



Generic Policies & Experiences in the United States

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Overview of Presentation

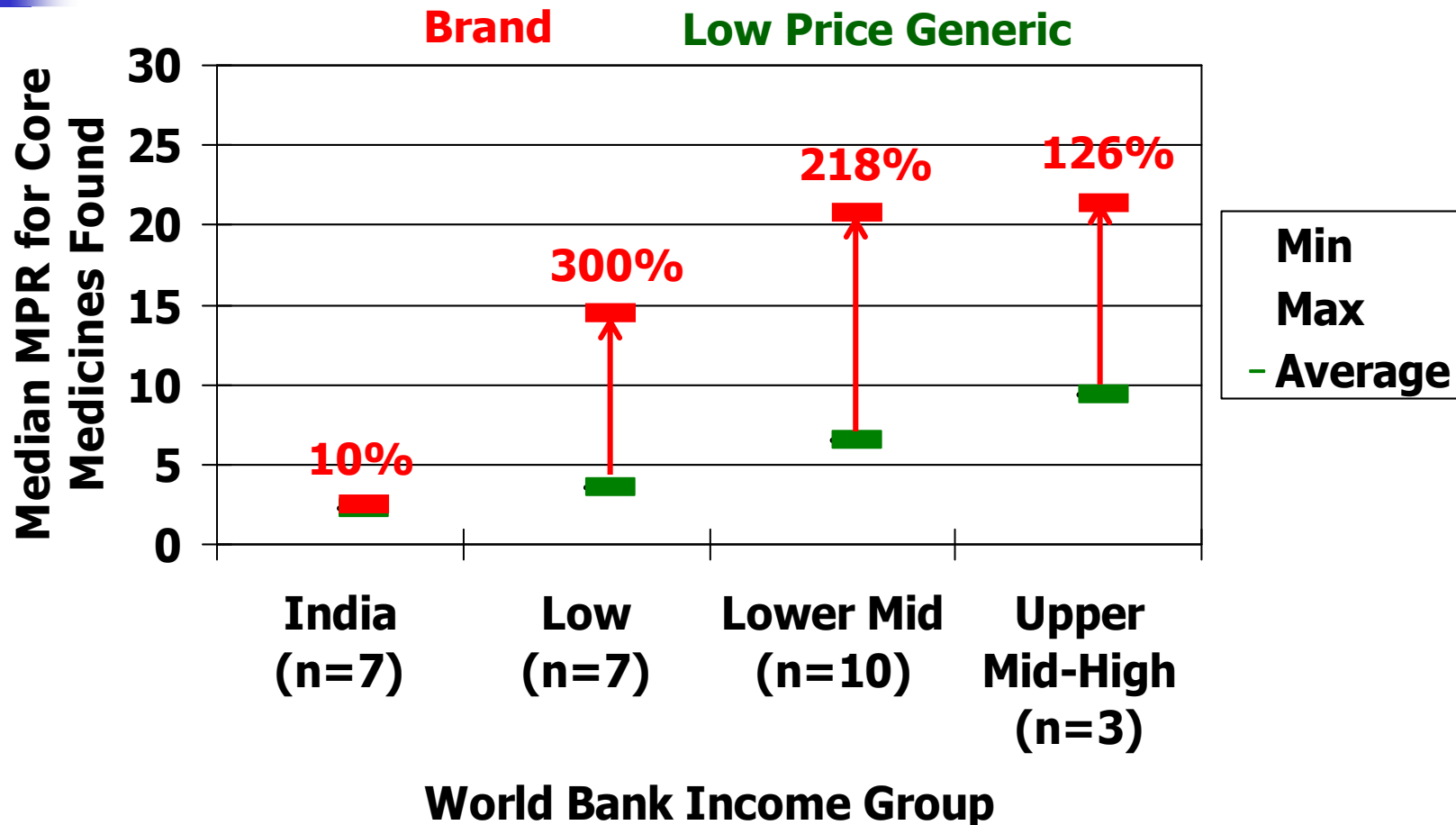
- Generic market
- US policy environment for generics
- Strategies for increasing generics use
- Future issues



Global Market of Generics

- 22.1% annual growth in seven leading markets
 - US, Canada, Germany, France, Italy, Spain, United Kingdom
- Generic market to reach \$60 billion by 2008
- However, current generic sales <10% of \$450b global pharmaceutical market

Lowest Price Generic and “Brand Premium” in Private Retail Outlets by Country Income



* MPR = Median price of core medicines found in 4+ outlets as ratio of MSH generic procurement price

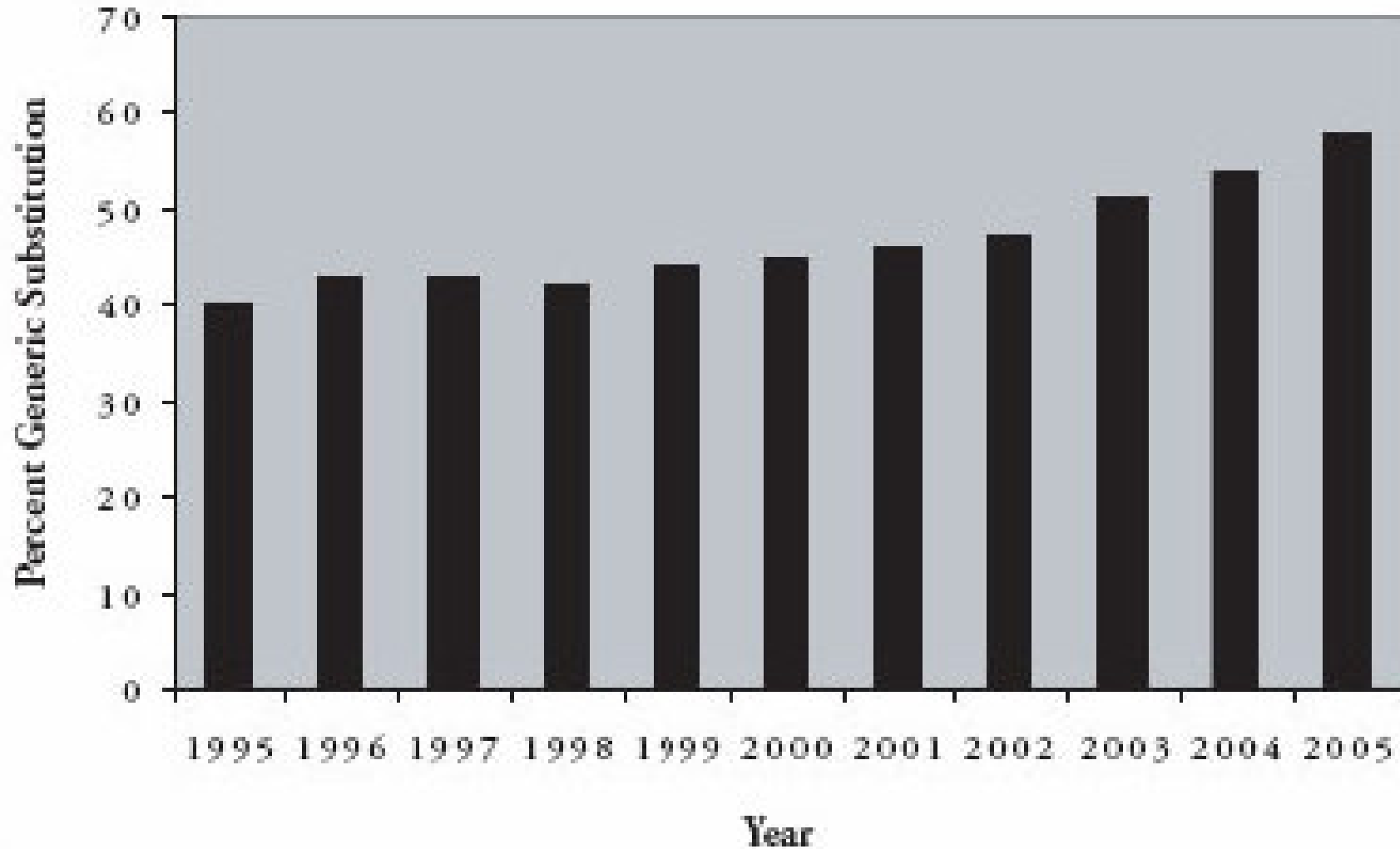
Note: Surveys with 8+ medicines on WHO-HAI core list found in both brand and LPG



Facts About Generics in the US

- 8,730 of the 11,487 drugs listed by FDA have generic counterparts
- \$22.3b in sales in 2005 of \$252b market
- 63% of Rxs dispensed generic in 2005
- U.S. market for unbranded generics grew by 22.3% in 2006
- Average 2005 retail price: generic \$29.82 vs. brand \$101.71 (cost 30%-80% less than equivalent brand)

Rise in Rate of Generic Dispensing as Percent of All Prescriptions



Source: Growing Influence of Generic Drugs (www.powerpak.com)



Filling New Prescription as Generic or Preferred Class Associated with Adherence >80% at 1 Year

Table 5. Logistic Regression Evaluating Predictors of Adequate Adherence*

Predictor†	Odds Ratio	95% CI
Generic	1.62‡	1.39-1.89
Preferred formulary agent	1.30‡	1.15-1.47
Annual income		
Middle	1.10	0.95-1.28
High	1.17	0.98-1.39
Male sex	1.16‡	1.03-1.31

Abbreviation: CI, confidence interval.

*Controlling for drug class and age. Adequate adherence is defined as proportion of days covered >80%.

†The referent categories were as follows: nonpreferred formulary agents, low income, and female sex.

‡Statistically significant ($P < .05$).

Source: Shrank et al. (Arch Intern Med 2006)



Encouraging Generic Market Entry and Competition in the US

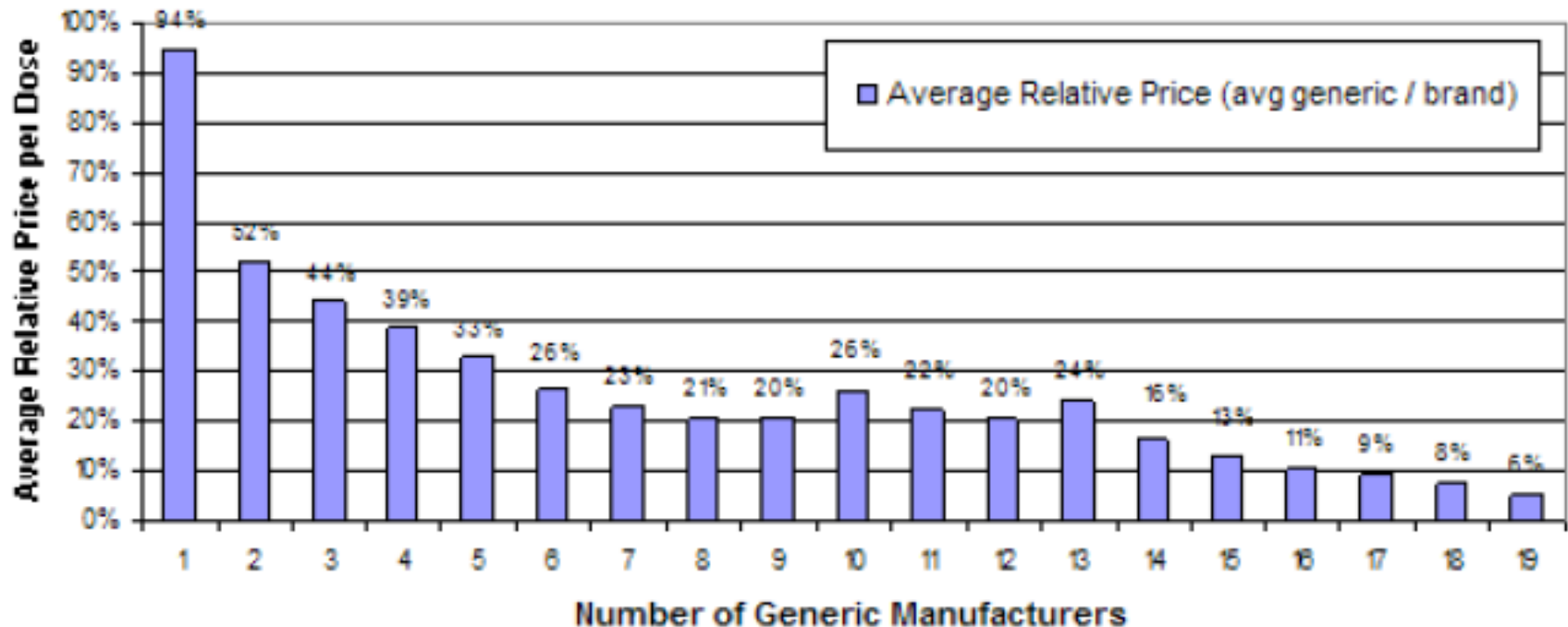
- 1984 Hatch-Waxman Act
 - Abbreviated New Drug Application (ANDA)
 - Generics generally do not require safety/efficacy data
 - Must establish bioequivalence usually by measuring bioavailability
 - Lower registration fee
- Paragraph IV certification
 - 180-day market exclusivity for first filer challenging invalid patent or developing non-infringing process
 - May be challenged and delayed for 30 months by brand firm
- Reduced market entry from >3 years to <3 months after patent expiry



Generic Manufacturers in US

- 50 generic manufacturers in US
- 4 of 5 top US pharmaceutical companies by volume are generic companies
 - Mylan Labs, Sandoz (Novartis), Teva, Watson
- Authorized generics
 - Introduced by brand firms before patent expiration
 - In early 1990's brand name firms or subsidiaries controlled 70% of generic market
 - Under investigation by FTC

Impact of Generic Competition in US on Medicine Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005



\$78b in Blockbuster Products Coming Off Patent 2006-2008

Product	Market 2005
Ambien (zolpidem)	\$1.9b
Zocor (simvastatin)	\$3.1b
Zoloft (sertraline)	\$2.6b
Advair (fluticasone and salmeterol)	\$2.8b
Effexor XR (venlafaxine)	\$2.2b
Fosamax (alendronate)	\$1.5b
Risperdal (risperidone)	\$1.5b
Lexapro (escitalopram)	\$1.9b
Prevacid (lansoprazole)	\$3.3b



Strategies for Increasing Generic Use: Substitution and Interchange

➤ Generic substitution

- Dispense generic for multisource drug
- Bioequivalence established for most drugs
- Allowed in all states
- Mandated by many health care organizations

➤ Therapeutic interchange

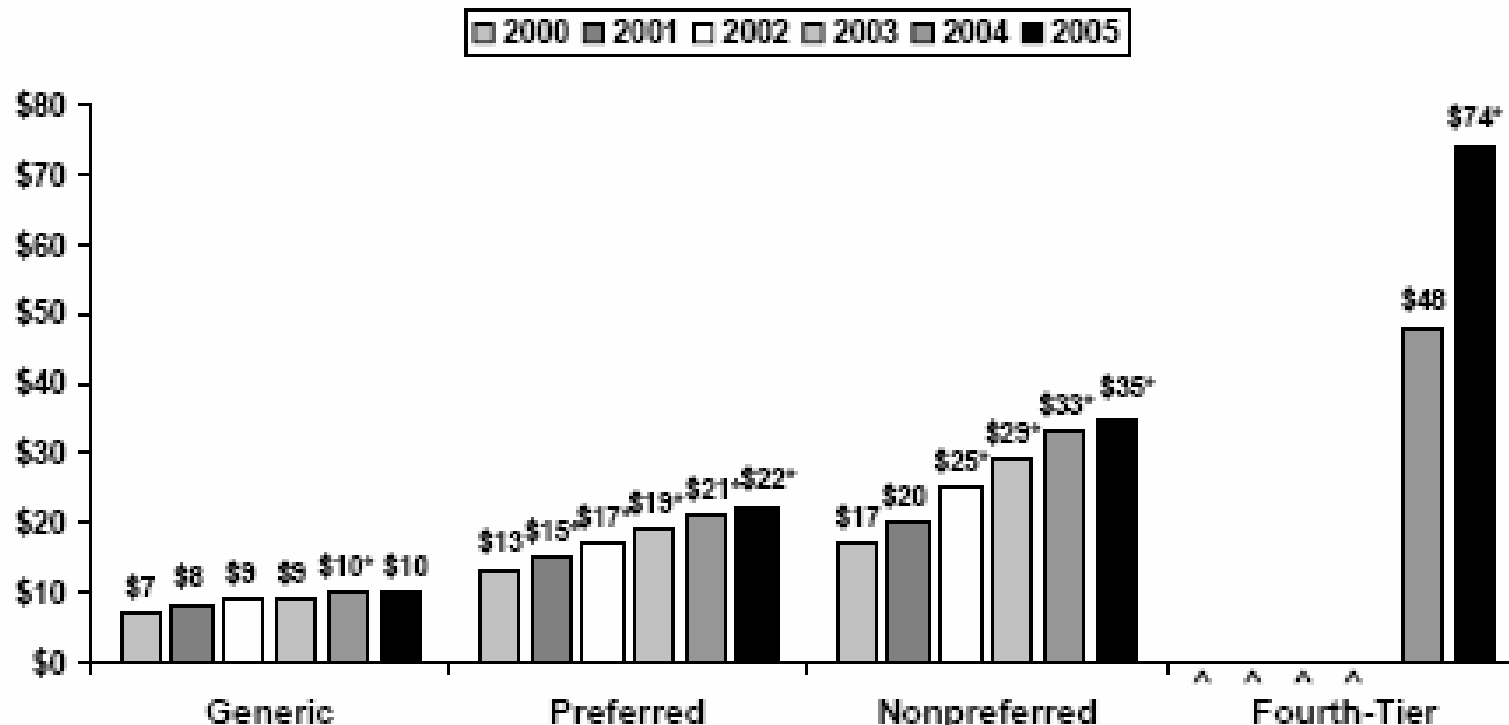
- Chemically different, therapeutically similar
- Equivalence more controversial
- Common in hospitals, more limited in insurance systems



Strategies for Increasing Generic Use: Formulary Controls

- Most public (except Medicare Part D) and private insurance systems in US have open formularies with utilization controls
- Utilization controls
 - Patient cost sharing (deductibles, copayments, coinsurance, caps, reference pricing)
 - Preferred drug lists, prior authorization, and step therapy programs
 - Pharmacy incentives for generic dispensing
 - Mail order dispensing

Trends in Tiered Copayments in Employer Pharmacy Benefit Plans, 2000-2005



* Estimate is statistically different from the previous year shown at $p < .05$.

^ Fourth-tier copayment information was not obtained prior to 2004.

Notes: Average copayments for generic, preferred, and nonpreferred drugs are calculated by combining the weighted average copayments for those types of drugs among firms with a single copayment amount or a multi-tier cost-sharing structure. The average copayment for fourth-tier drugs is calculated using information from only those plans that have a fourth-tier copayment amount.

Source: Kaiser Family Foundation and Health Research and Educational Trust, Annual Surveys of Employer-Sponsored Health Benefits, 2000-2005, at <http://www.kff.org/insurance/7315/index.cfm>.

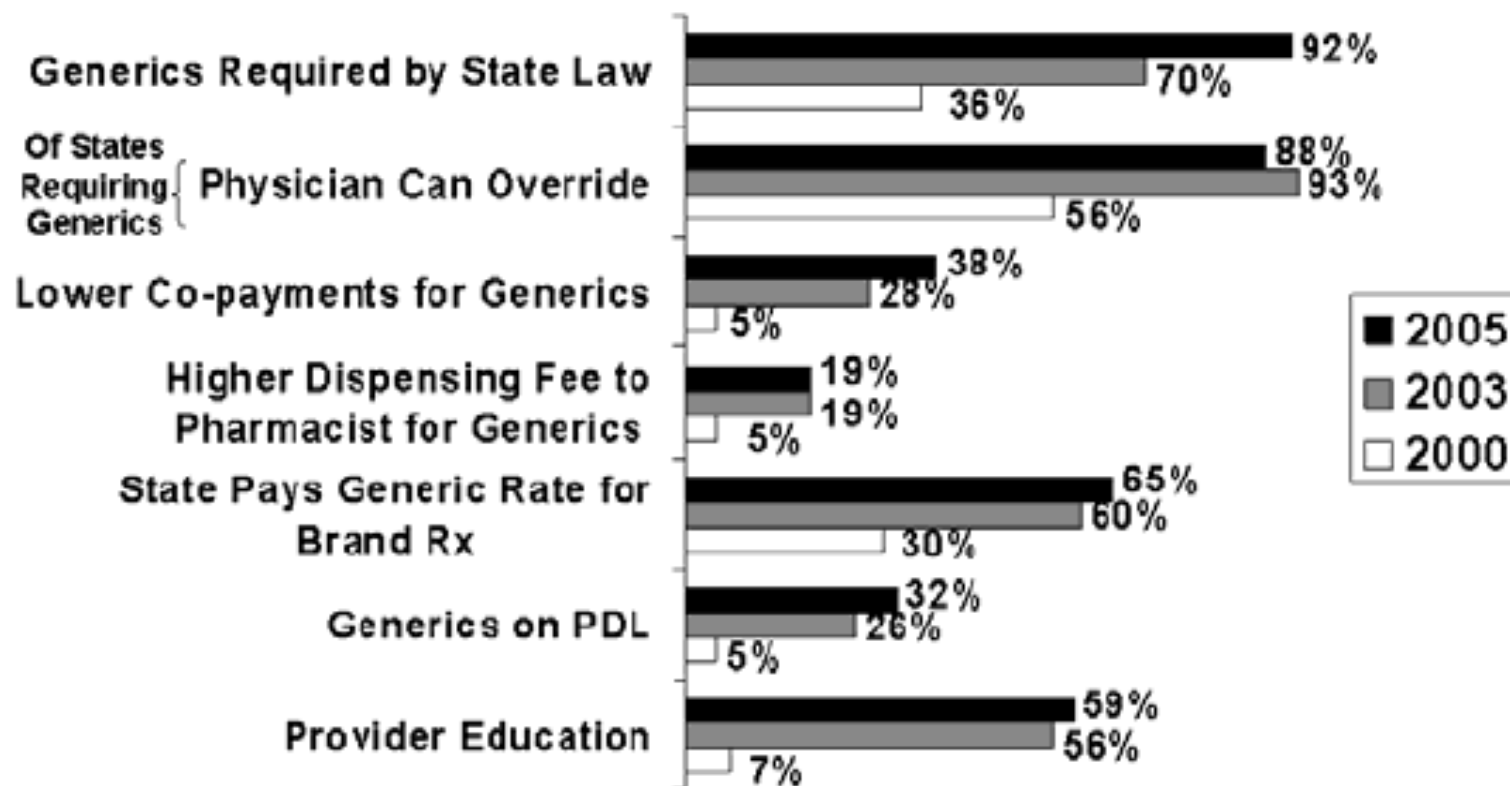


Medicare Part D and Generics

- Major expansion of pharmacy benefits with subsidies for low income
- Competing private plans with different premiums and formularies
- “Donut hole” in coverage (from \$2700-\$5400) will encourage shift to generics
- Part D plan cost containment strategies
 - Limited # of drugs covered within class
 - Tiered formularies
 - Price negotiation with manufacturers
 - Active therapy management

US State Medicaid Program Generic Drug Policies

(percentage of states reporting)



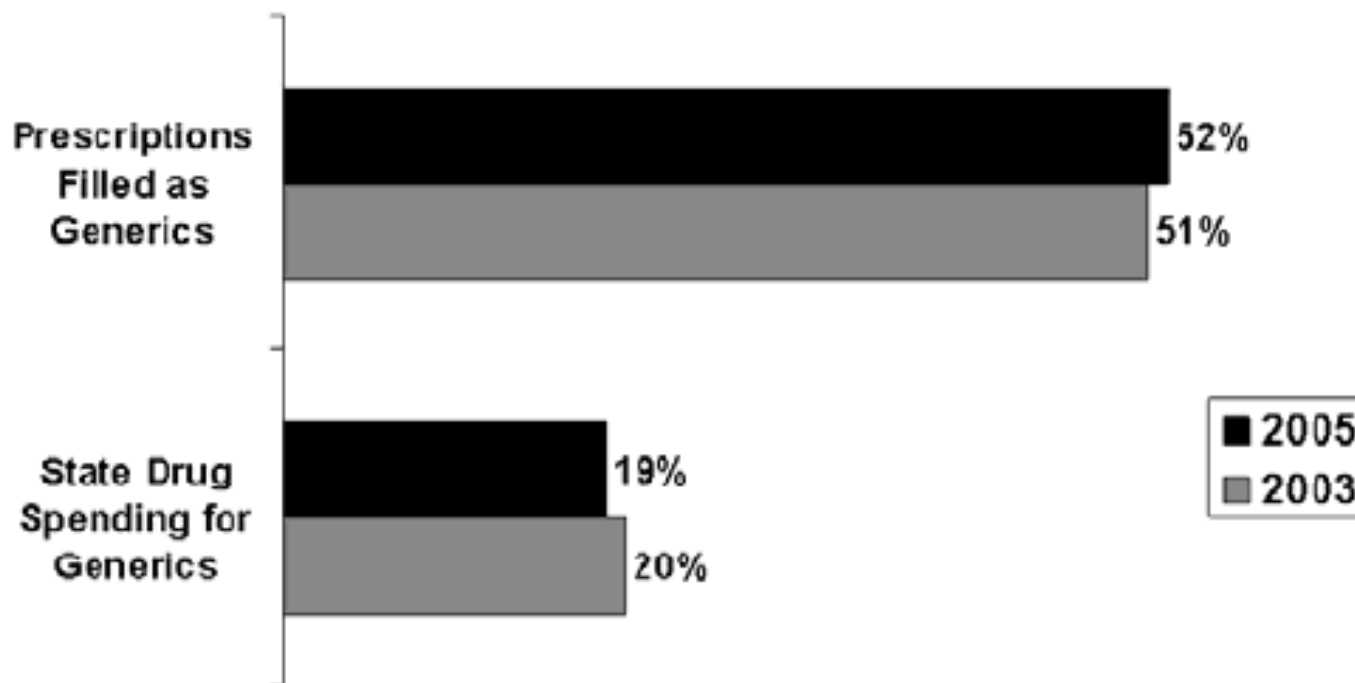
SOURCE: KCMU state Medicaid prescription drug survey conducted by the Health Policy Institute, Georgetown University (2005).

NOTE: Based on survey responses from 37 states in 2005, 43 states in 2003 and 44 states in 2000. In 2005, 34 of 37 states require generics, in 2003, 30 of 43 states required generics and in 2000 16 of 44 states required generics.

**K A I S E R C O M M I S S I O N O N
Medicaid and the Uninsured**

Estimated Use of Generic Medicines in State Medicaid Programs

(average state estimate)



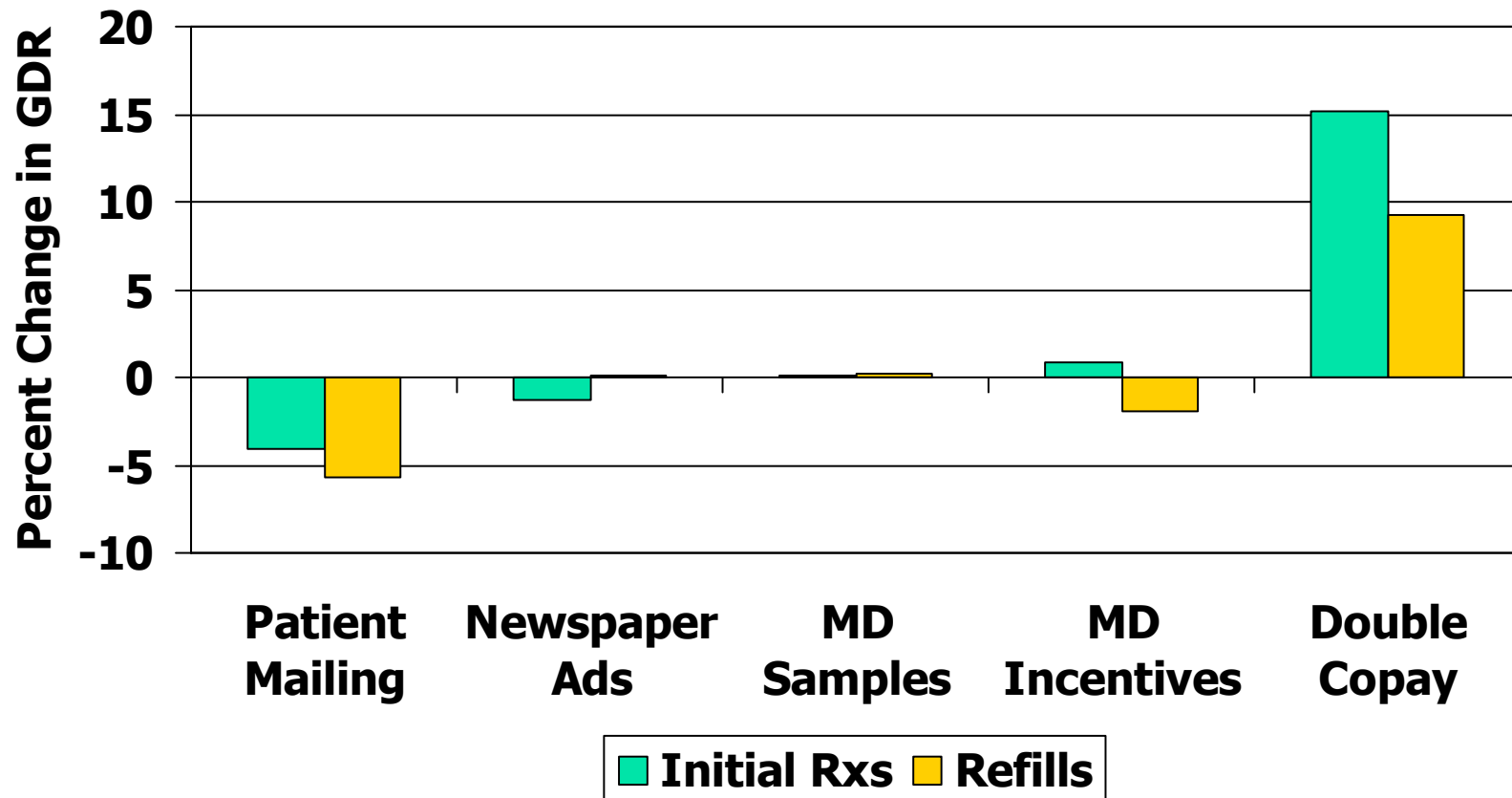
SOURCE: KCMU state Medicaid prescription drug survey conducted by the Health Policy Institute, Georgetown University (2005).

NOTE: Based on survey responses from 37 states in 2005 and 43 states in 2003. Averages based on 34 states providing estimates of Rx filled as generics in 2005 and 22 states in 2003; and 30 states providing estimates of Rx spending on generics in 2005 and 24 states in 2003.

**K A I S E R C O M M I S S I O N O N
M e d i c a i d a n d t h e U n i n s u r e d**

Impact of Michigan Blue Cross Blue Shield Interventions to Increase Generic Dispensing

Change in GDR for Pre-Intervention GDR of 45%



Source: O'malley AJ et al. (Health Services Research 2006)



Future Growth in Use of Generics

- Generic substitution reaching saturation
 - 89% of Rxs for multisource drugs dispensed as generics in chain pharmacies and Medicaid
 - Each additional 1% increase would save \$4b
- BUT 44% of Rxs and 87% of spending are for single source brands
 - Increase therapeutic interchange programs?
 - Electronic prescribing to facilitate interchange?
 - Reference pricing within therapy classes?
- Generic versions of biotechnology drugs
 - \$42 billion market, 17% annual growth