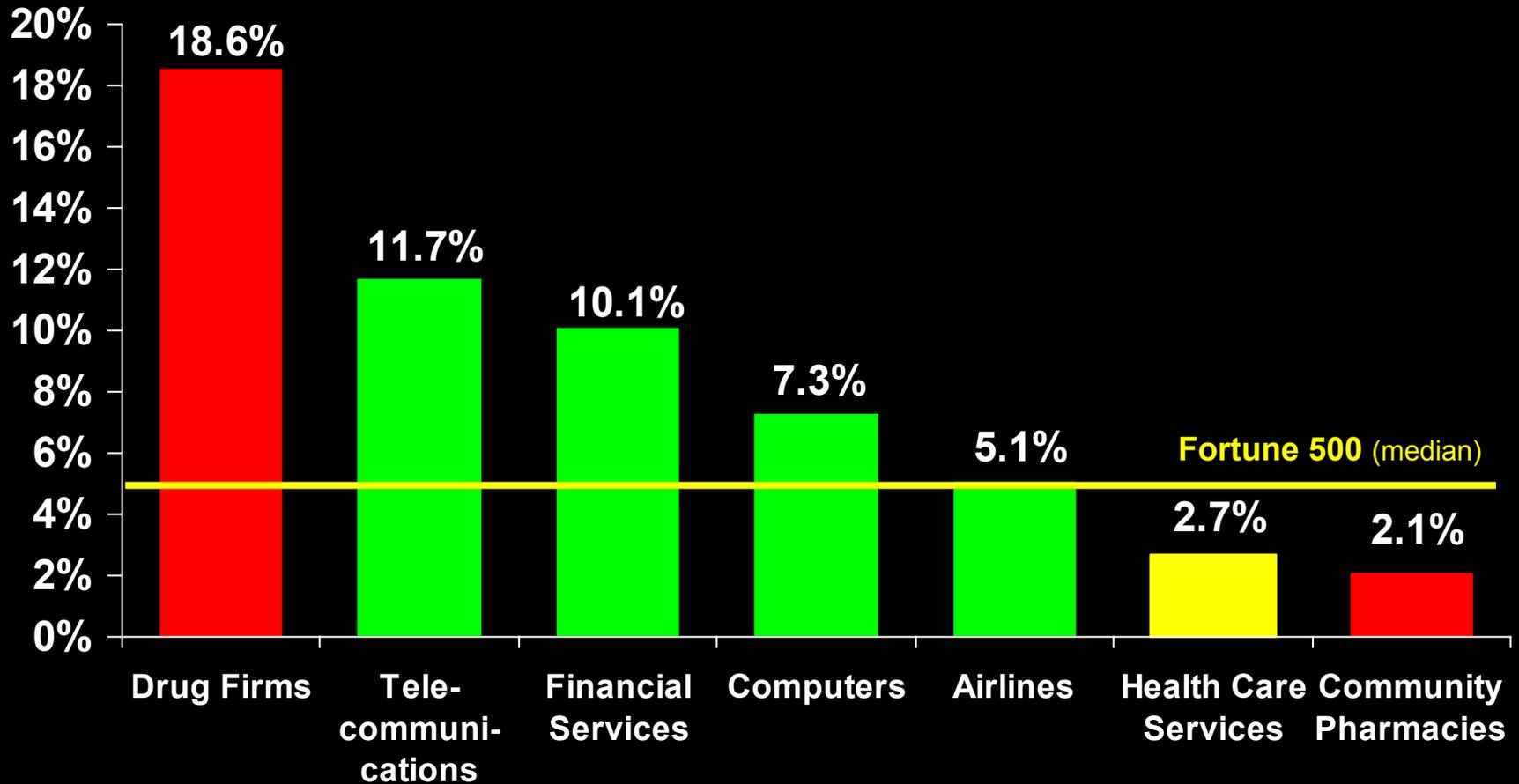
**“The value of innovation is realized only when a person has access to, and properly uses, a needed medication.**

# Drug Firm, Fortune 500 Firm & Pharmacies



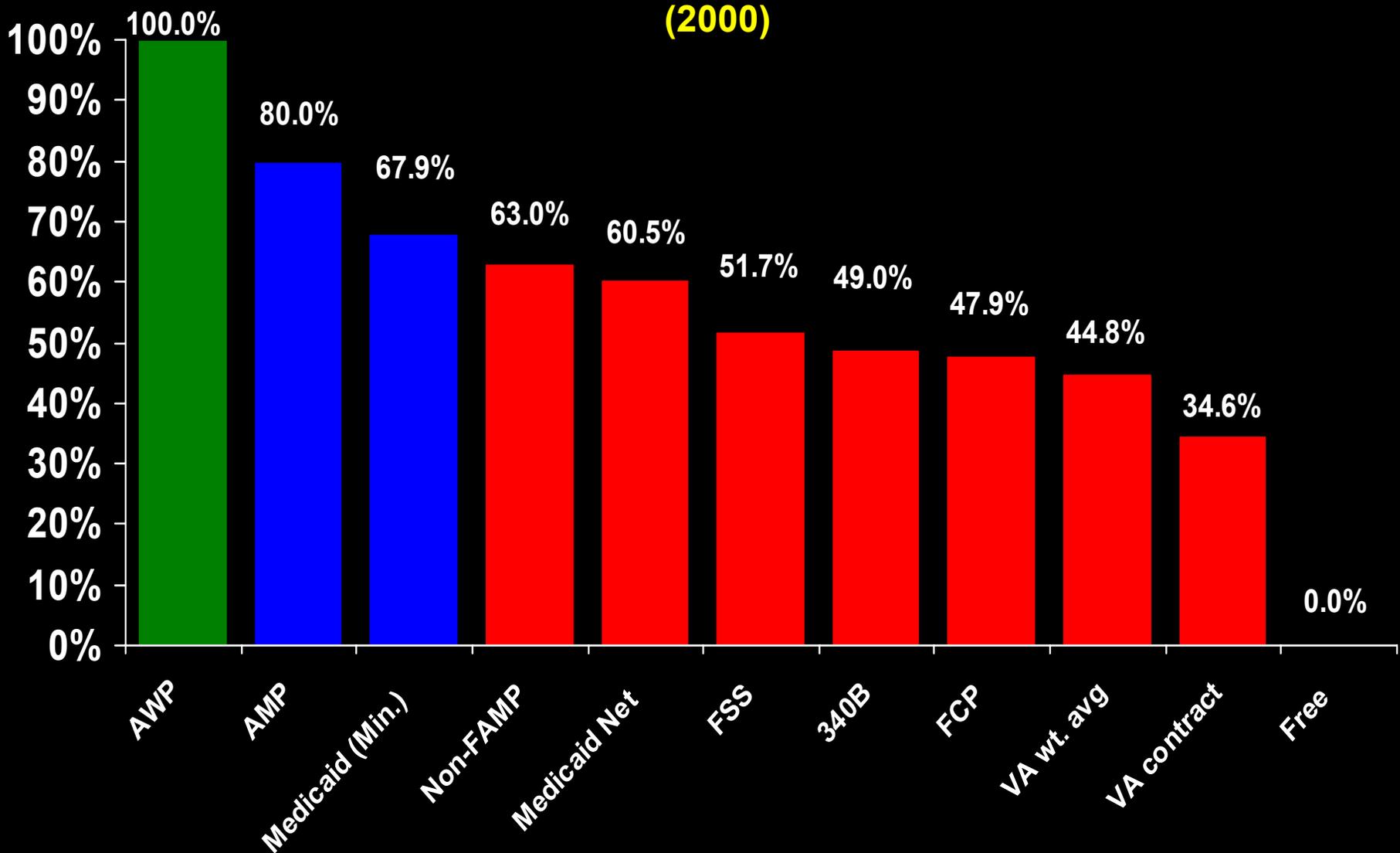
# Profit as % of Sales for Selected Industries (Fortune Magazine)

Profit as % of Sales



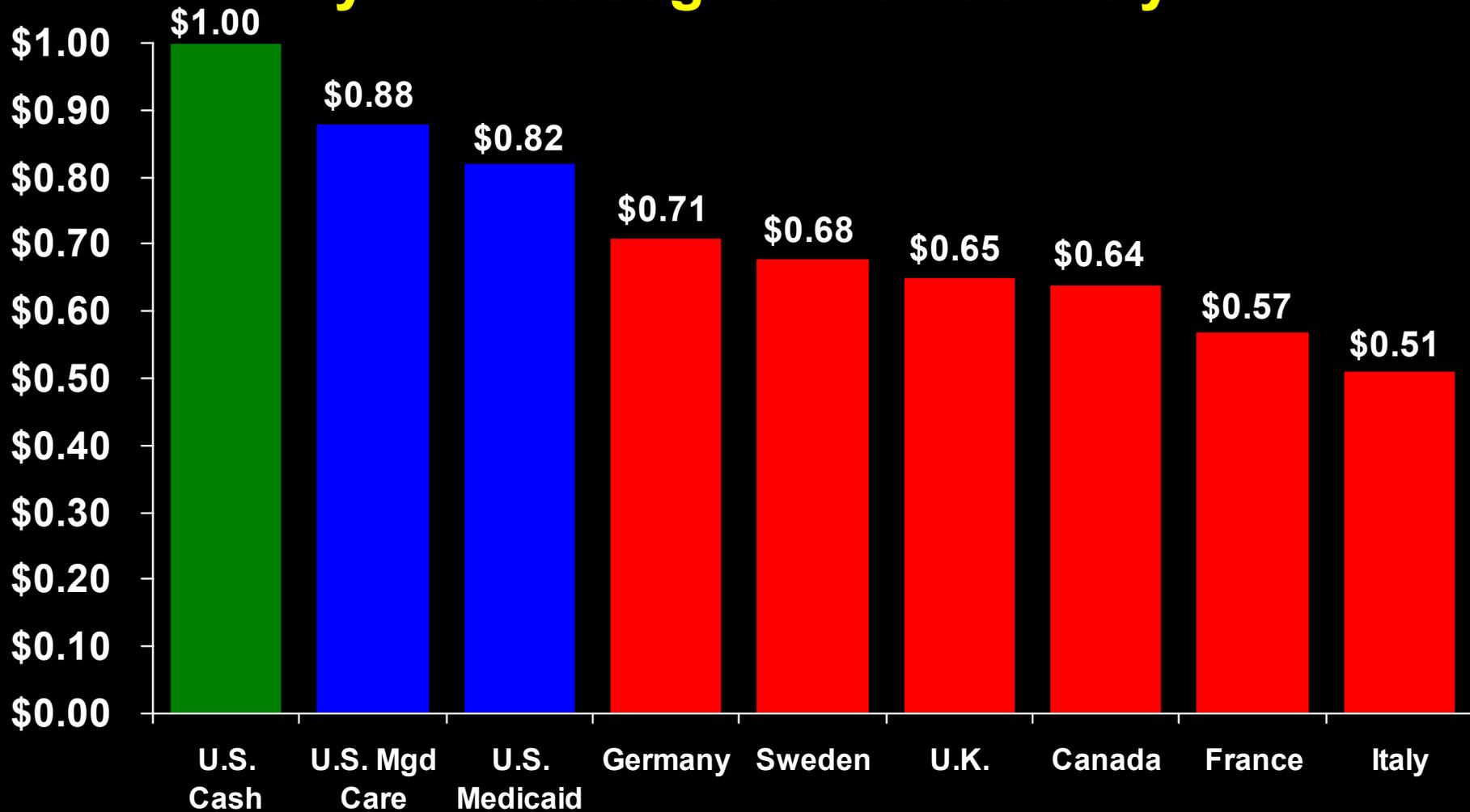
Source: Compiled by the PRIME Institute, University of Minnesota from data found in Fortune magazine.2000

# Estimated Relative Price Compared to AWP for Prescription Drugs at Manufacturer Level

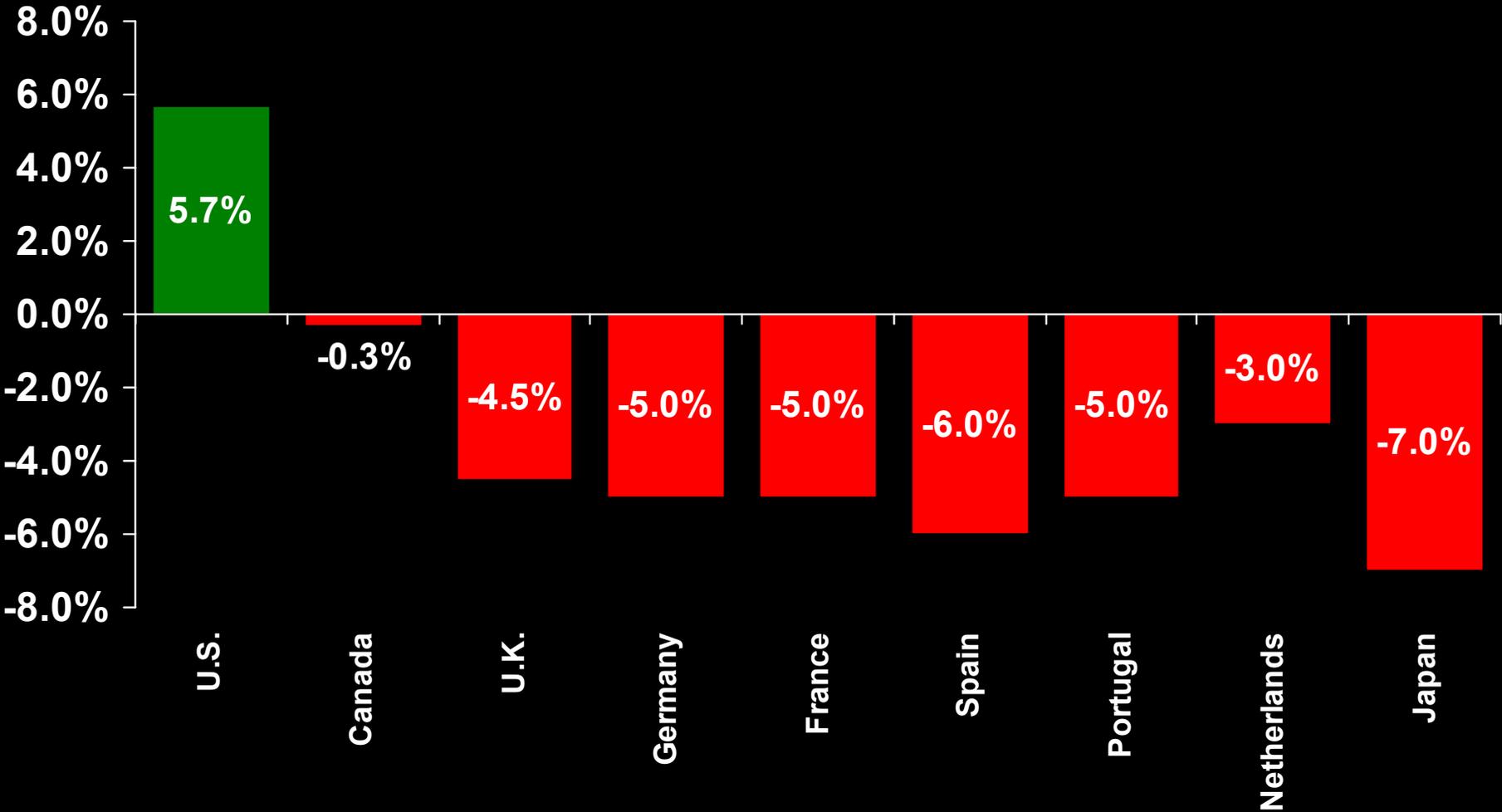


Source: Data derived from Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes, U.S. General Accounting Office, GAO/HEHS-00-118, August 2000 and [How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Market](#), Congressional Budget Office Papers, January 1996.

# Relative Price Level for Same Branded Drug at Manufacturer Level by Market Segment or Country



# Drug Price Changes in the U.S. & Various Countries: 1999-2000



Source: Data from various articles in Scrip during 1999 and 2000.

# Role of Drug Firm Voluntary Efforts

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*What is role of drug firm efforts?*

- ◆ Drug samples
- ◆ Indigent care programs
- ◆ Senior discount cards
- ◆ Temporary Help:
  - ◆ But Can Disappear at Will of Drug Firm

# Pharmaceuticals Are An Asymmetric Market

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*The Pharmaceutical Market Differs from  
Other Markets:*

- ◆ **Directed-Demand** (physicians, pharmacists, PBMs, others)
- ◆ **Insurance Coverage & Subsidies** (govt. & private)
- ◆ **Prices, Discounts, & Rebates Hidden**
- ◆ **Economics of Industry vs. Therapeutic Market**

# Reverse & Perverse Economics

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*Pharmaceutical Firms have been able to reverse the economic flow in the Rx market to co-opt major players:*

## ◆ PBM revenue from drug firms

- PBM gets hidden rebates, not
- Drug firms pay other fees for data, research studies, etc.
- Higher-priced drugs sometimes preferred drug on formulary

## ◆ Medicare Over-Pays Office-Based Drug

- Physicians & clinics receive discount > community pharmacies
- Physician makes more from Medicare on higher cost drugs
- Higher-priced drugs become the most prescribed drugs

## ◆ Generic Firms Paid Not to Enter Market

- Brand firms pay 1<sup>st</sup> generic approved not to market
- Payments more than generic firm would make in market
- Brand firm continues with price at 2 to 4 times the market-based price

# Reverse & Perverse Economics

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*Pharmaceutical Firms have been able to reverse the economic flow in the Rx market to co-opt major players:*

- ◆ **PBM Revenue from Drug Firms**
  - ◆ *Creates Conflict of Interest with Client's Expectations*
- ◆ **Medicare Over-Pays for Office-Based Drug**
  - ◆ *Doctor Has Incentive to Prescribe Highest Priced Drug*
- ◆ **Brand Firms Pay Generic Firms Not to Enter Market**
  - ◆ *Cost of Settling Lawsuit Less than Added Revenue*

# ***What Can States Do?***



# State Strategies to Increase Access

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- **State as Regulator** [ME, VT, most developed countries]
  - *Utility Model: Drugs as Public Good*
- **State as Wholesaler** [Europe, VT considered, untested in US]
  - *Controlled Distribution: State Liquor Stores*
- **State as Prudent Purchaser** [IA market, OR ref prices]
  - *Market-based Competition: Competitive Bidding*
  - *Payment-Limits Model: Set Maximum Payment / Reference Price*
- **State as Subsidizer** [PA, NY, NJ ME, SD, VT, border states]
  - *Welfare Program Model: Medicaid or Food Stamps*
- **State as Importer** [VT, ME, SD, border states]
  - *Importation from Canada: Free Trade Approach*

# What Have We Learned?

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- **Source of Growth is  $\uparrow$  Use & Mfg Price**
  - *Inappropriate Use & High or Growing Prices*
- **Volume Alone Does Not Lower Price**
  - *Market Share Movement Does Influence Price*
- **Price Controls Do Not Flow Upstream**
  - *Pharmacy Prices Controlled, Drug Mfg Price is Not*
  - *Limiting Pharmacy Fees Will Not Control \$/Rx Growth*
- **Must Anticipate Behavior of All Players**
  - *Patients, Physicians, Pharmacists, Drug Firms & Federal & State Policymakers*

# Don't Accept the Obvious Assumptions

- ◆ Drugs are a Small Part of Health Spending
- ◆ Drug Price Is a Small Part of the Problem
- ◆ Volume Gets You Lower Price
- ◆ PBMs Are Working for Your Best Interests
- ◆ Mail Order Will Increase Generic Use
- ◆ More Rebates Means Lower Net Cost

**Trust and verify!**

-- *former President Ronald Reagan  
speaking on nuclear disarmament.*

# **How Can the Market Forces Be Restored?**

**Require Transparency of  
Relationships & Prices  
At All Levels in the Market**

# Goals of Price Transparency

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## *5 Basic Goals:*

- ◆ **Economic Efficiency in Rx Market**
- ◆ **Accurate Price Information in Market**
- ◆ **Empower Buyers to Better Negotiate**
- ◆ **Access to Actual Price Information by Buyers, Policymakers & Researchers**
- ◆ **Accountability of Pharmaceutical Firms for Price & R&D Investment**

# Partnership With:

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- **Patient**
- **Physician**
- **Pharmacist**
- **Payer** *(If someone else is helping to pay)*
- **Policymakers**

***All parties must collaborate to choose the best value for the money!***

***PRIME*** Institute

***P*** ***h*** ***a*** ***r*** ***m*** ***a*** ***c*** ***e*** ***u*** ***t*** ***i*** ***c*** ***a*** ***l*** ***e*** ***s*** ***e*** ***r*** ***c*** ***h***  
***R*** ***e*** ***s*** ***e*** ***a*** ***r*** ***c*** ***h***  
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***E*** ***c*** ***o*** ***n*** ***o*** ***m*** ***i*** ***c*** ***s***

**University of Minnesota**