# Whose rebate is it anyway?

## Making PBM's Work for North Dakota

Presentation to the North Dakota Legislature's
Interim Committee on Industry, Business and Labor
by

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**Jack Ohman, Portland OR -- From The Portland Oregonian**

# Defining the Problem

# What is Driving the Cost of Prescription Drugs?

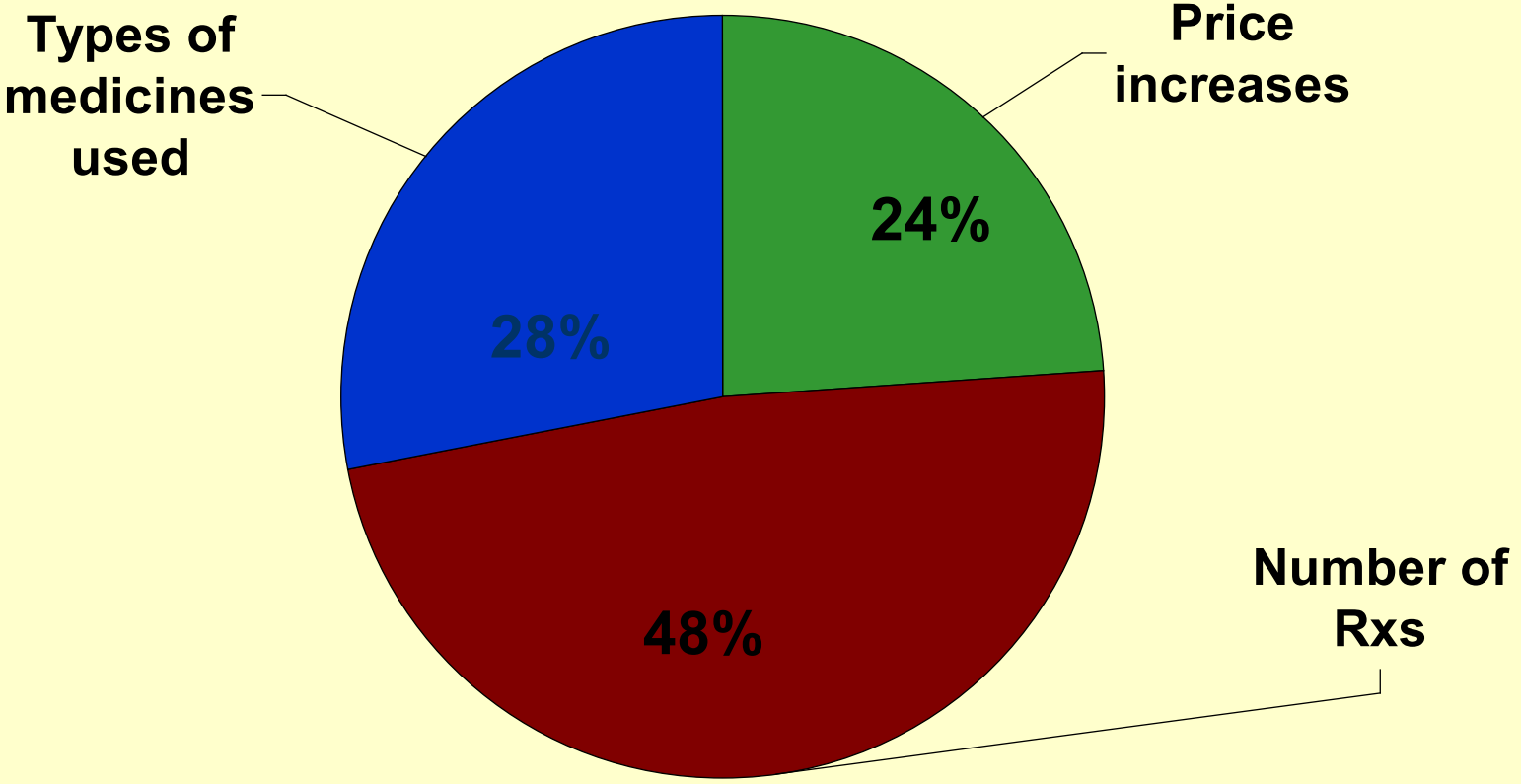
Three trends have been driving this rapid, sustained growth:

- The number of prescriptions per person is increasing;
- newer, higher-cost prescriptions are replacing older, less-costly medications; and
- the prices of prescription drugs are rising.

More than one-third of the increase in national prescription drug spending from 2000 to 2001 was directly attributable to increases in drug prices.

National Institute for Health Care Management Research and Educational Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* (Washington: National Institute for Health Care Management, May 2002)

# What Has Driven Drug Spending Growth?



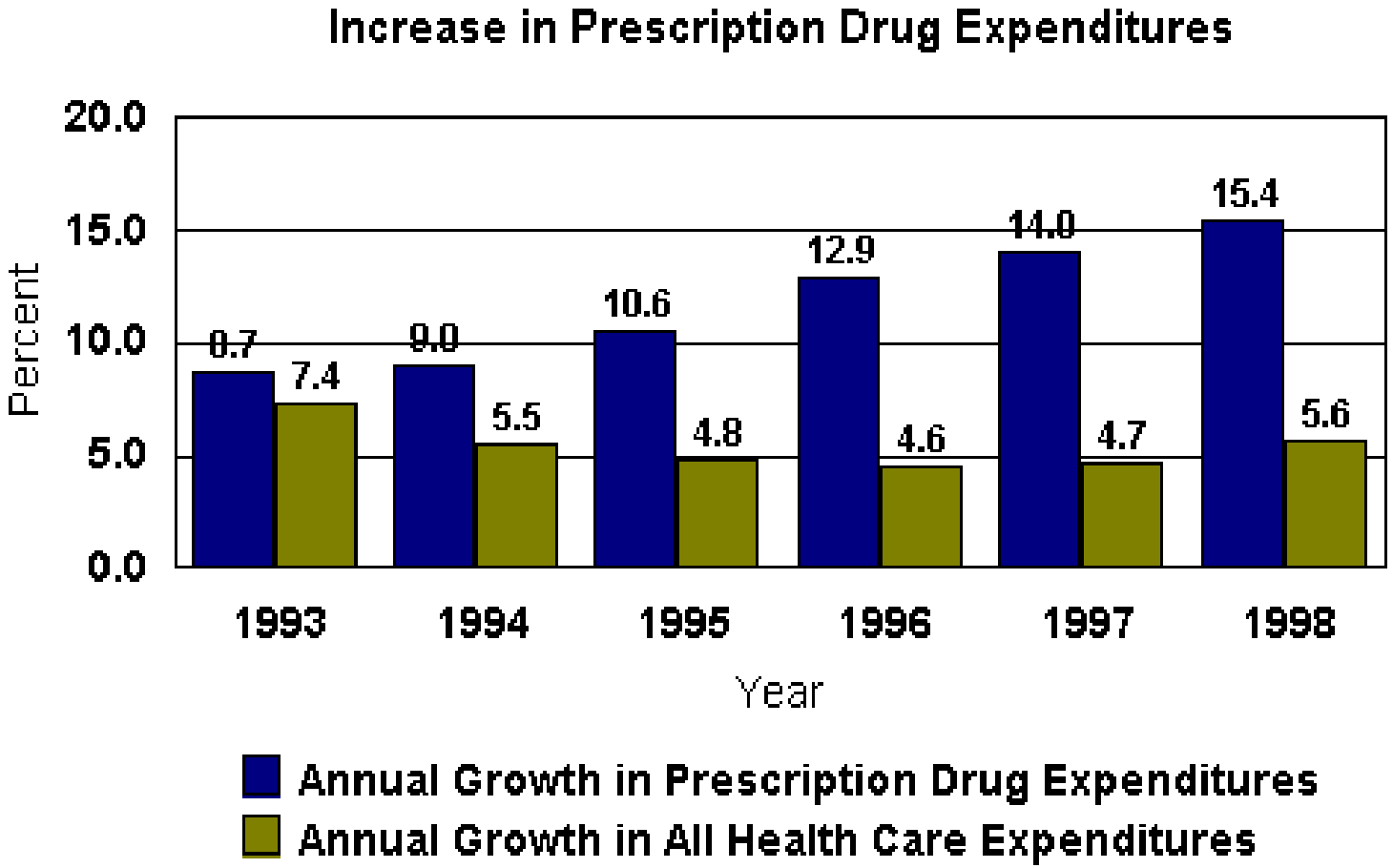

Data are for 1997-2000. Source: D. Kreling, et al., *Prescription Drug Trends: A Chartbook Update*, Kaiser Family Foundation (Melno Park, CA), Nov. 2001, p.40

# What is Driving the Cost of Prescription Drugs

- Prescription drug expenditures are the fastest-growing component of health care spending.
- Since 1995, national spending on prescription drugs has grown by over 10 percent every year, more than double the rate of growth for spending on hospital care or physician and clinical services.

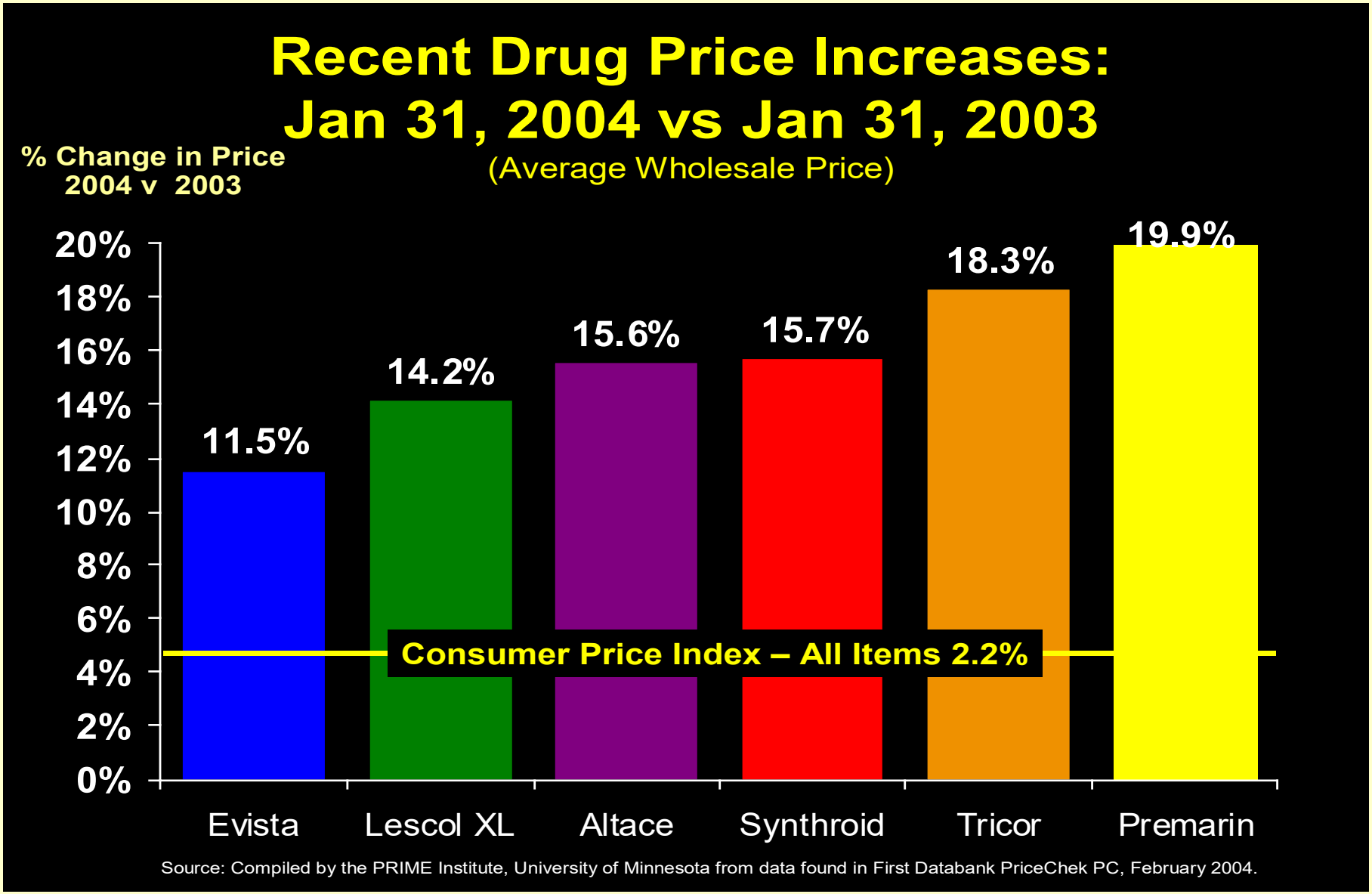
National Institute for Health Care Management Research and Educational Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* (Washington: National Institute for Health Care Management, May 2002)

# Growth in Annual Expenditures: Rx vs. All Health Care




Source: General Accounting Office

# Rx Spending Compared to CPI



# US Drug Costs vs. the World

- **Americans pay the highest prices for brand name drugs in the world.** Last year, for the same patented brand-name drugs, Americans on average paid 81 percent more than buyers in Canada and six western European countries (October 2005 Boston University School of Public Health Study)
- That's …
  - 108 percent more than the French
  - 118 percent more than Italians (the largest gap found in the study)
  - "Only" 58 percent more than the Swiss, the country with prices closest to those in the United States.

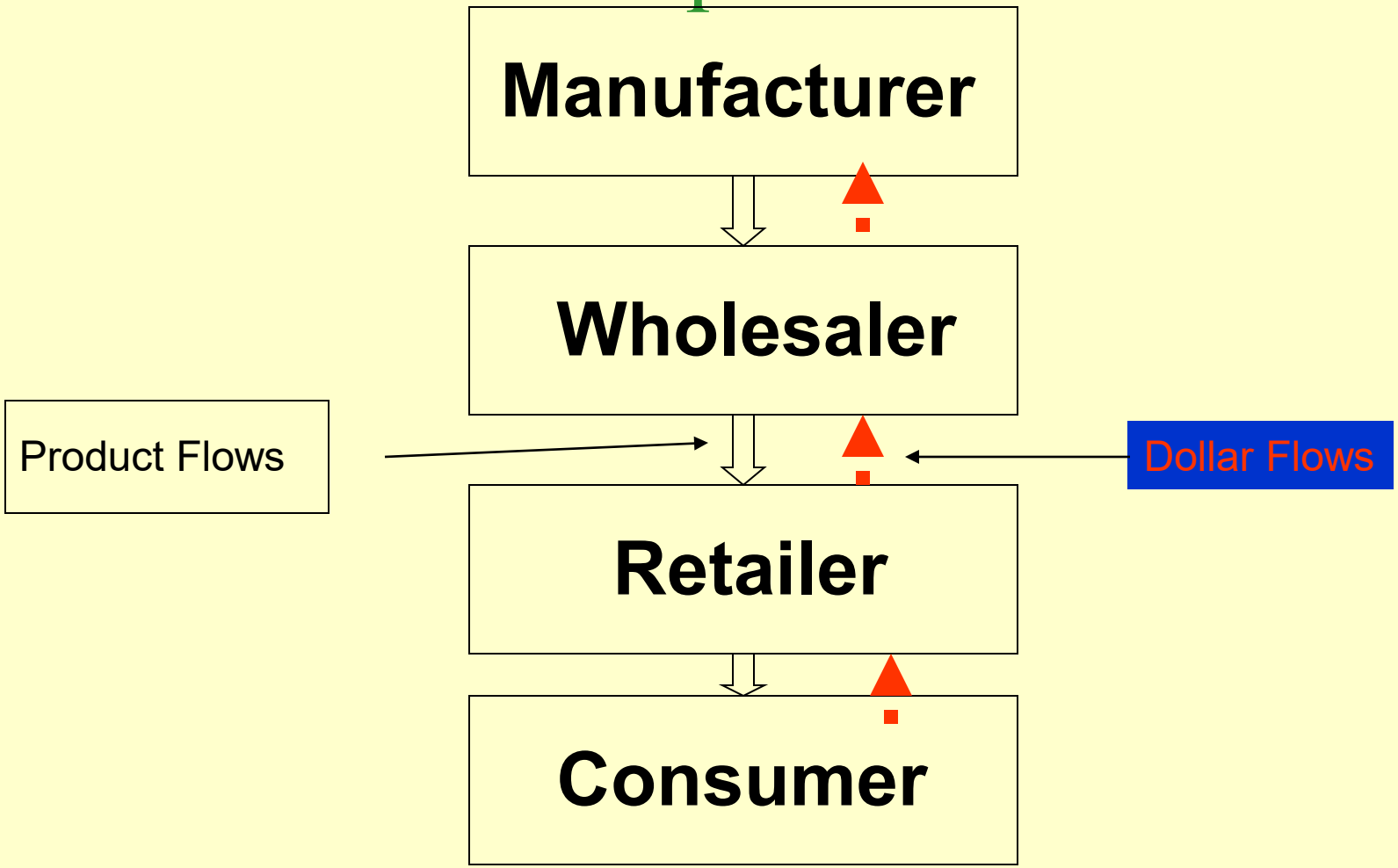
(See 2004 reports on drug importation by the U.S. Health and Human Services and Commerce Departments).

# *Who pays more when Prices increase?*

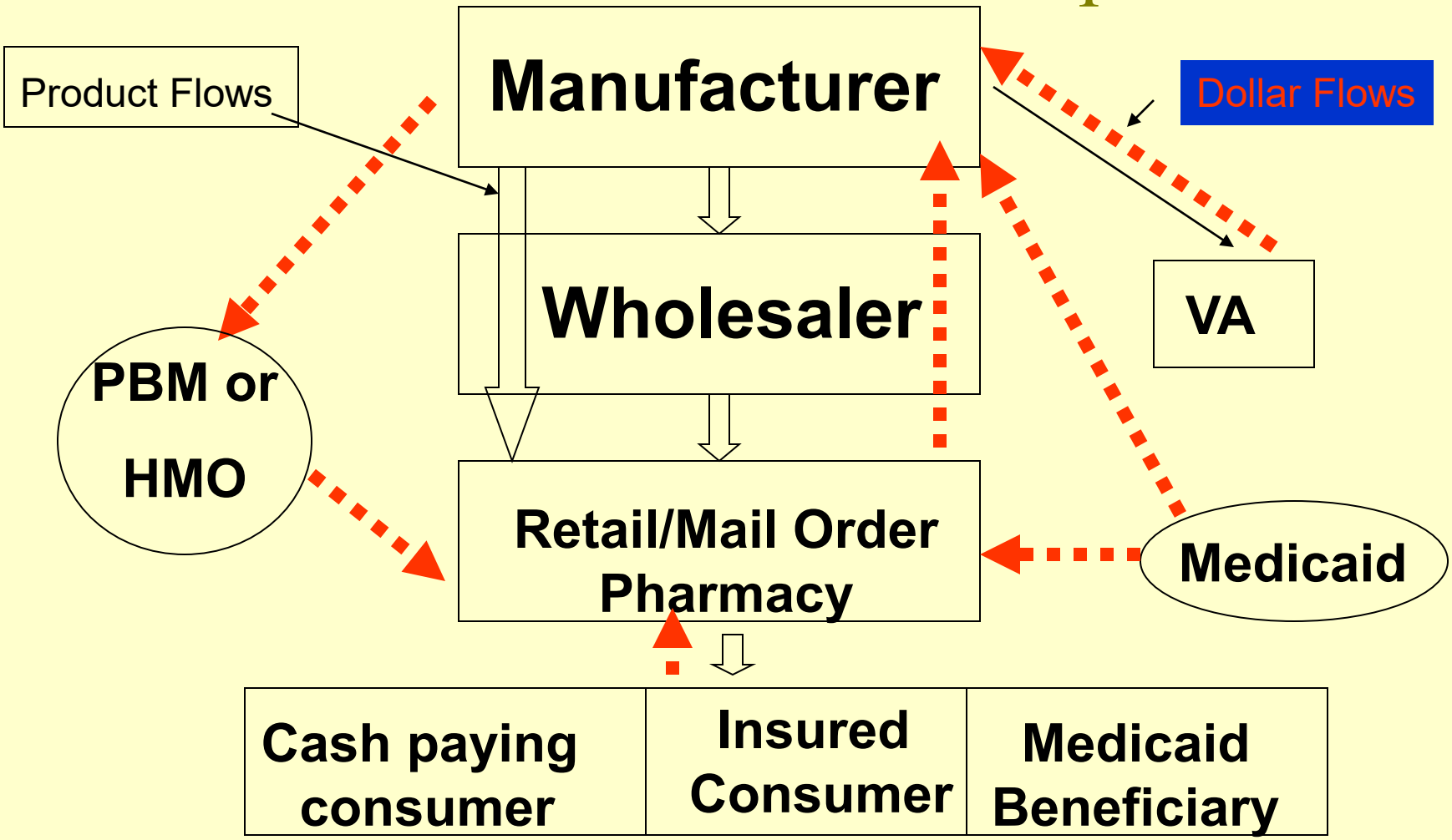
- **Cash Pay Consumers**
- **Employer Health Plans**
- **State Medicaid & SPAP Programs**
- **Medicare Part B & Discount Card**
- **State & Federal Employees**

# How does the System Work?

# Drug Distribution Chain—The Simple View



# Distribution Chain—The Complex View



# What do PBM's Do?

- Pharmacy Benefit Managers ("PBMs") middlemen between drug manufacturers, retail pharmacies and health plans. (PBM's never actually purchase or handle prescription drugs unless they own a mail order)
- PBMs have unique power to influence the market for prescription drugs, including prices, market share, and total benefit costs.
- They negotiate the customer's ultimate cost, including reimbursement to the retail pharmacy and payment to the manufacturer of the drug.

# How do PBM's Work?

- Establish *network* of *participating pharmacies* that accept a given reimbursement rate, e.g.
  - –AWP-x% for ingredient cost, plus a dispensing fee (e.g., $2.00 per prescription)
  - –Leverage: Take the deal, or risk being out of the network (and losing business to other pharmacies)
- Negotiate *rebates* with drug manufacturers
  - –Rebates typically expressed as % of AWP (or other list price)
  - –Higher rebates obtained for achieving greater market share for manufacturer
  - –Leverage: placement on formulary or PDL

# Who are the PBM Players?

The national PBM market is dominated by three players:

| PBM | approx. covered lives |
| --- | --- |
| • Caremark, Inc. (merged with Advance PCS) | 90 million |
| • Medco Health Solutions, Inc., | 60 million |
| • Express Scripts, Inc., | 40 million |

# How does a PBM find savings?

- Reducing pharmacy cost is possible
  - But squeezing pharmacies won't provide large discounts on brand name drugs, since most of their cost comes from the manufacturer
  - Pharmacies have little or no leverage to reduce manufacturer price
  - Pharmacy cost reductions may reduce access to counseling on appropriate use—for which pharmacist is not typically paid
- Reducing manufacturer cost requires use of formularies/PDLs, and other drug benefit management tools

# Where are the Savings in Pharmacy?

- Pharmacies have a limited ability to lower prices on brand-name drugs
  - Obtains product at same price regardless of customer
  - Manufacturer cost is largest component of price
  - So, savings from pharmacies largely come from the pharmacy's bottom line

# Where are the Savings with Manufacturers?

- **Rebates** PBM's act as the middlemen and negotiate rebates with manufacturers:

  **NOTE:** PBMs are not wholesalers and do not generally purchase and sell prescription drugs (except mail order).

  **Problem:** Sometimes PBM's are paid for services which they don't consider rebates such as "data fees" or "grants" which they may not disclose or pass thru to the client

# Where are the Savings with Manufacturers?

**Drug Intervention or "Switching**

- Some PBMs use calling centers to actively encourage doctors to "switch" individual patients to a preferred drug to maximize a profit from the manufacturer
- Government authorities have become concerned that call centers and other PBM "intervention" efforts prompt a doctor to switch drugs on the basis of deceptive or incomplete information, especially information about the PBMs own financial interests.
- The result is not just inconvenience to the patient, but possibly an adverse impact on health.

# Facts About Drug Manufacturer Rebates

- Rebates are often confidential between PBM and manufacturer
  - Paid *after point of sale*, so neither customer nor pharmacy know the amount
  - Rebate amount often considered proprietary
  - Most of the time, not even insurer/employer knows the specific product rebate
  - As a result, payer may not know what share of rebate PBM is keeping

# Q: Why do Legislatures Need to Get Involved?

A: Because state government and businesses are making spending decisions without access to all of the information.

# Ronald Reagan Had it Right!

"Trust but Verify"

# Trust but verify . . .

## Transparency is critical for fair dealing

- While PBMs have been helpful in reducing drug costs by winning price breaks based on volume discounts, it has been revealed through successful law suits that **PBMs sometimes engage in questionable and unethical practices.** These practices include:

# PBMs: Trust but verify . . .

*… what are the issues?*

- **Conflicts of interest**: PBMs are hired to negotiate price breaks on prescription drugs, but some PBMs have financial interests that conflict with this mission.

- *Sometimes PBM's have a distinct financial interest that conflicts with the clients interest, such as self-dealing to their own mail order pharmacy. While this isn't always bad, it sometimes results in deals which advantage the PBM instead of the client.*

# PBMs: Trust but verify . . .

## *. . . what are the issues?*

- **The "Spread"** Paying the pharmacy less than the PBM charges the client, and then failing to pass savings through discounts to consumers.

- **Drug switching** to maximize rebate payments to PBMs
  - *Example: 20 states settled claims for over $20 million against Medco in April 2004 for encouraging prescribers to switch medications but failing to pass through savings where rebates from mfrs. were increased. Drug switches increased costs to state health plans, requiring follow up patient visits and tests*

# PBMs: Trust but verify . . .

*… what are the issues?*

- **Refusal to be audited or release information** on pricing structure, rebate deals and other fee structures. Health Plans have no way of knowing if they are getting a good deal or what the drugs actually cost.
- **Collection and sale of PBM data on patients** or prescribing patterns used to enhance drugmaker marketing efforts rather than promote the goals of health plans.

# This isn't *just* a story: PBM's in the News

A recent article in the Detroit Free Press reported that PBMs hired by the University of Michigan:

- Encouraged doctors to use high-cost, brand-name drugs even when less-expensive generic drugs or lower-cost, brand-name drugs were available.
- Took money from drug companies to include their products on the list of approved drugs the university would pay for -- even if they were more costly than effective, competing medicines.

The university dropped the five benefit managers it had been working with, hired a single new manager that has less control over how the drug plan is administered, and imposed strict new rules. These changes enabled UM to hold its drug spending to $43 million in 2003, or $8.6 million less than it would have paid under the previous plans. (Free Press, 5/18/05)

# State Action and Model Laws:

## You can make a difference

# State Legislation

**During the past Session,**

**13 states considered PBM regulation**

# The Major themes:

## Maine and DC PBM Regulation Laws

***Provisions of the Maine and DC PBM laws include:***

- **Prevent conflicts of interest** and require disclosure of activities such as drug switching (disclosure is only between the PBM and its client health plan)
- **Require pass-through of benefits of drug pricing deals** negotiated by PBMs to health plans, in order to benefit consumers and not PBM profits
- **Protect against unethical behavior** by requiring duty of due care between PBMs and health plans **(fiduciary duty)**
- **Protect health of patients** by discouraging drug-switching to enhance drug maker and PBM profits instead of promoting improved medical outcomes
- **Can be enforced** by AG in Unfair Trade Practices Action, or by health plan for breach of fiduciary duty

# The Major themes:
## South Dakota PBM laws

- **South Dakota** law enacted June 2004
  - Requires licensing of PBMs as "third party administrators;" Division of Insurance oversees
  - Transparency, audit and drug-switching provisions
  - Permits civil action to enforce or for damages by "any covered entity"
  - Lacks "fiduciary" language of Maine and DC laws; does require PBM "to perform its duties exercising good faith and fair dealing toward covered entity"
  - Lacks savings "pass through" provisions of ME and DC laws

# How Maine and South Dakota Compare: Duty

**Maine**

- See 22 M.R.S.A. §2699 et seq. (as amended).

- PBM owes its clients a fiduciary duty:

- "A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law. . . . A pharmacy benefits manager shall perform its duties with care, skill, prudence and diligence and in accordance with the provisions of state and federal law."

**South Dakota**

- PBM owes its clients a duty of good faith and fair dealing.

- "Each pharmacy benefits manager shall perform its duties exercising good faith and fair dealing toward the covered entity."

# How Maine and South Dakota Compare: **Disclosure**

## Maine

- Requires PBMs to disclose, upon request, "all financial and utilization information . . . . relating to the provision of benefits . . . [or] services" to their immediate customer.
- Requires PBMs to automatically disclose to their immediate customers "all financial terms and arrangements for remuneration of any kind" with drug manufacturers.
- Also requires the PBM to disclose to its client health plans the net costs and its own financial interests any time a PBM
- takes steps to substitute a more expensive drug for the drug originally prescribed.

## South Dakota

- Requires disclosure of utilization information requested by the covered entity.
- Upon request from a client health plan, requires PBM to disclose "the amount of all rebate revenues and the nature, type, and amounts of all other revenues . . . ."

# How Maine and South Dakota Compare: **Confidentiality**

## Maine

- Allows the PBM to designate disclosed information as confidential to prevent the further disclosure of such information to competing PBMs, health plans or drug manufacturers.

## South Dakota

- Information disclosed by the PBM must be maintained as confidential and proprietary information and may not be used for any other purpose or disclosed to others.
- Gives PBMs strong confidentiality protections, including a legal cause of action for injunctive relief and damages in the case of violations of confidentiality.

# How Maine and South Dakota Compare: **Rebate**

**Maine**

- Any discount given to a PBM based on "the volume of sales" within the state must passed-through in full to the client health plans.
- Any payment received by the PBM from a drug manufacturer in connection with drug switching must also be passed through in full.

**South Dakota**

- No pass-through requirement.

# How Maine and South Dakota Compare: **Enforcement**

| **Maine** | **South Dakota** |
| --- | --- |
| • Enforceable by the Attorney general as unfair trade practices, or by the plans themselves under contract law. | • Enforceable only by the plans themselves. |

# How Maine and South Dakota Compare: **Licensure**

| **Maine** | **South Dakota** |
| --- | --- |
| • NO | • YES |

# How Maine and South Dakota Compare: **Rx Substitution**

## Maine

- If a PBM makes a substitution in which the substitute drug costs more than the prescribed drug, the pharmacy benefits manager shall disclose to the covered entity the cost of both drugs and any benefit to the PBM.
- The PBM shall transfer in full to the covered entity any benefit or payment received in any form by the pharmacy benefits manager either as a result of a prescription drug substitution

## South Dakota

- Allows the PBM to substitute lower-priced drugs for more costly drugs, but prohibits the PBM from substituting a higher-priced drug for a lower-priced one unless for medical reasons.

# How Maine and South Dakota Compare: **Audit Rights**

| **Maine** | **South Dakota** |
| --- | --- |
| • Not specified | • Client health plan may audit the PBM annually to ensure compliance with the disclosure provisions.<br><br>• If no contractual audit rights exist, however, statutory audit right takes effect only if PBM notifies the covered entity that other audit arrangements are "subject to negotiation." |

# What is the Legal Status of the Law?

# Legal status of PBM Laws

- PCMA filed Sept. 2003 in Federal district court in Maine for preliminary injunction to prevent implementation of ME law; similar lawsuit challenges DC law
- Preliminary injunction granted March 2004 in Maine case; DC district court followed suit
- In April 2005, Judge D. Brock Hornby upheld the law and lifted the injunction, finding for Maine Attorney general on all issues:
  - Does not violates Commerce Clause
  - Is not an unconstitutional taking of property (trade secrets) without just compensation
  - Is not preempted by ERISA
- S. Dakota law hasn't been challenged in court

# Legal Status of Cases *against* PBM's

- Medco 2004:
  - $29 million to the states
  - Prohibited from soliciting drug switches when:
    - the net cost of the proposed drug exceeds the prescribed drug
    - The prescribed drug has a generic equivalent
  - Must disclose financial incentives for switches

# Goals for Legislation

- Make sure that transactions are transparent
- Have some means of state enforcement
- Establish a legal duty between the PBM and their clients
- Make the Court settlements law