The United States' Pharmaceutical Market: Background & Leading Issues

Alan Lyles, ScD, MPH, RPh

Points from This Session

- Costs ⇑ but the Paradox of Containment
- Under use of Recommended Services **? Quality**
  ⇑ Variations ⇓ Rx Adherence
- Interrelationships Among Services ⇒ Integrated Strategies
- PBM Role(s)
- Medicare Rx Benefit
- Focus: Value & Evidence-base
- Unintended Consequences:
  ACSCs (Ambulatory Care Sensitive Conditions)
  Unfilled / Underused Rx

- International Market

World Drug Purchases – Retail Pharmacies

IMS Health – Retail Drug Monitor: 12 Months to Sept 2006*

US $ Millions	12 months July 2006	12 months July 2005	% Growth US$	% Growth Constant Exchange
Selected World	**377,388**	**365,184**	**3**	**5**
N America	**203,517**	**192,601**	**6**	**5**
- USA	**190,414**	**181,232**	**5**	**5**
- Canada	**13,103**	**11,369**	**15**	**7**
Europe (5 listed)	**92,376**	**91,938**	**0**	**4**
- Germany	26,960	26,655	1	5
- France	24,613	24,392	1	5
- Italy	14,716	14,497	2	6
- UK	15,025	15,551	(3)	0
- Spain	11,062	10,843	2	6

Source: IMS Health, Retail Drug Monitor July 2006 in US $ millions

http://www.imshealth.com/vgn/images/portal/cit_40000873/16/21/78948150Drug_%20Monitor_July2006.pdf

World Drug Purchases – Retail Pharmacies

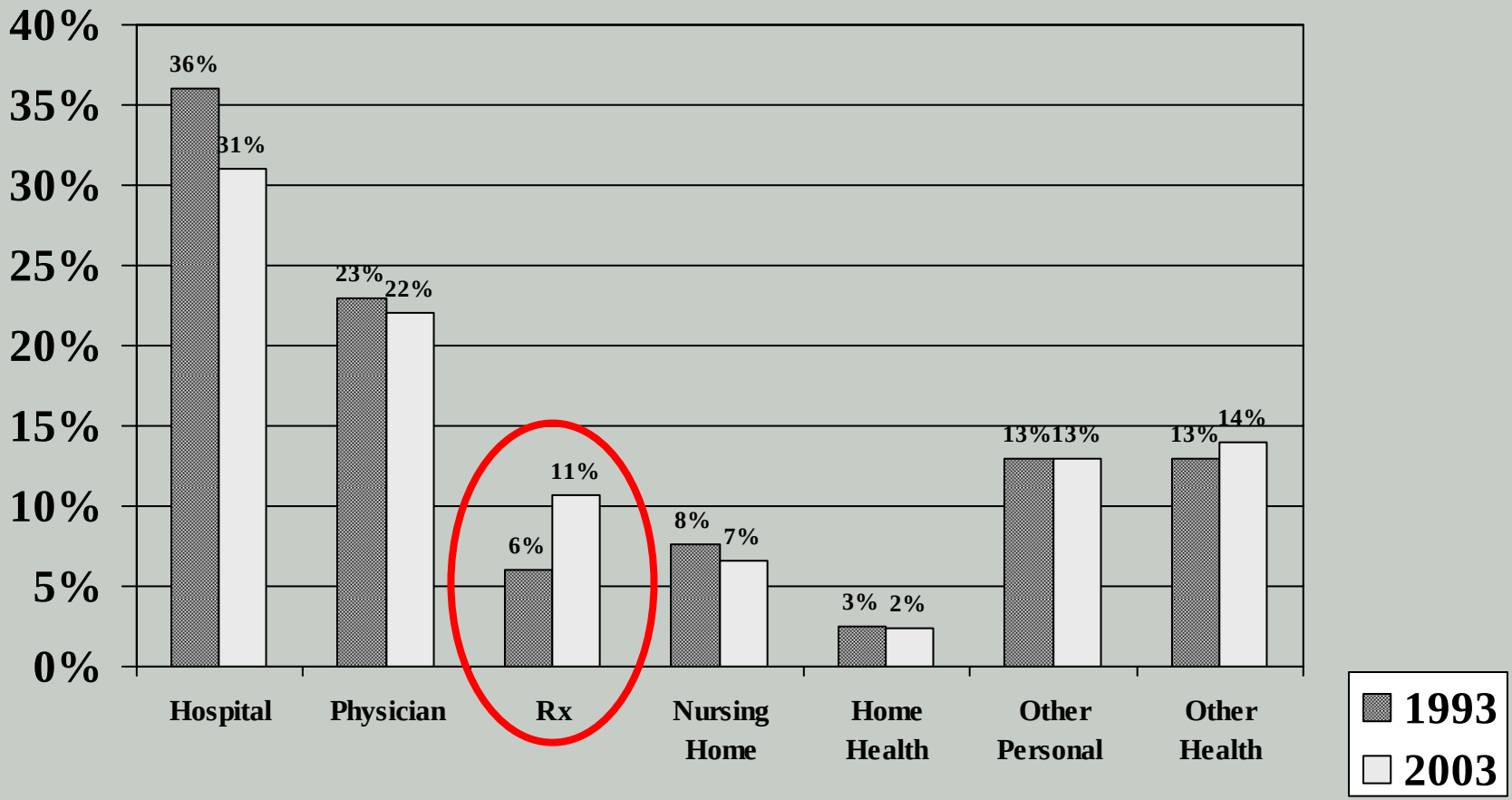
IMS Health – Drug Monitor: 12 Months to Sept 2006*

US $ Millions	12 months July 2006	12 months July 2005	% Growth US$	% Growth Constant Exchange
Selected World	377,388	365,184	3	5
Japan (*including hospital)	57,472	60,115	(4)	3
Latin America (Leading 3)	18,325	14,983	22	12
- Mexico	7,864	6,978	13	9
-Brazil	8,295	6,095	36	14
-Argentina	2,166	1,911	13	17
Australia/NZ	5,699	5,547	3	4

Source: IMS Health, Retail Drug Monitor July 2006 in US $ millions

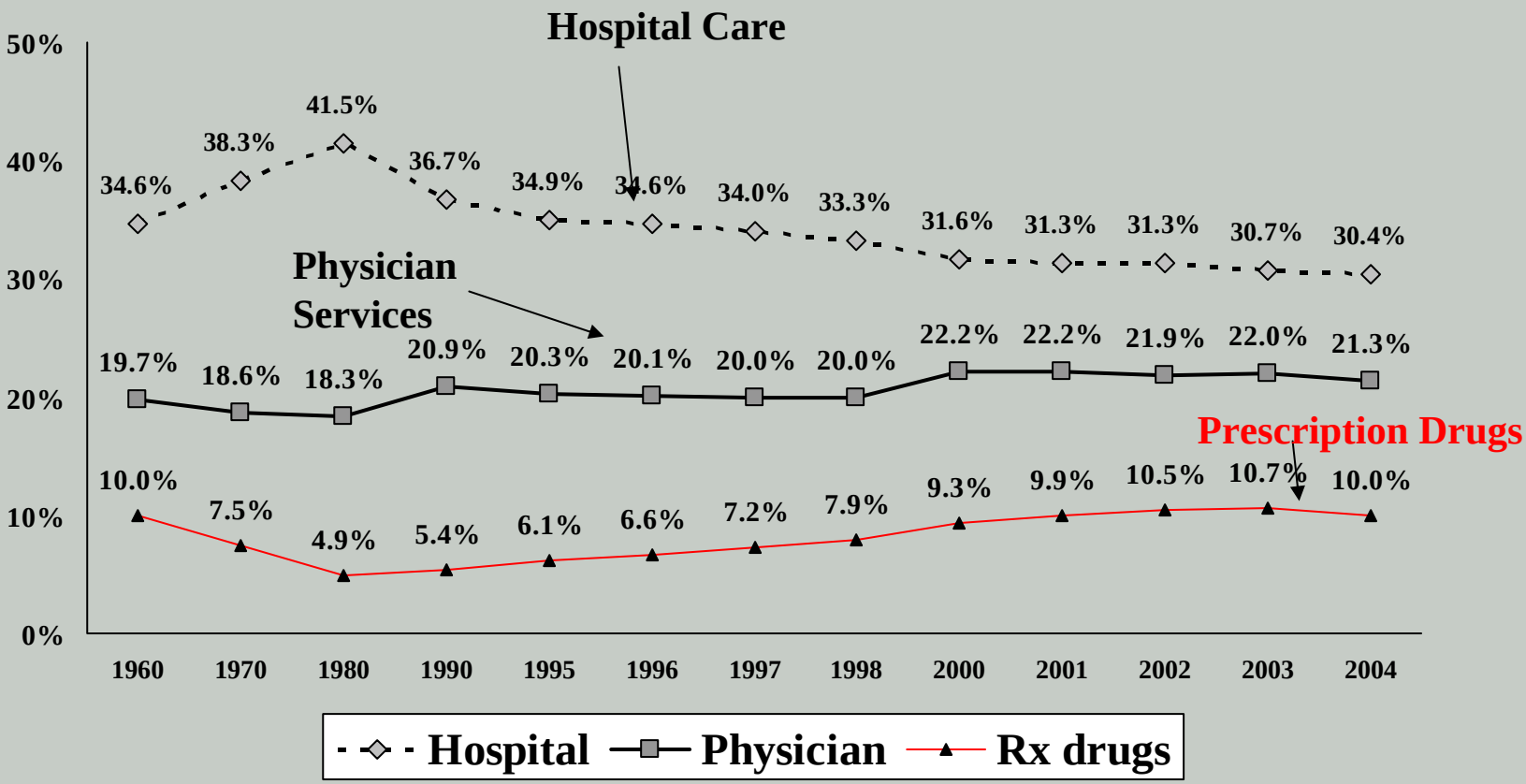
http://www.imshealth.com/vgn/images/portal/cit_40000873/16/21/78948150Drug_%20Monitor_July2006.pdf

OP Prescription Drugs as a Percentage of the U S National Health Expenditures, 1993 v 2003



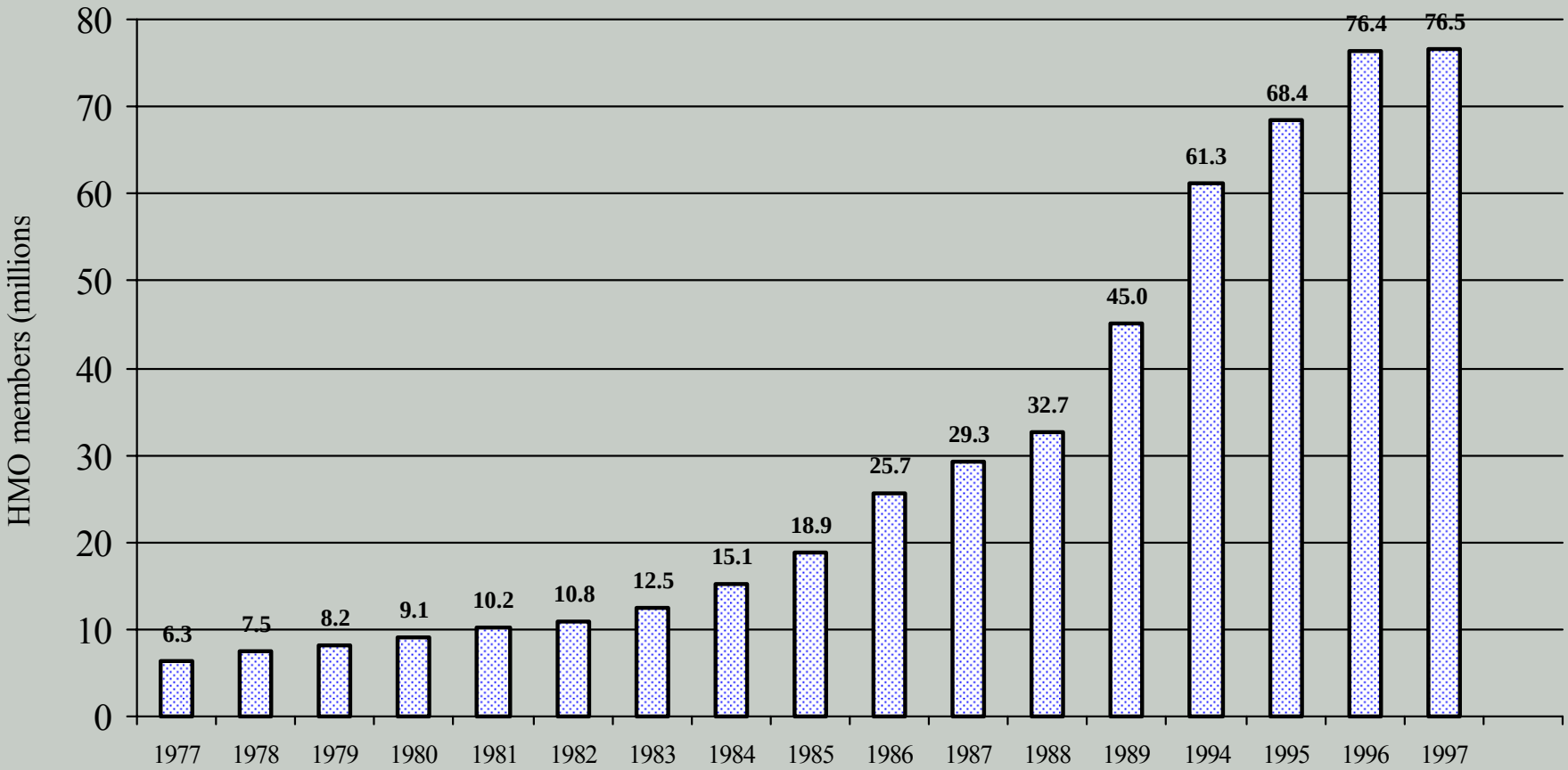
Source: Smith C, et al. Health Spending Growth Slows in 2003. *Health Affairs* 2005;24(1):185-194. Exhibit 5.

National Health Care Expenditure Cost Components, United States, 1960-2004



Sources: K. Levit et al., Health Spending Rebound Continues in 2002 *Health Affairs* 2004;23(1):147-159.; Smith C, et al. Health Spending Growth Slows in 2003. Health Affairs 2005;24(1):185-194; Smith C, et al. National Health Spending in 2003: Recent Slowdown Led By Prescription Drug Spending. *Health Affairs* 2006;25(1):186-196.

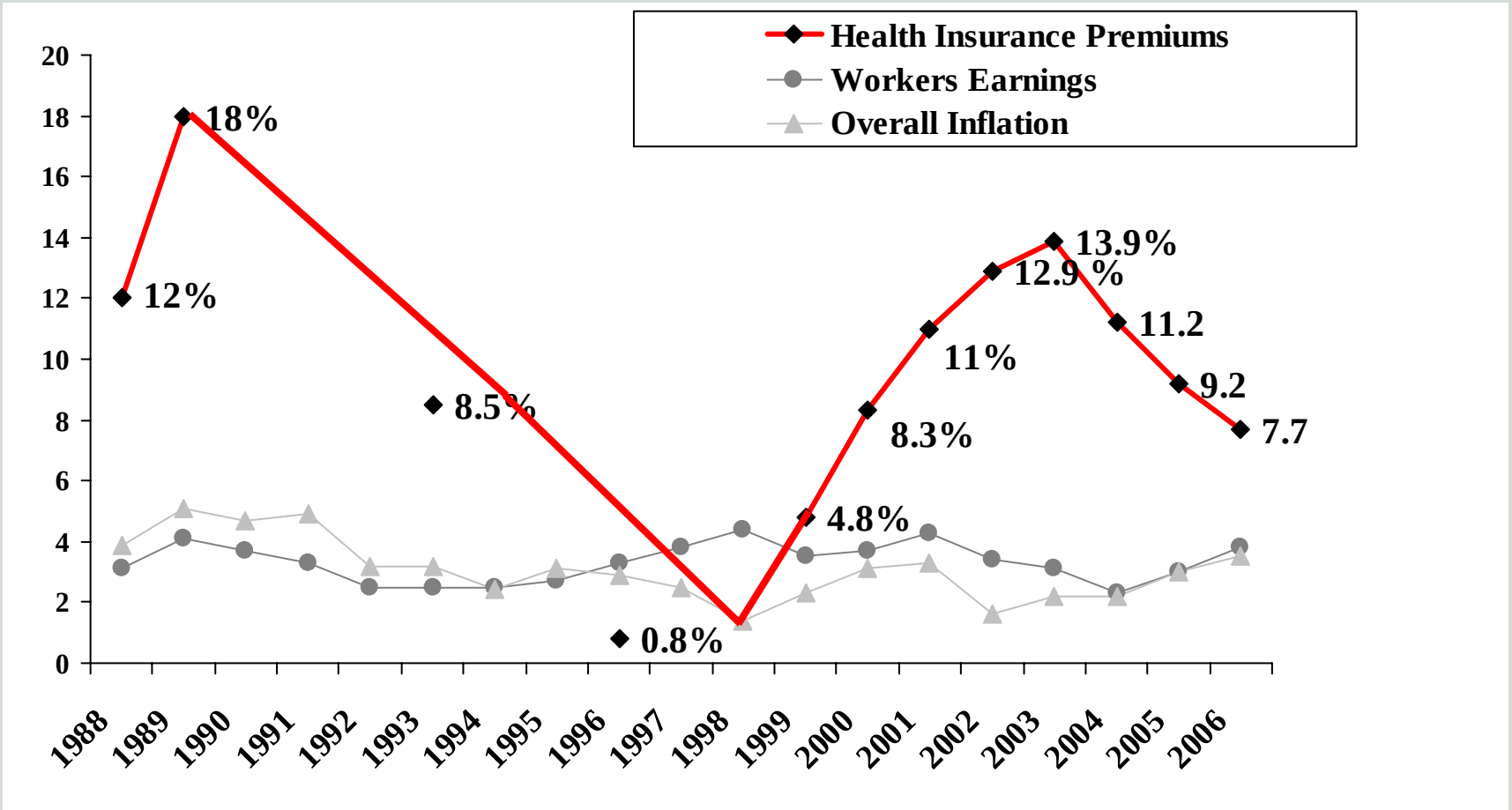
Persons Enrolled in HMOs, 1976 through 1997



Source 1: The data for 1976 through 1985 are for June of the year specified; those for 1986 through 1991 are for December. Data are from Hoy et al and Group Health Association of America, with the permission of the publisher.

Source 2: New England Journal of Medicine, Sept 3, 1992, pp 744.; Health US 1999 Table 131

Increases in Health Insurance Premiums Compared to Other Indicators, 1988-2006

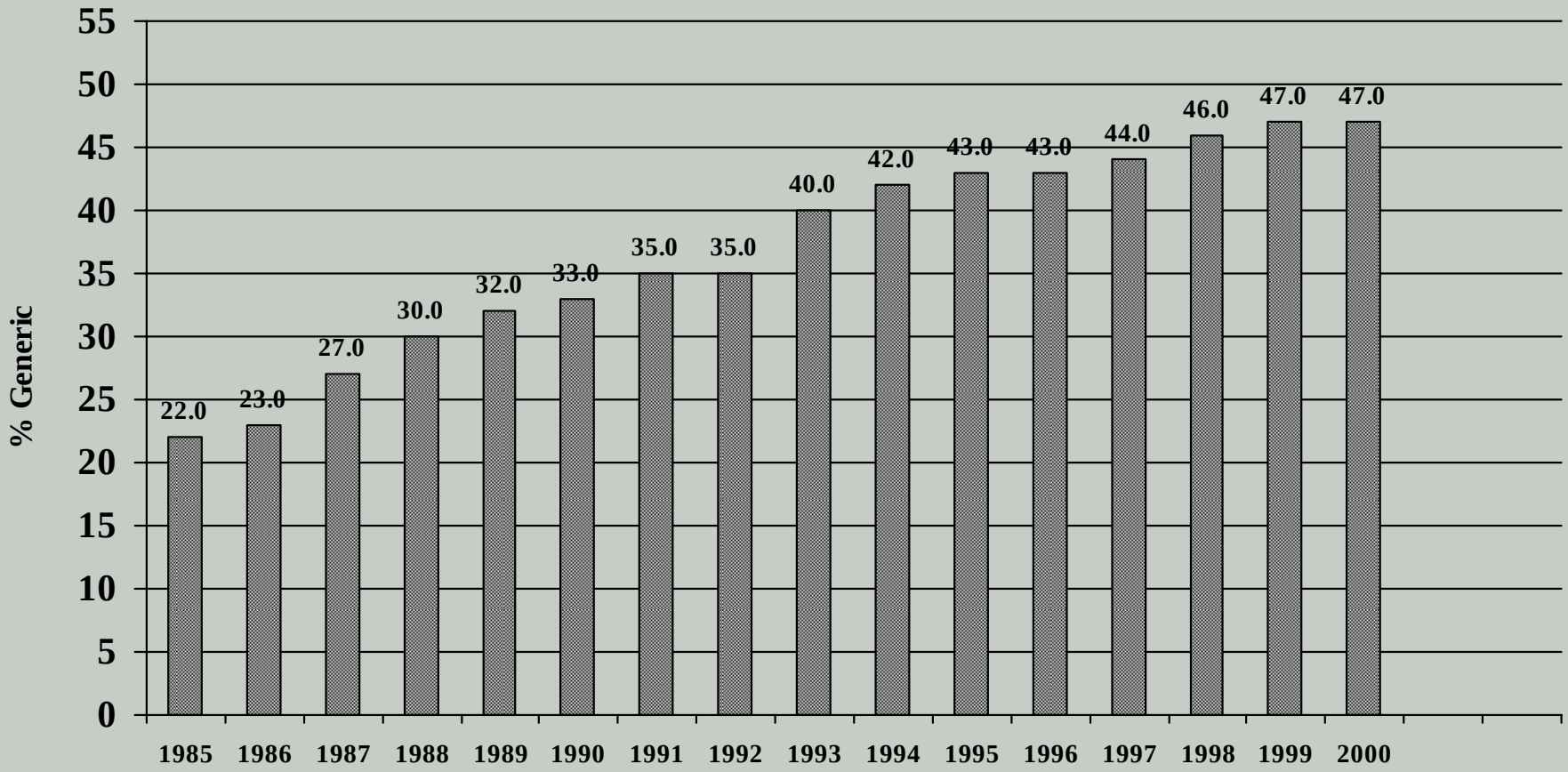


Source: Kaiser Family Foundation/Hewitt 2006 Survey Exhibit 1.1 http://www.kff.org/insurance/7527/upload/7527.pdf

Impact of Managed Care on Prescribing Practices

- More people with Rx insurance benefits
- More profiling
- More review / oversight
- More restrictions / less choice in covered items
- Benchmarks (Practice Guidelines)
- ⇑ use of generic medications & questioning cost-effectiveness of pharmaceuticals

Generic Prescriptions as a Percentage of the U S Pharmaceutical Market



Source: IMS Health, 2001. Reported in PhRMA Industry Profile 2002. Generic share of countable units, such as tablets

Drugs expected to come off-patent 2005-2006:
http://www.gphaonline.org/AM/Template.cfm?Section=Resources1&CONTENTID=1597&TEMPLATE=/CM/HTMLDisplay.cfm

Prescription Drug Trends

• Utilization:	1993	2003	Change
• # Rx	2.0 B	3.4 B	70 %
• Avg Rx/capita	7.8	11.8	13 %

- Price: Avg increase 7.4 % / yr
- Spending Projections, 2004-2013: 10.7 % / yr

Source: Heffler S, et al. Health Spending Projections Through 2013
Health Affairs *Web Exclusive* 2004;W4-79 – W4-93.

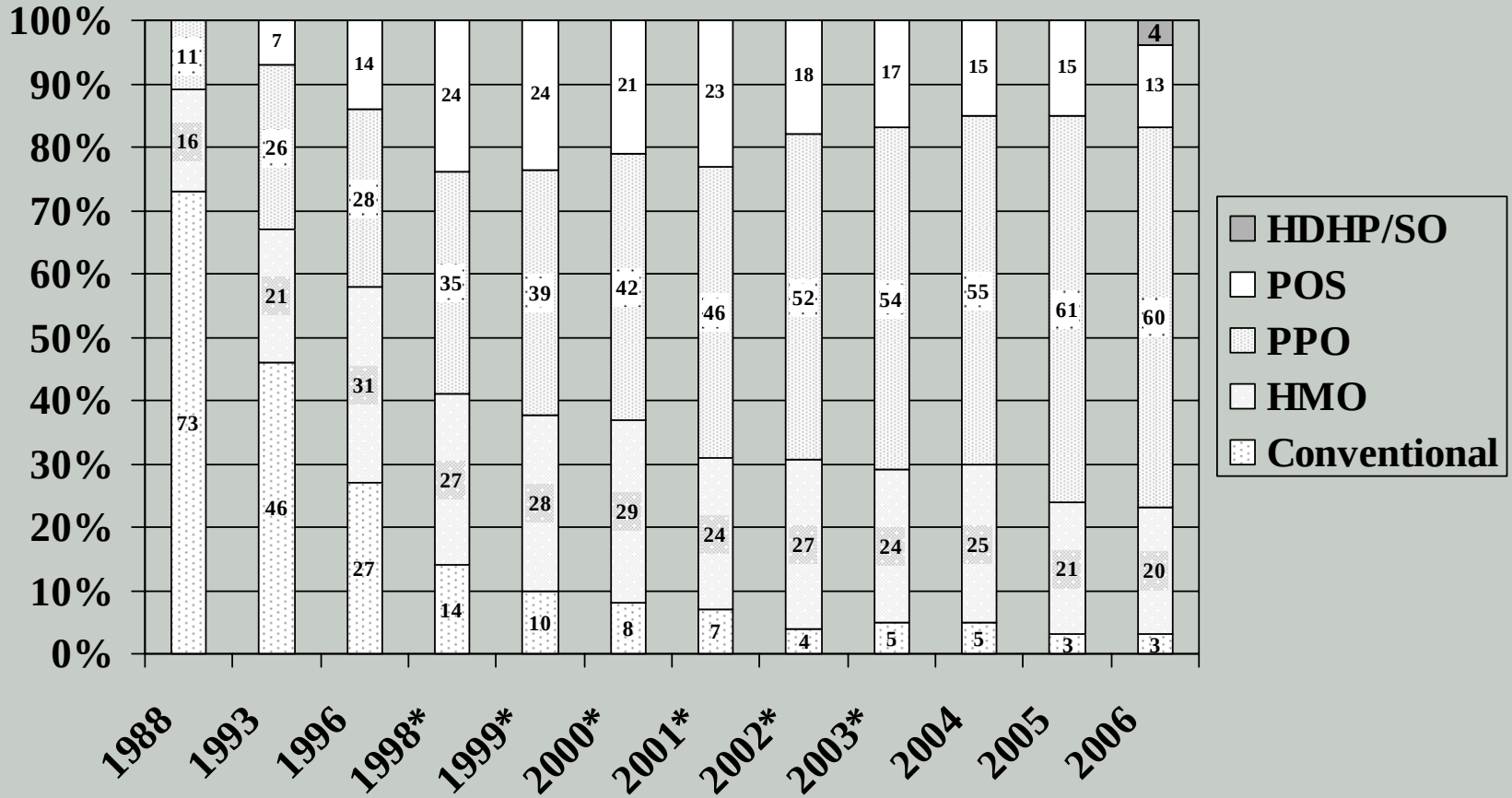
Relative Contributions to Rising Rx Expenditures, 1993-1997 vs 1997-2002

- Price = 19 %
- Rx type = 34 %
- Utilization = 47 %

- Price = 25 %
- Rx type = 34 %
- Utilization = 42 %

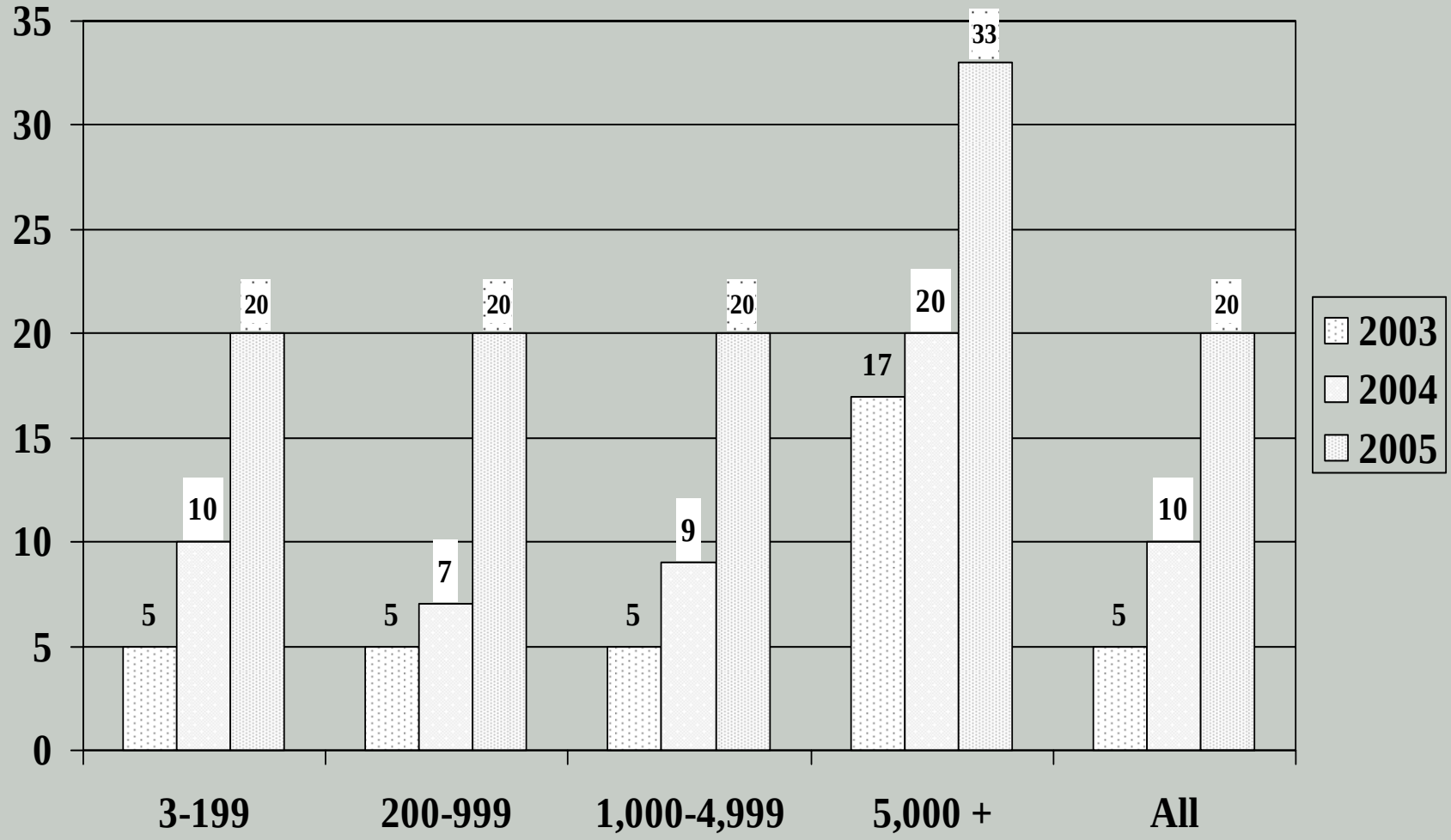
Source: Kaiser Family Foundation. Trends and Indicators, 2004 Update, Exhibit 1.17.

Health Plan Enrollment for Covered Workers, by Plan Type, 1988-2006



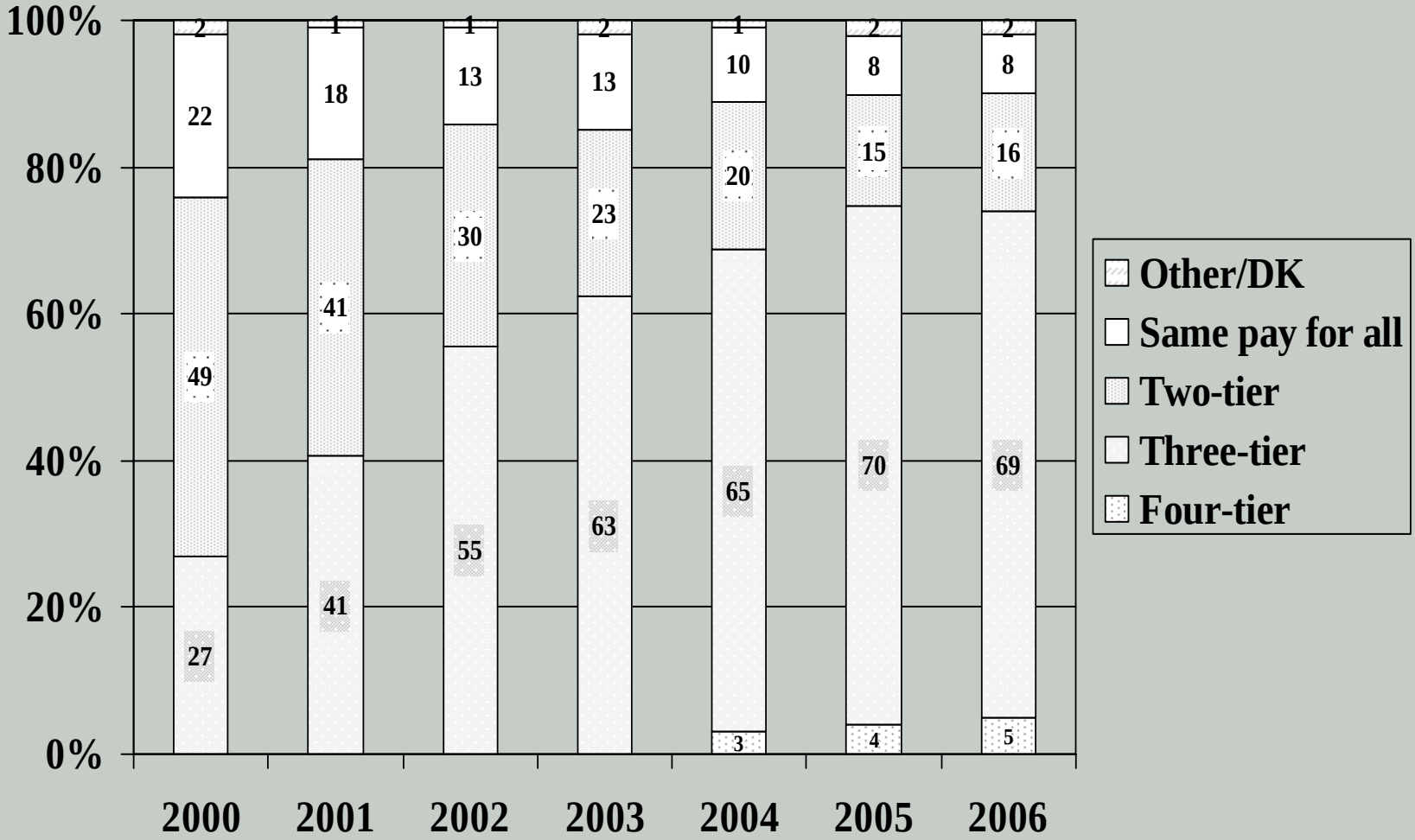
Source: KFF 2006 Annual Employer Health Benefits Survey, Exhibit 5.1 http://www.kff.org/insurance/7527/upload/7527.pdf

Percent of Firms That Offer Employees a High-Deductible Plan, by Firm Size, 2003-2005



Source: KFF 2005 Annual Employer Health Benefits Survey, Chart 15

Distribution of Covered Workers Facing Different Cost Sharing Formulas for Prescription Drug Benefits 2000-2006



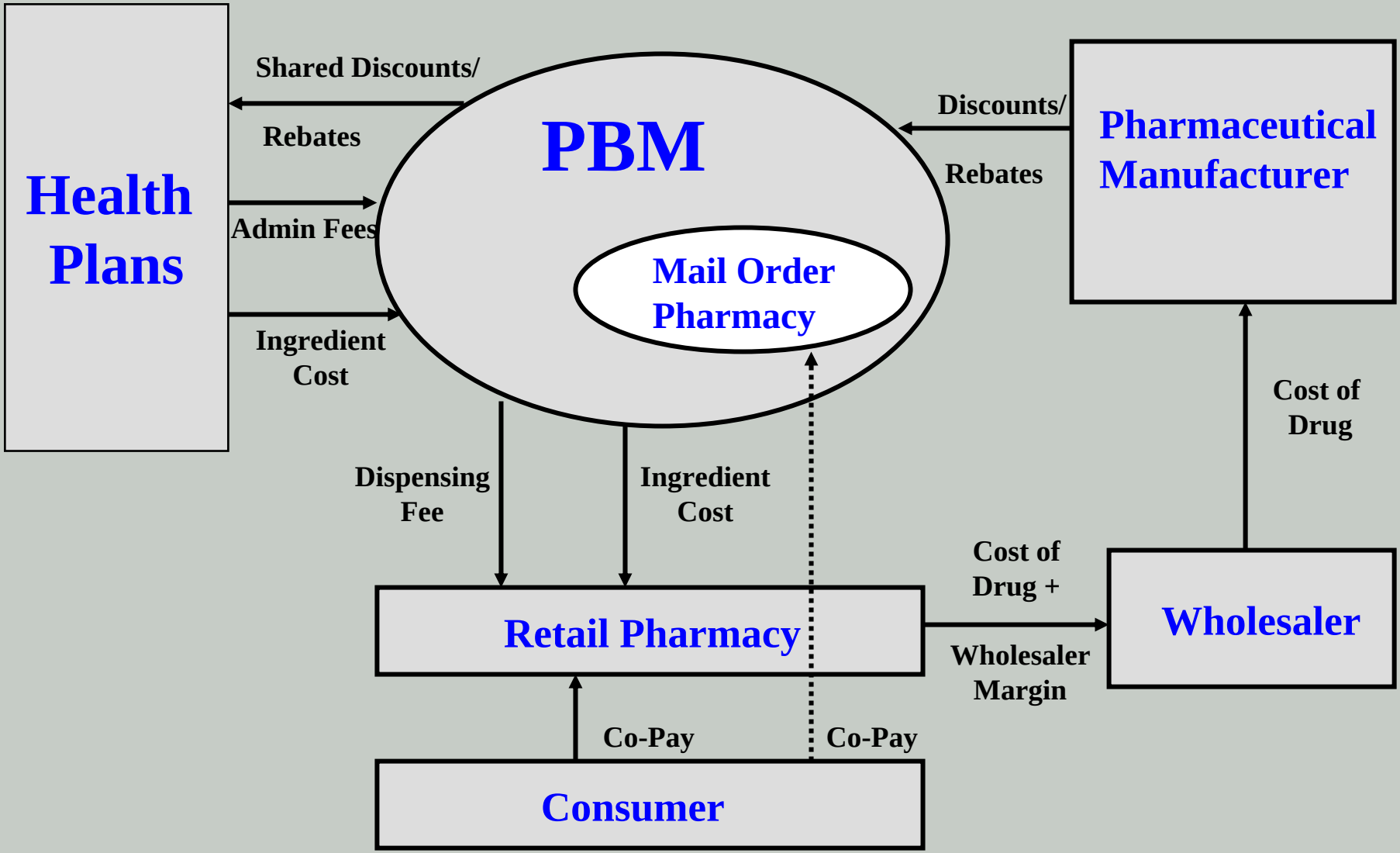
Source: KFF 2006 Annual Employer Health Benefits Survey, Exhibit 9.2

Health Care Products & Services Rated on Value for Money*

%	VG/ FG	VG	FG	Avg	Sl. Poor	Very poor	Not sure
Generic Rx	63	24	39	25	6	3	3
Med Devices	43	19	24	23	8	5	21
OTC drugs	36	8	28	43	13	4	2
Vitamins / supplements	36	9	27	43	13	4	4
Doctors	35	10	25	36	16	10	3
Pharmacies	32	8	24	41	16	8	3
Hospitals	24	7	18	33	23	15	5
Brand-name Rx	21	5	16	31	23	21	4
Health ins co.	14	4	10	26	29	26	5
Nursing homes	12	3	9	27	26	18	17

•HarrisInteractive Vol 2 issue 5, Sept 9, 2003 v
http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline_HI_Health-CarePoll2003vol2_iss5.pdf

Money Flow in The Pharmaceutical Distribution Chain*



*Source: CMS, Office of Research, Development & Information

Disease Management

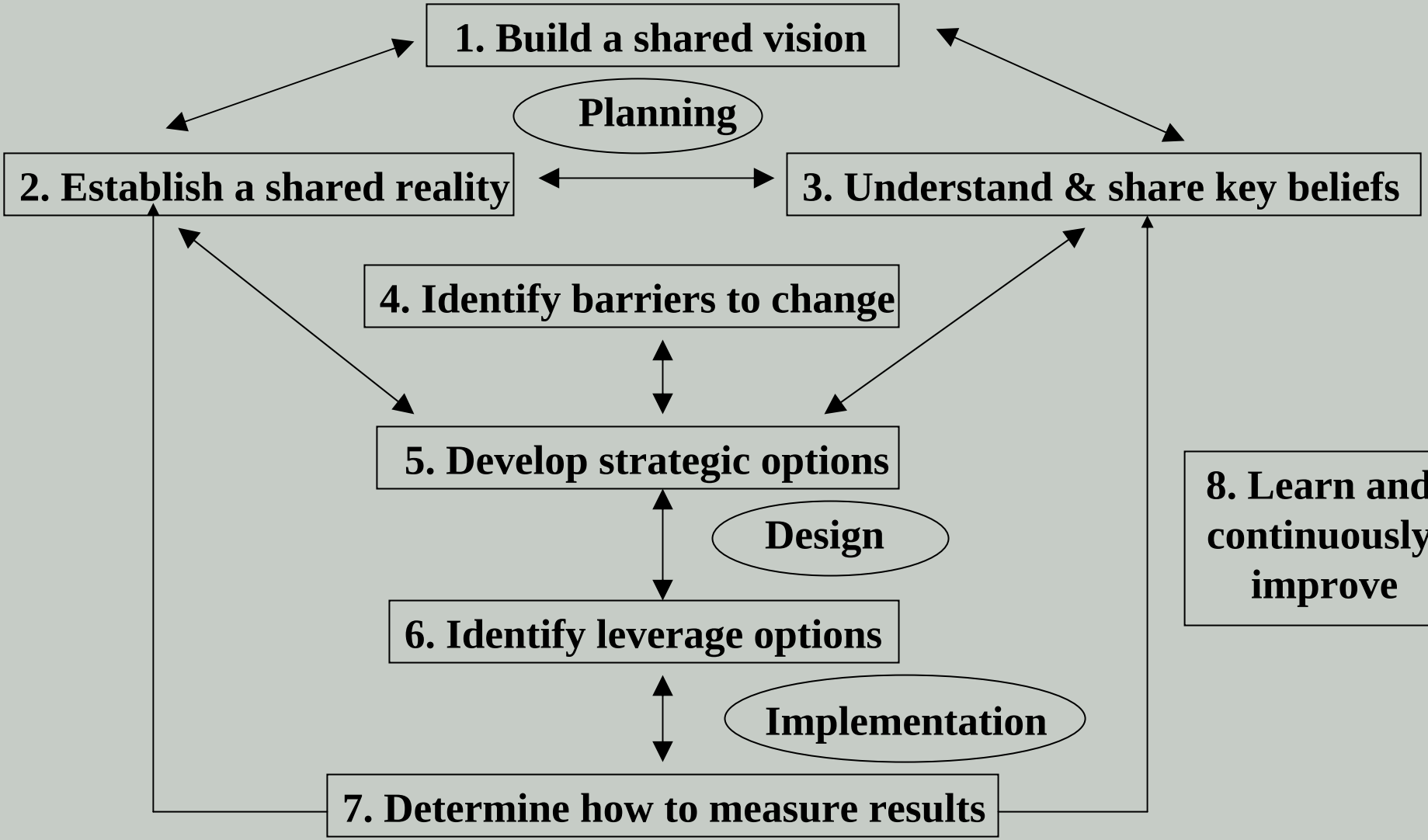
Definition:

"A process by which patients are identified and managed to achieve optimal clinical outcomes in the most cost effective manner."

i.e. Comprehensive Patient Health Management

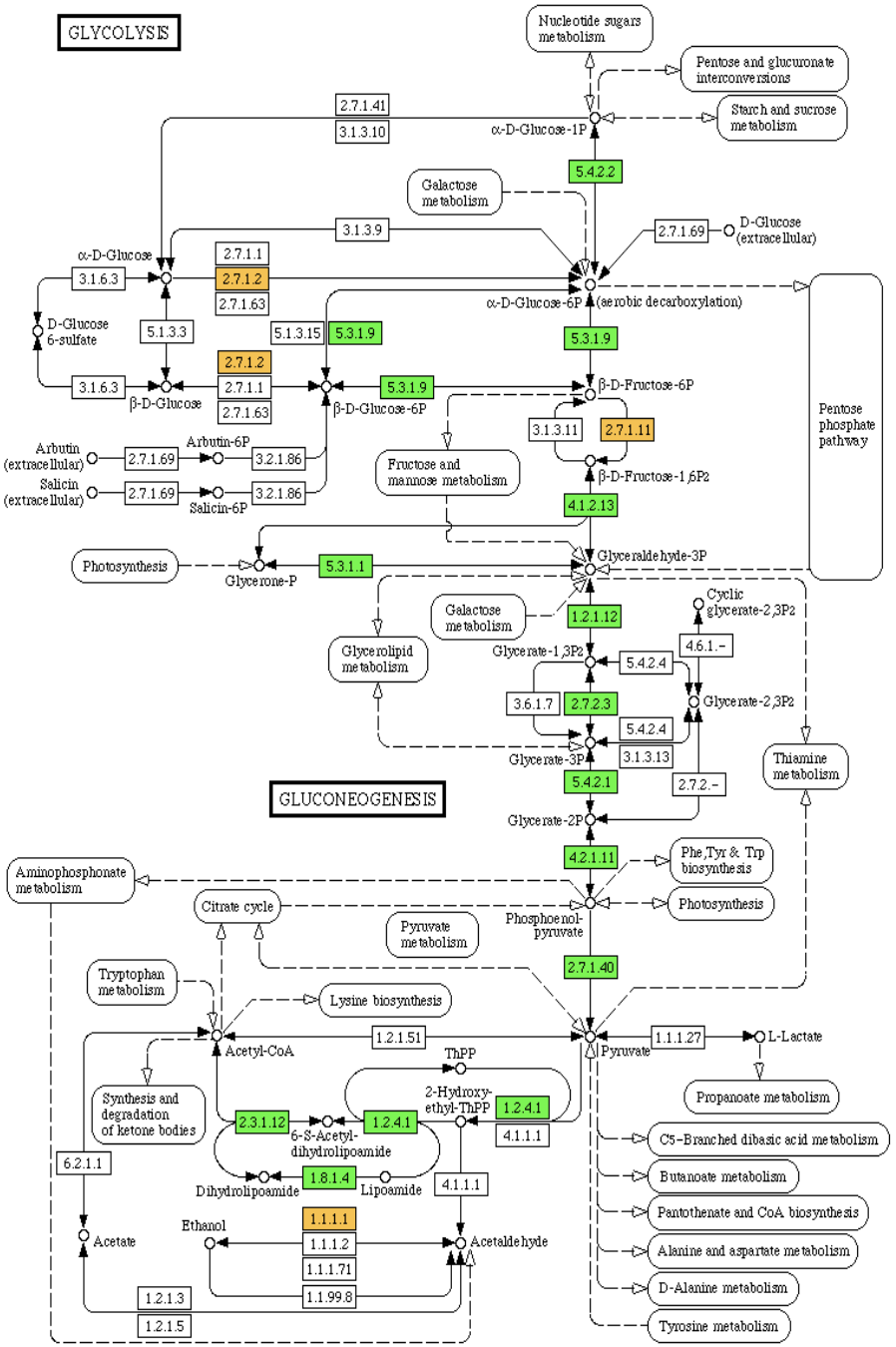
- API, Inc

The Disease Management Process as a System*



Reference: Eichert JH, Wong H and Smith DR. 'The Disease Management Development Process,' Chapter 2 in *Disease Management: A Systems Approach to Improving Patient Outcomes*. Todd WE and Nash D (editors). American Hospital Publishing, Chicago. 1997. ISBN 1-55648-168-3.

Gluconeogenesis



Medicare Part D Prescription Drug Benefit

- **Voluntary**, effective January 1, 2006
- Prescription Drug Benefit: PDPs or MedicareAdvantage
- Private entities negotiate price discounts with pharmaceutical manufacturers
- Est 2006 Rx monthly premium ~ $35
- Deductible ⇑ over time (**indexed to MC overall Rx costs**)
- Low-income beneficiaries:
  - Income and modified asset test
  - Sliding-scale or no premium or deductible
  - Different co-pays
- Employer incentives for retiree coverage

CMS: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [MMA]*

- **Passage****:
- Political Process: Part D = largest program expansion
- Administration's focus:
  - **program** = privatization
    (market vs regulatory approach)
  - **politics** = everyone benefits [MCCA lesson]
- Conference Report Process
- House Roll Call [Nov 22] **longest in history**

* http://www.cms.hhs.gov/medicarereform/

** Iglehart J. The New Medicare Prescription-Drug Benefit – A Pure Power Play. NEJM 2004 350(8):826-833.

MMA:
Selected Stakeholders & Securing Passage

- **Employers**: direct, untaxed subsidies ~ **$ 89 B**
- **Physicians**: repeal 4.5% fee decreases for 2004 & 2005, add 1.5% increase
- **Rural providers**: ~ **$ 20 B**
- **States**: Disabled Rx coverage shift to federal government ~ **$ 16 B** in 2002
- **Health Plans**: 01Mar2004 avg 10.6 % increase ; "Stabilization Fund" at Secty DHHS' discretion ~ **$ 12.5 B**
- **Rx Companies**: **ban on reimportation, no direct price negotiation by Medicare**

Iglehart J. The New Medicare Prescription-Drug Benefit – A Pure Power Play. NEJM 2004 350(8):826-833.

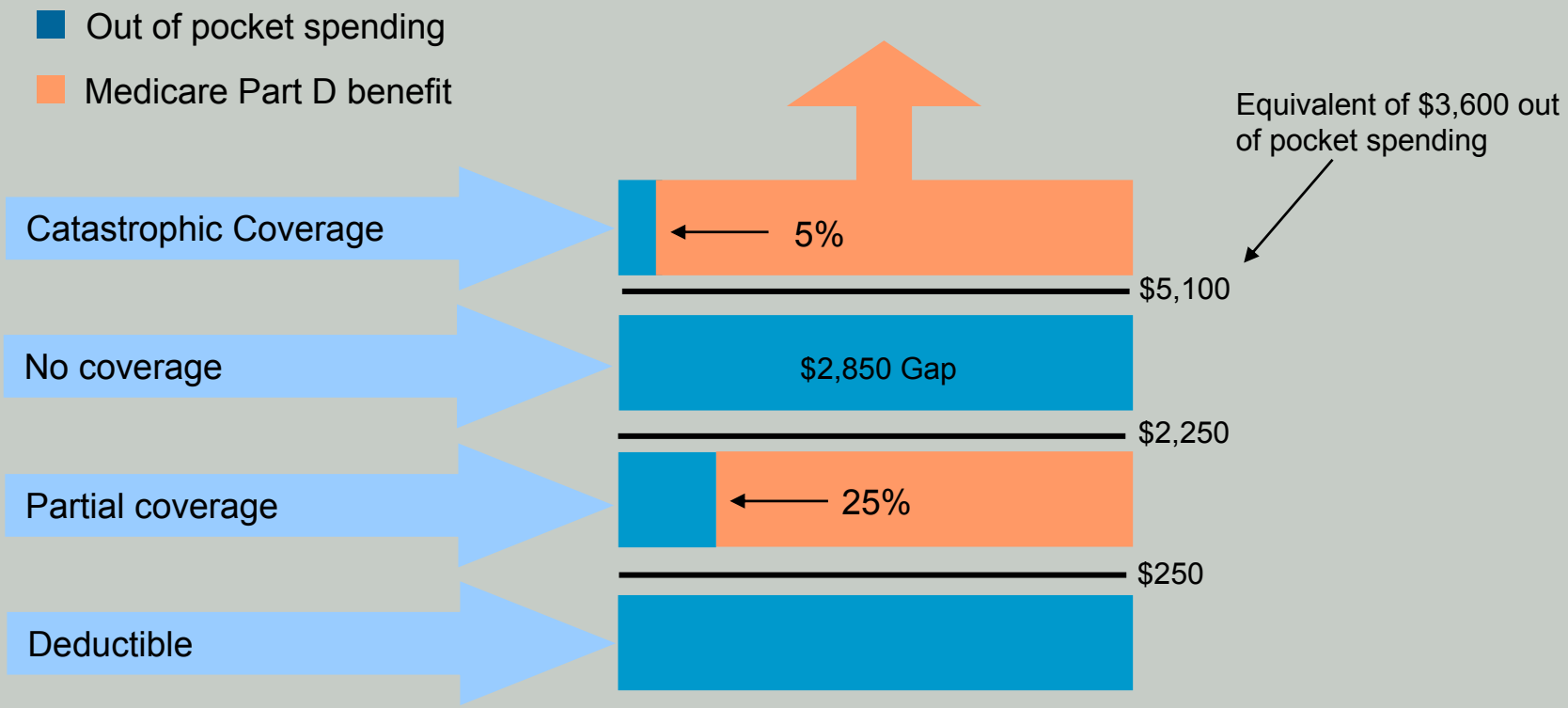
Promise and Perils for Patients and Physicians*

political compromise often begets convoluted policy,

but the Medicare drug benefit is particularly complex

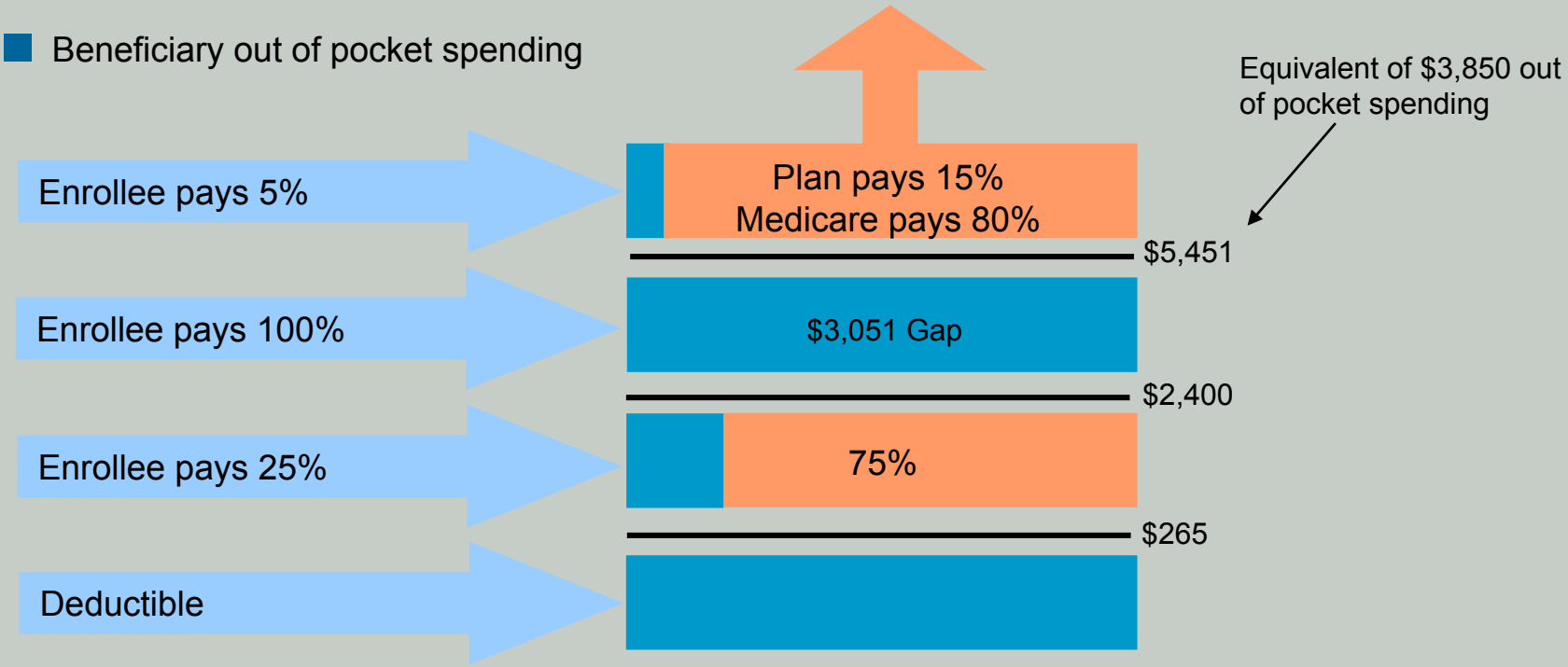
Source: Kravitz RL and Chang S. *New England Journal of Medicine* 2005;353:2735-2739

Out of Pocket Drug Spending in 2006 for Beneficiaries Under New Medicare Legislation



+ ~$420 in Annual Premiums

Standard Medicare Prescription Drug Benefit, 2007



+ $328.20 Average Annual Premium

Original Enrollment Timeline & Consequences

1) **Nov 15, 2005 – May 15, 2006:**
   Penalty free enrollment
2) **January 1, 2006:**
   New Benefit Begins
3) **May 16, 2006**:
   Late New Enrollment may carry a penalty
4) **November 15, 2006 – December 31, 2006:**
   Most recent enrollment period

True Out-of-Pocket (TrOOP) Expenses*

1) TrOOP: *The cost of prescription drugs that the beneficiary must pay on their own because they are not covered by Part D or any supplemental or 3rd Party Payor*

Incurred Expenses	Not incurred expenses
* beneficiary	* Non formulary items
* another on beneficiary's behalf	* reimbursed "through insurance … or 3rd Party arrangement
* under a SPAP	
* bona-fide charitable organization	

2) True Out-of-Pocket (TrOOP) Expense calculations, tracked by Medicare Part D plans ⇒ TrOOP Facilitation Process: routing information for Part D claims to calculate TrOOP vs payments not applicable to TrOOP

- NDCHealth. http://medifacd.ndchealth.com/home/MediFacd_home.htm
- COB Contractors http://www.cms.hhs.gov/COBGeneralInformation

Enrollment Assistance

Pharmacists counseling:

Permitted	**Prohibited**

Objective assessment of
- beneficiary's needs
- Plan options to meet those needs
  - Covered benefits
  - Formulary
  - UM tools
	Steering beneficiaries into plans based on financial self-interest

Source: CMS Part D Question and Answer Database. November 28, 2005; ID 6325.
Medicare Marketing Guide November 1, 2005 (p. 131)

Marketing Communication

What we've got here is failure to communicate.

Strother Martin
as the Prison Captain in *Cool Hand Luke*

Enrollment:
Medicare Drug Benefit: Uptake *

1) **January 28, 2005 Federal Register**:
   39 million estimated to receive MMA Rx or employer subsidized Rx benefit **
2) **June 2005**: 28 – 30 million mentioned by DHHS**
3) **Eligible beneficiaries**:
   1) Now ~ 43 M
   2) by 2030 Baby Boomer enrollments : ~ 71 M
4) **Enrolled (as of 23 Dec 2005)** ~ 21 M
   1) 10.6 M auto-enrolled by the federal gov't or HMO (includes 6.2 million Medicaid) **
   2) Individually enrolled ~ 1 M
5) Est. 9 M more to enroll in 2006

Caution: **~ 17 million must sign up individually or no coverage*****

*Zhang J. Seniors Are Slow to Sign Up on Own for Drug Benefit. WSJ 23 Dec 2005 ** Pear R. Over a Million on Medicare Sign up for New Drug Program. New York Times 23 Dec 2005
*** Avalere Health, cited in Pear.

Retirees

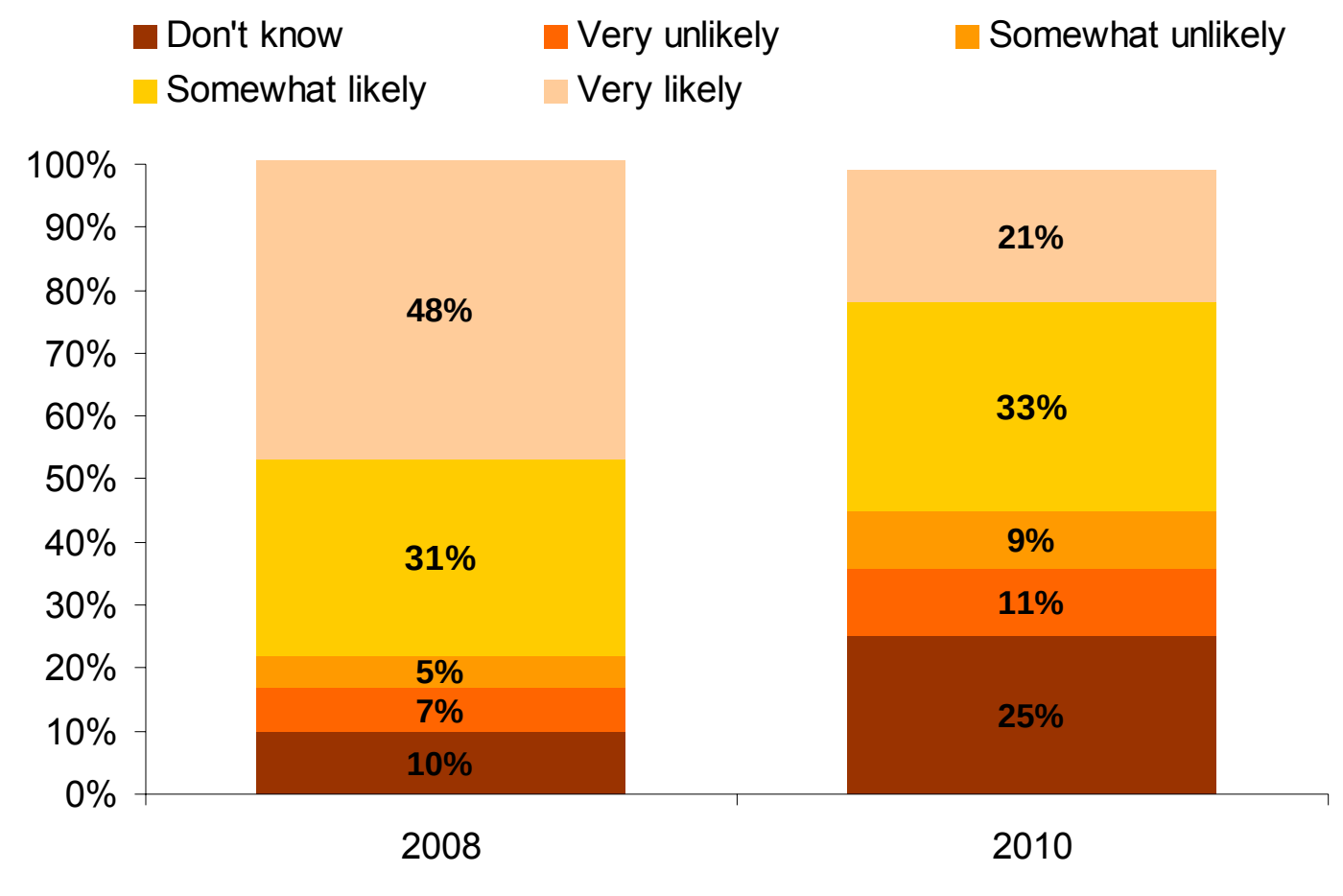
Impact on employer coverage for retirees who sign up for a Medicare drug plan among employers continuing to take the subsidy in 2007

Retirees will lose all retiree medical coverage	36%
Retirees will retain current employer-sponsored coverage	32%
Retirees will lose prescription drug coverage only	32%

Applies to plan with the largest number of age 65+ retirees. Based on responses from private sector firms with 1000 or more employees offering retiree health benefits.
Source: Kaiser/Hewitt 2006 Survey on Retiree Health Benefits, December 2006.

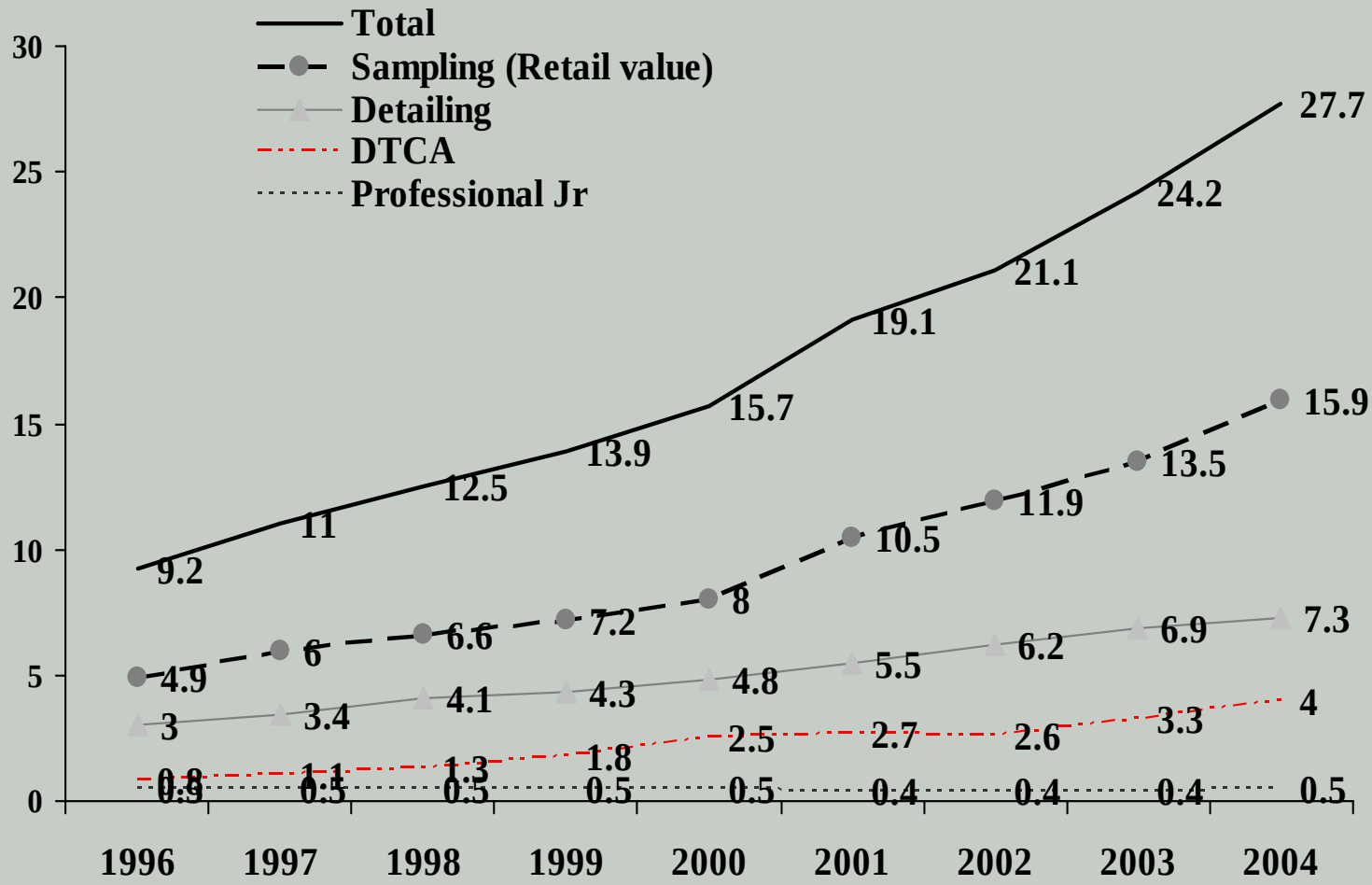
Retirees

Likelihood of continuing drug benefits and accepting employer subsidy in the future among employers taking the subsidy in 2006



Numbers do not add to 100% due to rounding. Data are for firms maintaining drug benefits and accepting the employer subsidy in 2006. Based on responses from private sector firms with 1,000 or more employees offering retiree health benefits. Source: Kaiser/Hewitt 2006 Survey on Retiree Health Benefits, December 2006

Trends in Promotional Spending for Prescription Drugs, 1996-2004 ($ in Billions)



Source: Kaiser Family Foundation. Trends and Indicators, 2005 Update, Exhibit 1.20.

http://www.kff.org/insurance/7031/ti2004-1-20.cfm

"The evidence for DTCA's impact on pharmaceutical sales is as impressive as is the lack of evidence concerning its impact on the public health."

- Lyles A. Ann Rev Pub Health 2002

SUPPLEMENTAL MATERIAL

Dual-Eligible: State Payments to the Federal Government

(The "Clawback" or "Phased-down State contribution")

Jan 1, 2006: Federal government pays for OP Rx for elderly & disabled; stops payments to states ; monthly payments by each state to the federal government based on expected OP Rx costs for these beneficiaries (as of Feb 2006)

*** Monthly state "Clawback" payment =**
Per capita expenditures * Full dual eligibles * Phased-Down %

> Per capita expenditures = state share of monthly per capita M/A expenditures on Rx covered under Part D for dual eligibles during 2003 trended forward to 2006 & adjusted for rebates and managed care
{Trending based on National Health Expenditure drug cost growth}
> Full Dual Eligibles = # of M/A dual Eligibles enrolled in a Medicare Part D plan in the month for which payment is based
> Phased Down % = 90 % in 2006, ⇓ 75 % 2015.

2006 payments from states to federal government ~ $6.6 B

Sources: State Financing of the Medicare Drug Benefit: New Data on the "Clawback" Nov 2005. http://www.kff.org/medicaid/upload/7438.pdf Schneider A. The "Clawback:" State Financing of Medicare Drug Coverage June 2004. http://www.kff.org/medicaid/upload/The-Clawback-State-Financing-of-Medicare-Drug-Coverage.pdf

Medicare Drug Benefit Political Timeline

1965 Medicare (Title XVIII of the Social Security Act)

- Part B excluded OP Rx "on the grounds of unpredictable and potentially high costs"* but did cover Rx administered in a physician's office

1967-1969 DHEW Task Force on Prescription Drugs

1988-1989 MCCA

1989 Reimbursement of Epoetin

1993-1994 [failed] Health Security Act

1998-1999 National Bipartisan Commission on the Future of Medicare

2000 Election & federal budget surplus

2003 Final Conference Report Nov 19th: http://www.ascp.com/medicarerx/docs/HR1conflegtext.pdf

2003 MMA

2004/2005 Discount Drug Card Program

2004 Final Regulations issued http://www.ascp.com/medicarerx/docs/PartDFinalRegs.pdf **= 1,162 pages**

2006 Prescription Drug Benefit begins

Source: Lee PR, Oliver TR, and Lipton HL. A history of Medicare and Prescription Drug Coverage: A Persistent Issue in a Changing Political Climate. Report to the Kaiser Family Foundation. June 2003.[Augumented]

Medicare Drug Benefit
Open Issues

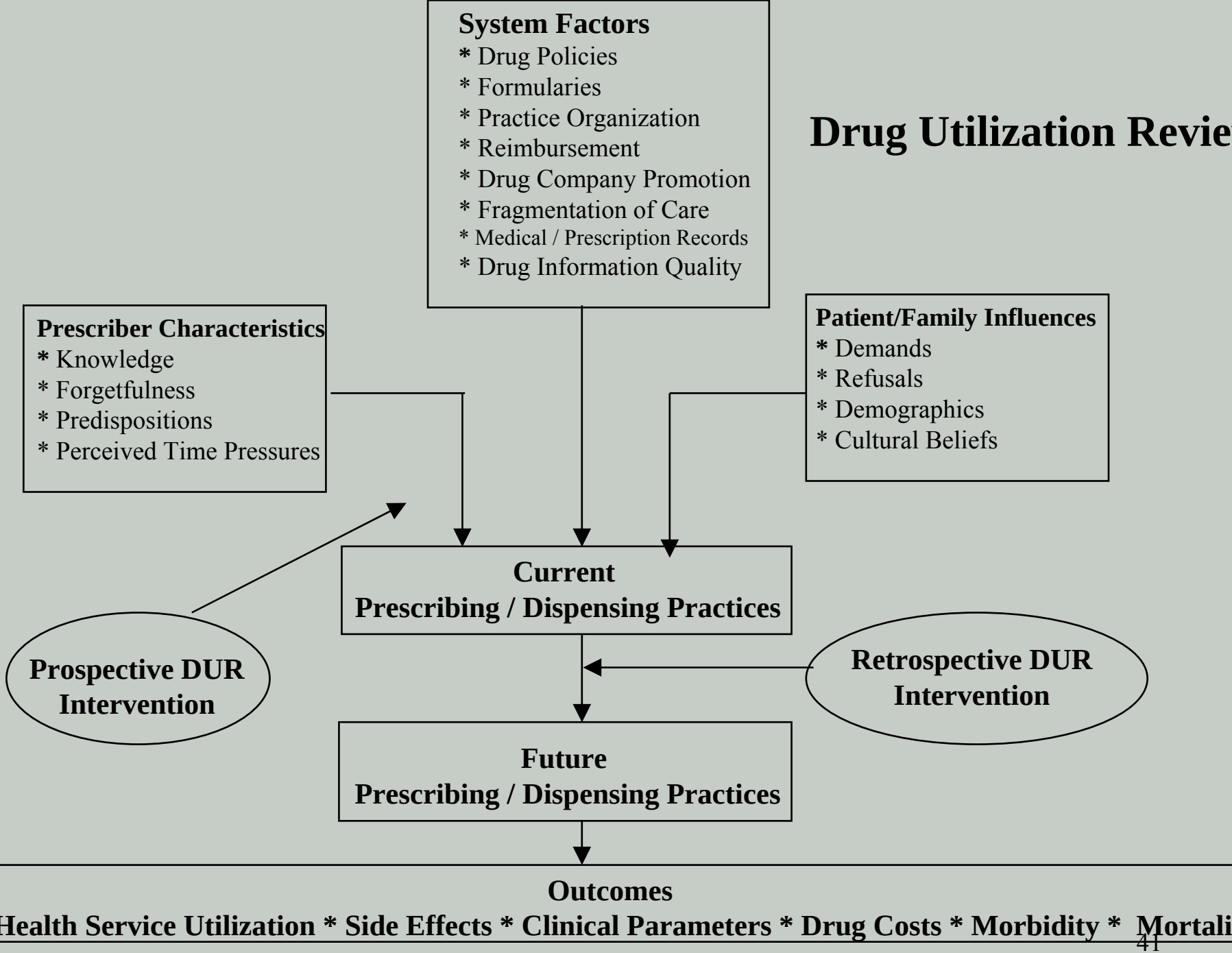
1) **Coverage gaps**
2) **Doughnut hole impact**
3) **Political resolution?**
    1) Initial vs current cost ests (over 10 yrs) & affordability
    2) Private sector dominant role … Dem / Rep differences
4) **Reexamine region definitions**, county of residence for regional health plan payments
5) **Retiree participation**
6) **Managing predicted rapid expansion in plan enrollments** in 2006* / **Sustainability**

UnitedHealth Group	3.7 M
Wellpoint, Humana, PacifiCare	2 M each
Aetna, Coventry Healthcare Inc	1 M

7) **Late enrollment penalties:** Mounting pressure to extend the sign-up period: Stark (D Rep Freemont); Fitzpatrick (R Rep PA) proposed legislative change to extend six months
8) **Reimportation:** *Delay is the deadliest form of denial* (C. Northcote Parkinson)
9) **Biotechnology / Biological products**

• Source: Medicare Advantage News. United Opens Fast on Part D Enrollment. November 24, 2005.
• Alonso-Zaldivar R. Pressure mounts to extend deadline for drug benefit. LA Times Dec 2, 2005.

Drug Utilization Review



Lipton & Bird, Medical Care 31(12), 1993

Reducing Variation

"Profession based practice aims to learn from and reduce (inappropriate) variation arising among clinicians while retaining (appropriate) variation arising from patients.

…

In an increasingly complex clinical care delivery environment, structure care delivery so that evidence-based best practice is the default course."

Brent James, MD, Mstat

Quality Improvement Opportunities in Health Care – Making it Easy to Do It Right

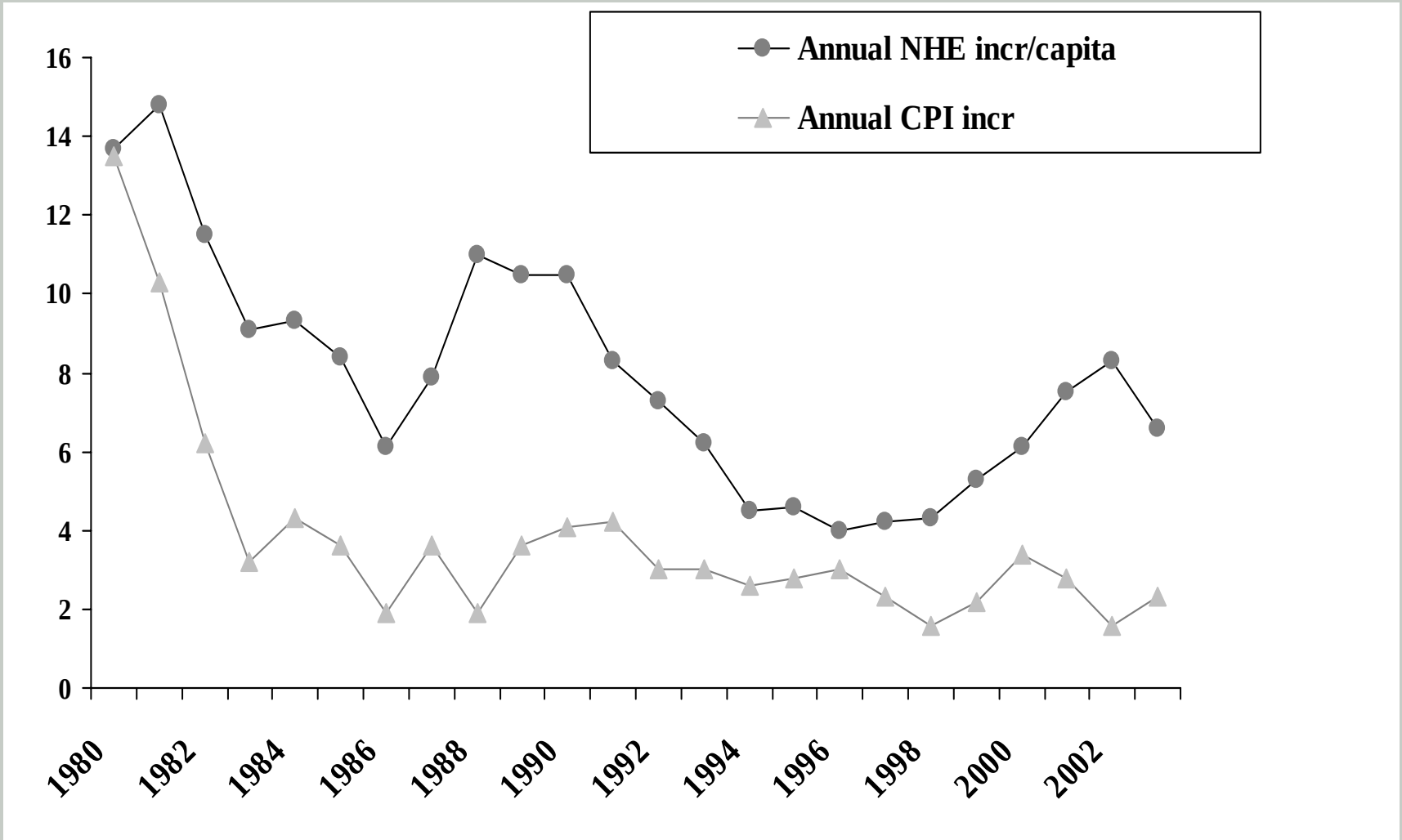
Journal of Managed Care Pharmacy 2002;8(5):394-399

The Pharmacist Workforce: A Study of Supply & Demand for Pharmacists*

- Retail Rx 1992 = 1.9 B; 1999 = 2.8 B (44 %);
- Contributing Factors to RPh Shortage:
  - Incr per capita use
  - Incr retail competition
  - More professional roles / opportunities
  - Incr workers part-time / shorter hrs
  - Incr Rx insurance coverage: incr Rx #, Incr paperwork
- Consequence(s):
  - Less time for counseling
  - More stress, less satisfaction
  - More faculty leave academia

* DHHS, HRSA, Bureau of Health Professions 2000

% Annual Increase in NHE per Capita vs Increase in CPI, 1980-2003



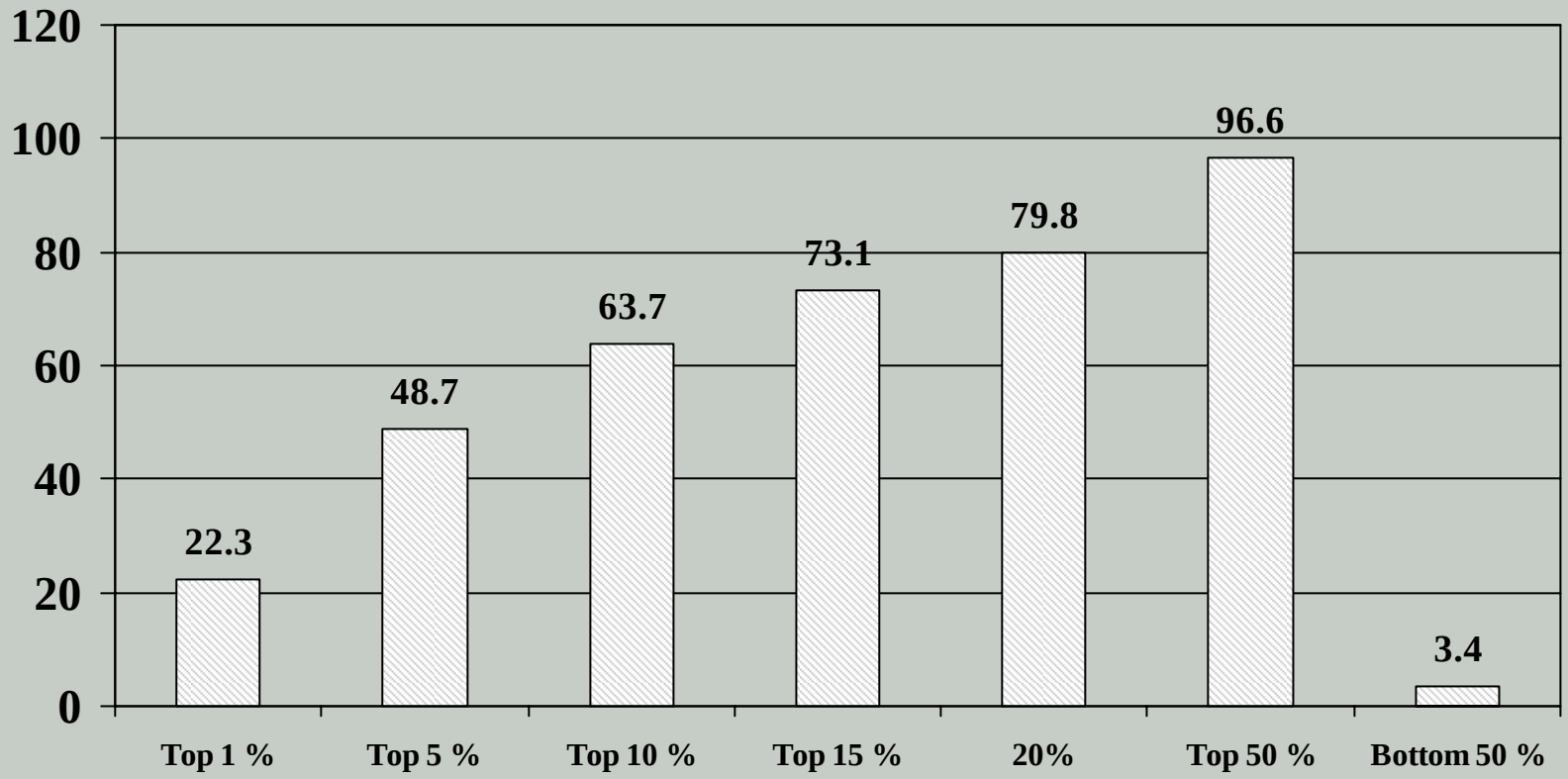
Source: Kaiser Family Foundation. Trends and Indicators, 2005 Update, Exhibit 1.3.

Per Capita % Growth in Health Care Spending (1995-2006)

	All Services	Hospital IP	Hospital OP	MD	Rx	Other	GDP
1995	**2.2%**	**-3.5%**	7.9%	1.9%	**10.6%**	n/a	**3.4%**
1996	2.0	-4.4	7.7	1.6	**11.0**	n/a	**4.4**
1997	3.3	-5.3	9.5	3.4	**11.5**	n/a	**5.0**
1998	5.3	-.02	7.5	4.7	**14.1**	n/a	**4.1**
1999	7.1	1.6	10.2	5.0	**18.4**	n/a	**4.8**
2000	7.8	4.1	9.8	6.3	**14.5**	n/a	**4.8**
2001	10.0	8.7	14.6	6.7	**13.8**	n/a	**2.1**
2001	10.4	8.5	14.6	7.7	**13.5**	8.5%	**2.1**
2002	10.1	8.2	13.0	7.9	**13.1**	6.9	**2.3**
2003	7.8	6.1	11.1	6.3	**8.9**	4.1	**3.7**
2004	7.5	5.3	11.2	6.0	**8.3**	6.3	**5.8**
2005	7.4	7.1	10.4	7.1	**4.8**	12.0	**5.4**
2006	7.7	5.1	10.3	7.7	**7.2**	10.8	**5.9**

Source: Center for Health System Change, Oct 2006;No. 33: Data Bulletin: Tracking Health Care Costs http://hschange.org/CONTENT/879/?topic=topic01/

Concentration of Health Spending in the Total U.S. and Family Populations, 2002*



Source: Kaiser Family Foundation. Trends and Indicators, 2005 Update, Exhibit 1.11.

Medication Therapy Management

Core Elements @ http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=3303

- **Pharmacist recognition** *to optimize therapeutic outcomes through improved medication use*
- **Targeted Beneficiaries**: Pharmacies negotiate an agreement to provide MTM services and bill a plan for its targeted beneficiaries
  1) Multiple chronic diseases 2) Taking multiple covered part D drugs
     ⇒ The specific diseases and drugs are determined by each PDP & MA-PD
  3) Drug costs exceed $4,000 in 2006

- Core Elements of an MTM Service: **Pharmacy Services Technical Advisory Coalition (APhA / NACDS Initiative & 9 other organizations) developed this model:**
  - *Medication Therapy Review* * *A personal medication record*
  - *A medication action plan* * *Intervention and referral, and*
  - *Documentation and follow-up*
  - *Services beyond the core elements must be evaluated against each state practice act, e.g., collaborative drug therapy management* **

- ***Caution*: Billing Medicare MTM services but not others (that is making it a free service for them) may be fraud ****

Source: **Hogue M. MTM Tip of the Month. Pharmacy Today 2005;11(10):13.

ePrescribing

- ***ePrescribing***: standards as of Jan 1, 2006 **required for all Medicare prescription drug plans**, optional for MDs and pharmacies
  - Ease of use * eligibility determination
  - Improved safety * reduced administrative costs
  - Support DUR
- **Longer term goal**: assist ID of evidence-based most cost-effective RX
- **Foundation ePrescribing Standards**:
  - NCPDP SCRIPT version 5: prescriber-pharmacy transactions
  - ASC X12N 270/271, version 4010 & Addenda: eligibility and benefits
  - NCPDP Telecommunications Standard, version 5.1 & NCPDP Batch Standard version 1.1: eligibility exchanges
- **Initial ePrescribing standards** between pharmacies and Part D plans:
  - Formulary and benefit * Patient instructions
  - Prior authorization messages * Clinical drug terminology
  - **Pilot Project: Jan 1, 2006, final rule by April 1, 2006**
- Southeastern Michigan Electronic Prescribing Initiative (among the largest ePrescribing programs) ⇒ grant to Medco Health Solutions to evaluate its impact

Source: CMS November 1, 2005. Electronic Prescribing Standards Announced to Make Medicar New Prescription Drug Benefit Easier and Safer. http://www.hhs.gov/news

CMS Formulary Review Draft Guidance *

- **P&T Committees**: "plans guarantee implementation & use consistent with" ASHP or AMCP principles for evidence-based decisions
- **Formulary lists**: Review classification systems & actual drugs (USP Model Guidelines** supported, but not required); non-discriminatory access; ≥ 2 Rx in each approved category & class (but CMS can require >)
- **Benefit management tools**: "clinically appropriate and non-discriminatory," e.g., PA; standards for appeals, exceptions and timely access

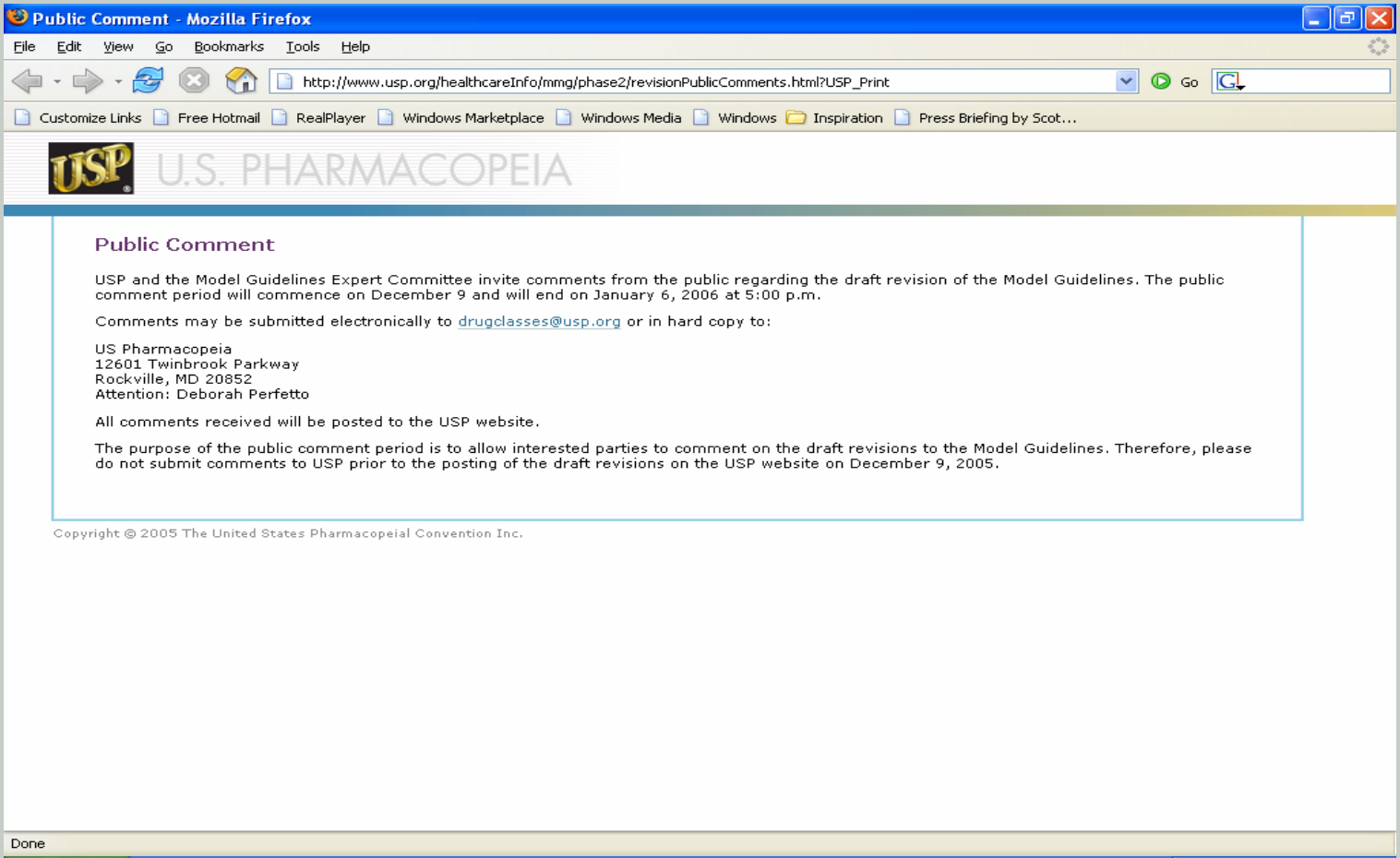
CMS Formulary Fact Sheet. http://www.cms.hhs.gov/pdps/formulary%20fact%20sheet.pdf
Final guidelines http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidance.pdf

USP Model Formulary Review

http://www.usp.org/healthcareInfo/mmg/phase2/revisionPublicComments.html?USP_Print

Revised Model 09 DEC 2005

http://www.usp.org/healthcareInfo/mmg/phase2/



Fraud and Abuse

- ***… even before the discount drug card …***
- ***Eight Medicare Drug Integrity Contractors (MEDICS):***
  - ***Data mining and analysis to ID possible fraud and abuse***
  - ***Investigate possible fraud and refer to law enforcement as appropriate:***
    - ***Enrollment*** **** "Unusual activities"***
    - ***Determining eligibility*** **** Fraud complaints***

- ***The eight are:***
  - Delmarva Foundation for Medical Care
  - Electronic Data Systems, Ins (EDS)
  - IntegriGuard, LLC
  - Livanta, LLC
  - Maximus Federal Services, Inc.
  - NDCHealth
  - Perot Systems Government Services
  - Science Applications International Corporation (SAIC)

Source: CMS Fact Sheet October , 2005. The New Prescription Drug Program: Attacking Fraud and Abuse. http://new.cms.hhs.gov/media

Long Term Care
Fraud and Abuse Concerns

Pharmacy rebates for Rx Covered by Medicare Part D

- CMS: *significant concerns … rebates or discounts paid to LTC pharmacies to provide access or move market share in the context of Part D could create significant fraud and abuse concerns, including potential Federal antikickback concerns under section 1128B(b) of the Social Security Act [42 U.S.C.*' 1320a-76(b)] … [because they] would affect the best price calculation …"*

2) LTCPA: *These price concessions are taken into consideration when negotiating competitive rates with Medicare Part D plans for drugs dispensed to Part D beneficiaries.*

Long Term Care Pharmacy Alliance Dec 5, 2005 (http://www.ltcpa.org/public/)

Source: *CMS. Part D Question and Answer Database. November 28, 2005, ID: 6326.

TrOOP & Patient Assistance Programs (PAPs)*: Antikickback Concerns

- **November 7, 2005: OIG Advisory Bulletin** $\Rightarrow$ manufacturers' expenditures for a covered Part D drug for a Part D enrollee may "present a heightened risk" for antikickback law violation
- ***The subsidies would be squarely prohibited by the statute****, because the manufacturer would be giving something of value (i.e., the subsidy) to beneficiaries to use its product* $\Rightarrow$ possible $\Uparrow$ Part D costs if the enrollee remains on a brand medication that is more expensive than alternatives
- **PAPs are permissible for**: uninsured, ineligible for Part D, not enrolled in a Part D plan.

* Bichel LA. Tracking TrOOP and Avoiding Antikickback Liability. Pharmacy Today 2005;11(12):25,35.

Drug Safety (Public-Private Arrangements)

- Institute of Medicine (IOM) of the National Academies: *science-based advice on matters of biomedical science, [it] work[s] outside the framework of government to ensure scientifically informed analysis and independent guidance*

- Medicare Modernization Act of 2003:
  - **charge to IOM =** "carry out a comprehensive study … of drug safety and quality issues in order to provide a blue print for system-wide change"
  - Report from the Institute of Medicine Committee on the Assessment of the US Drug Safety System = **"The Future of Drug Safety: Promoting and Protecting the Health of the Public."** (released September 22, 2006) http://www.iom.edu/CMS/3793/26341.aspx

Future Costs: Table S-13 Outlay Impact of Prescription Drug and Medicare Improvement Act of 2003 (PL 108-173)
[$ USD in Billions]

	2004	2005	2006	2007	2008	2009	2004-2008	2004 - 2013
DHHS Actuary (Est)	8	13	43	56	58	60	178	**534**
CBO (Est)	4	6	28	40	44	47	122	**395**

Source: The United States' Budget for Fiscal Year 2005, page 387.

Main source of differences: Assumptions concerning beneficiary participation, market changes & cost growth rates.

Future Costs

- Treasury Department est of the Medicare Rx benefit costs = $6.306 trillion (over 75 years)

- "The new prescription drug benefit … is one of the largest unfunded liabilities ever undertaken by the federal government."
  - David Walker,

Comptroller General of the United States

(1) http://fms.treas.gov/fr/04frusg/04frusg.pdf (2) Source: Wessel D. Treasury Says Drug Benefit Will Cost More Than $6 Trillion. WSJ 20DEC2004 page A4.

Core Functions of a PBM

- Claims processing and adjudication
- Managing pharmacy networks
- Developing and managing formularies
- Negotiating rebates and contracts
- (Increasingly) Disease Management Programs

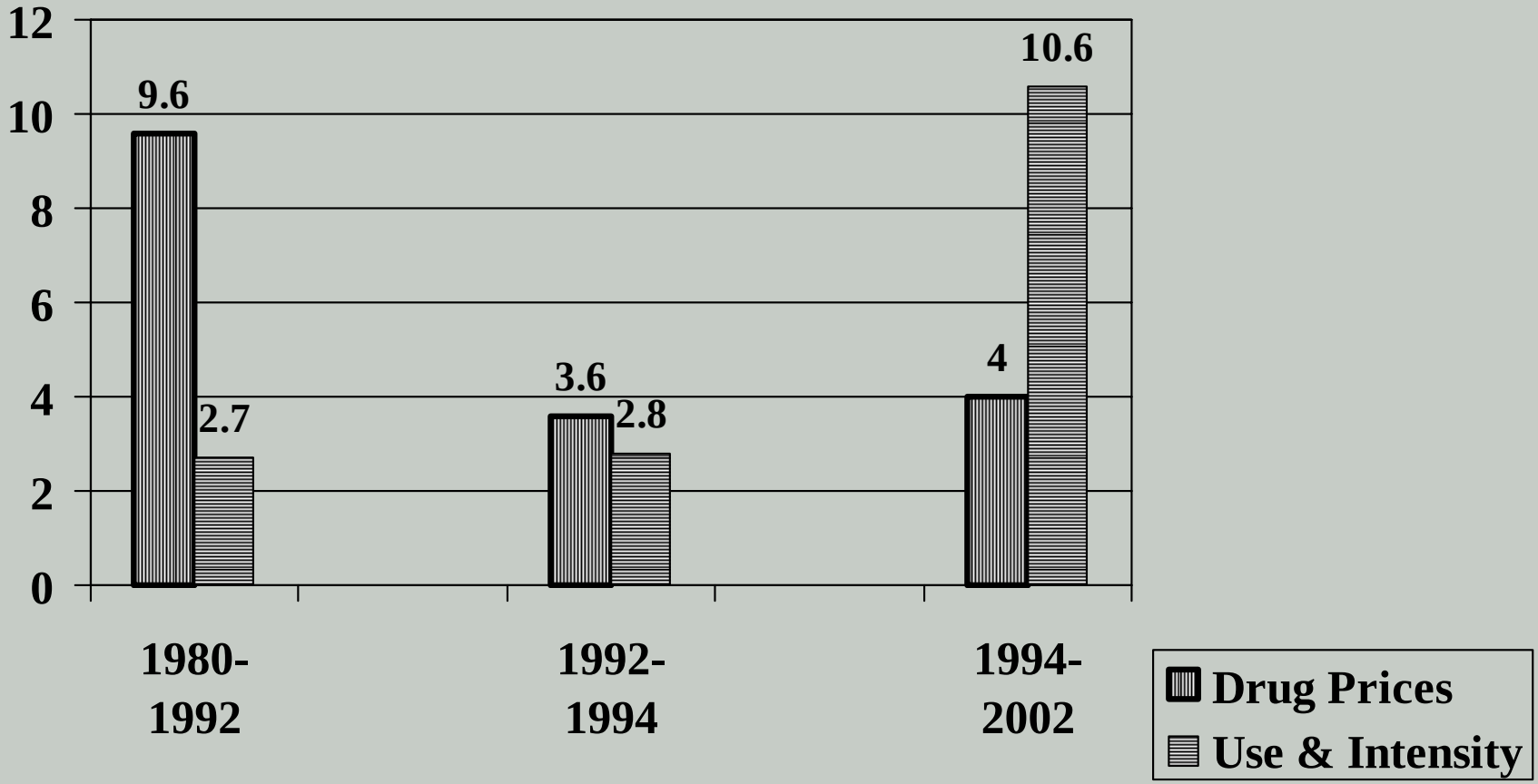
Kreling, et al., 1996

Rebate

A sum of money given to an organization by a drug manufacturer in exchange for the inclusion of the manufacturer's drug product on formulary or, more recently, in exchange for moving market share of a particular drug ("preferred") or combination of drugs ("bundled").

- Lipton, et al., 1999

Factors Explaining US Drug Expenses 1980-2002



Smith C. Retail Prescription Drug Spending in the National Health Accounts. *Health Affairs* 2004;23(1):160-167.

Required

Kongstvedt Chapter 15, Prescription Drug Benefits in Managed Care, p. 293.

Cubanski J, Neuman P. Status Report On Medicare Part D Enrollment In 2006: Analysis Of Plan-Specific Market Share And Coverage. *Health Affairs*. January/February 2007; 26(1):w1-w12. http://content.healtaffairs.org/cgi/reprint/26/1/w1

Kaiser Family Foundation. Prescription Drug Trends Fact Sheet. November 2005. http://www.kff.org/insurance/upload/3057-04.pdf

Kaiser Family Foundation. Medicare Prescription Drug Benefit Fact Sheet. November 2006. http://www.kff.org/medicare/upload/7044.cfm

Additional

Wallack SS, Weinberg DB, Thomas CP. Health plans' strategies to control prescription drug spending. *Health Affairs*. 2004 Nov-Dec;23(6):141-8. http://content.healthaffairs.org/cgi/reprint/23/6/141

Lyles A, Palumbo FB. The Effect of Managed Care on Prescription Drug Costs and Benefits. *Pharmacoeconomics* 1999;15(2):129-140.