# US Trends, Issues, Outlook

STRATEGIC MANAGEMENT REVIEW 2006

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Presented to: 7th Annual Generic Drugs Summit

September 28, 2006

# The World Pharmaceutical Market

# Agenda

- Industry overview
  - Global and regional trends
  - US
- Key trends and issues
- Performance overview
- Future outlook

# Converging forces are increasing the complexity of the global pharmaceutical market

**Growth patterns shifting**

- Market growth slows especially in U.S.
- Growth more vigorous in emerging economies
- Specialist products strengthen
- Divergence of company performance

**Interaction between stakeholders**

- Specifically between payers, regulators, physicians and patients
- Convergence of cost control and generic availability

**Market leaders under pressure**

- Delivering sales and marketing productivity
- Replenishing the pipeline

# Ten key markets no longer drive growth but still command 81% of world volume

| World Audited Market | MAT June 2006 | | % Growth Constant $ | |
|---|---|---|---|---|
| | US$ Bil | % Share | 2006 | CAGR 01-05 |
| Latin America | $ 26.1 | 4.5 % | + 12.9 | + 13.1 |
| Asia / Africa / Australia | $ 49.0 | 8.4 % | + 10.8 | + 11.6 |
| Japan | $ 57.7 | 9.9 % | + 3.5 | +3.2 |
| Europe | $ 173.5 | 29.8 % | + 5.9 | + 8.9 |
| North America | $ 276.0 | 47.4 % | +5.6 | + 11.1 |
| **Worldwide** | **$ 582.3** | **100.0 %** | **+6.2** | **+ 9.6** |
| 10 Key Markets | $ 470.0 | 81.0 % | +5.4 | +9.1 |

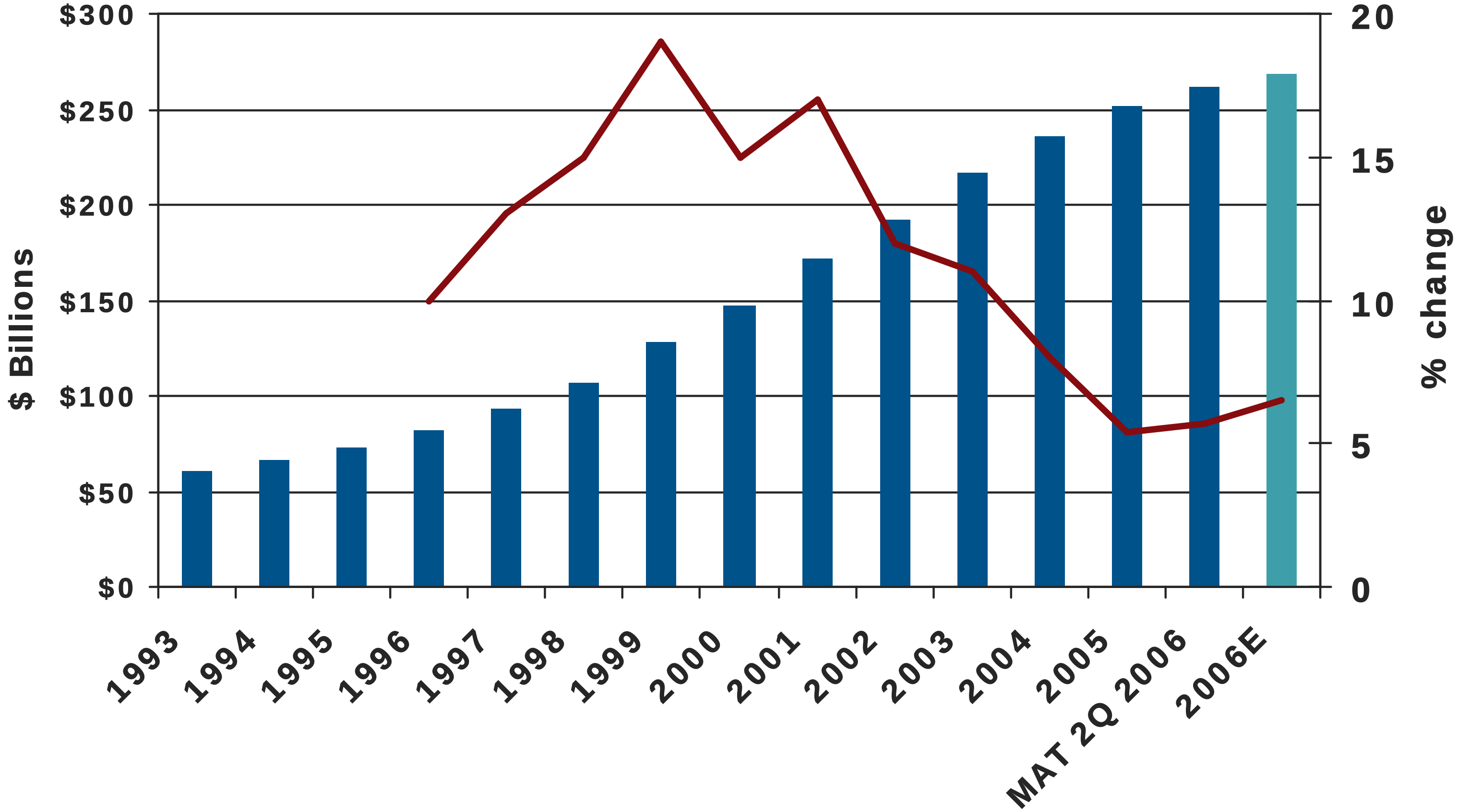
Source: IMS Health MIDAS MAT June 2006

# US growth slows due to adverse trends, but some optimism prevails for future

| ADVERSE TRENDS | SILVER LINING |
|---|---|
| Delayed NCES | Aging Population |
| More Aggressive Generics | Stronger Flu Season (1Q05) |
| COX2 Withdrawals | Medicare Modernization Act |
| Stronger OTC | Continued Innovation |
| Safety Concerns | Areas of Unmet Needs |
| Cost Containment Intensifies | |

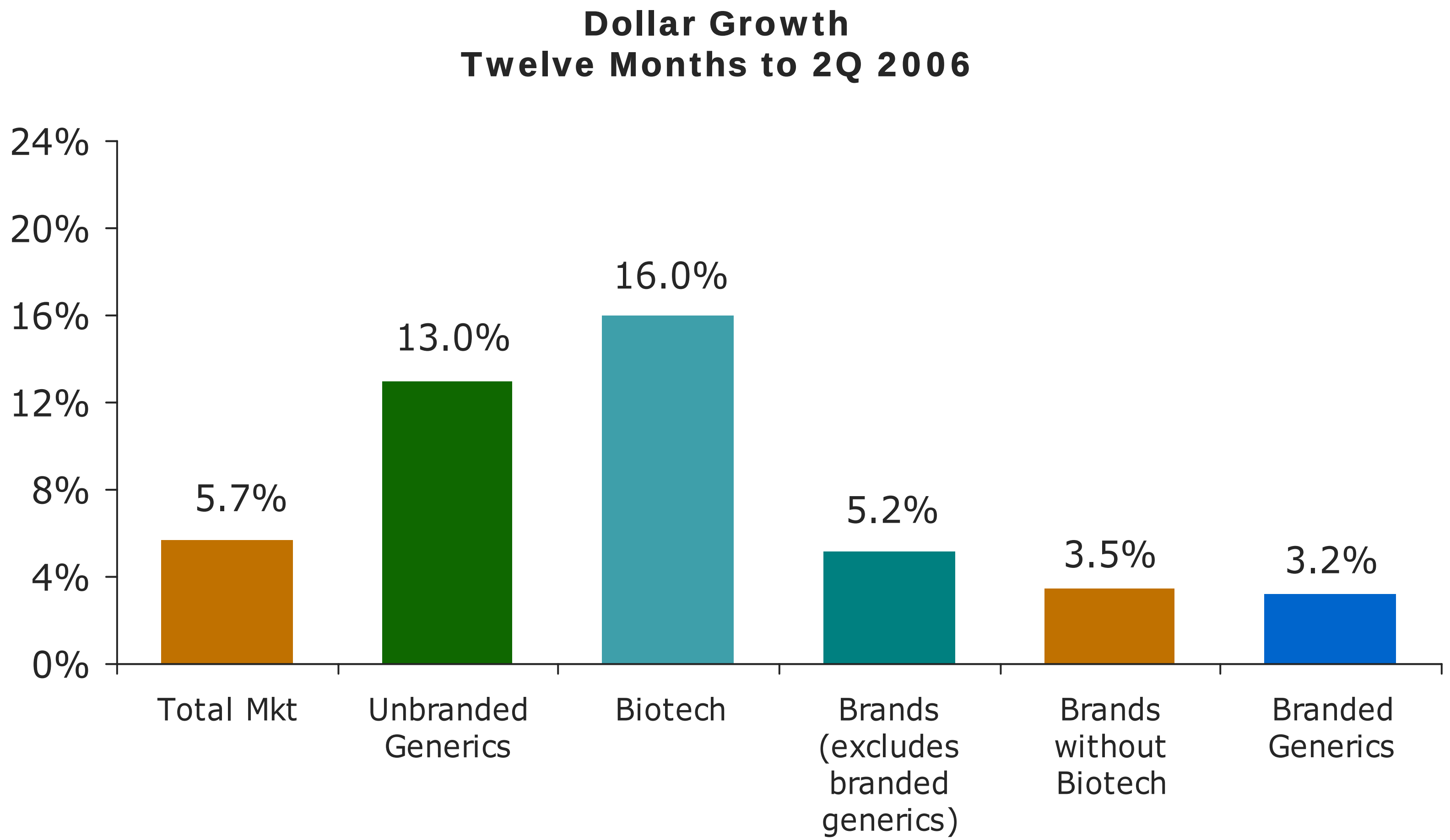
# The US market exceeds $261B in year ending 2Q-06

## 2Q growth up to 5.7%, and upturn expected to continue



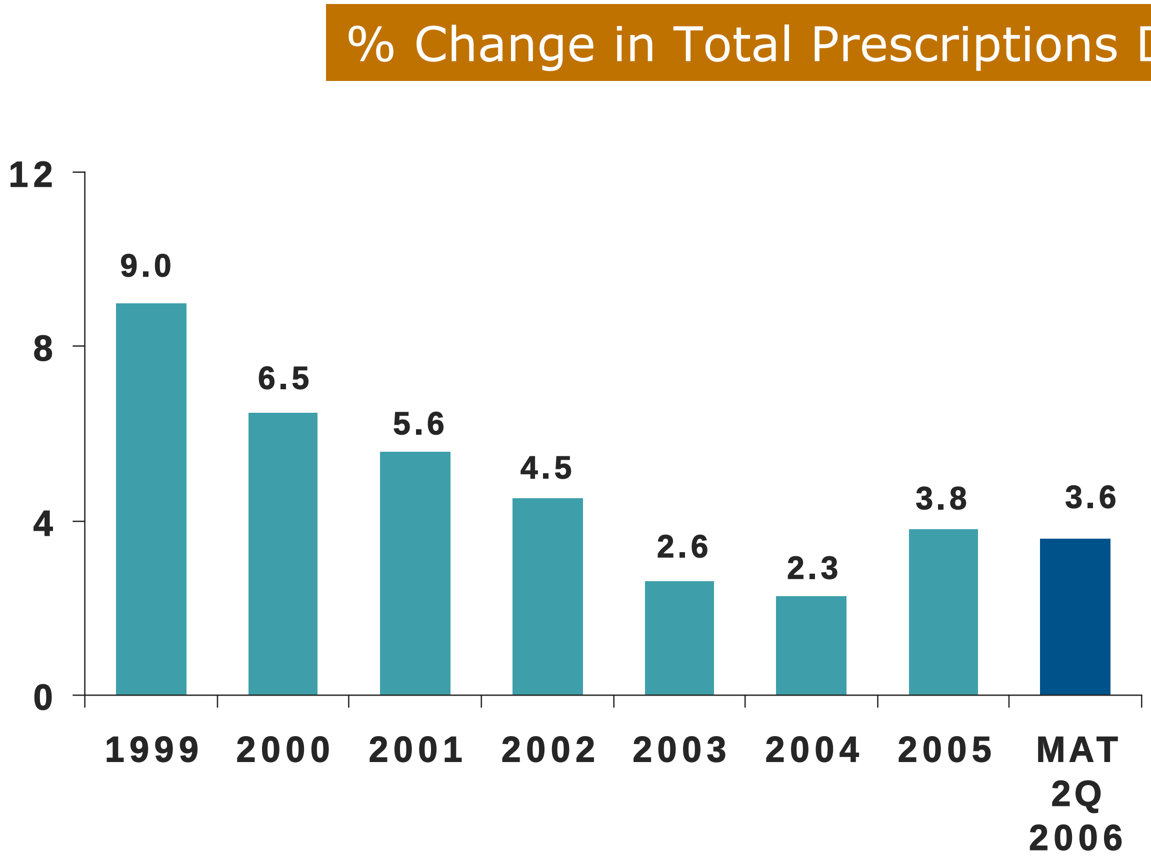

Source: IMS National Sales Perspective, June 2006

# US growth of biotech and generics still beats non-biotech brands and total market




Source: IMS National Sales Perspectives™, June 2006

# US prescription growth stays strong despite weak flu season in 1Q 2006




- Multi-tier co-pays
- Rx to OTCs
- Vioxx/Bextra withdrawal & other safety concerns
- Weak flu season in 1Q 2006
- Generics driving growth

Source: IMS National Prescription Audit (NPA) Plus, July 2006

# Key trends and issues

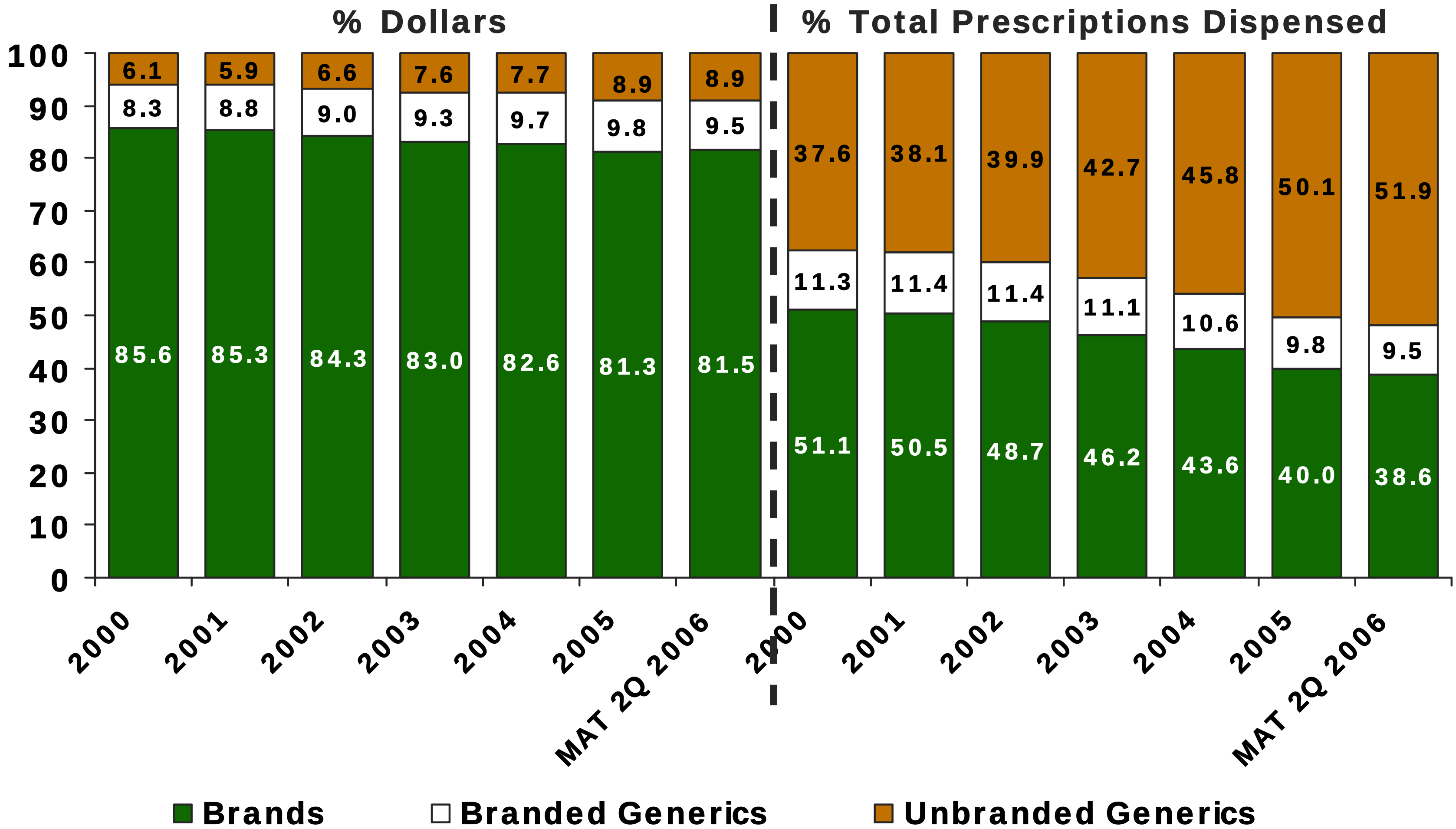
# Agenda

- Industry overview
- Key trends and issues
  - Generic trends
  - Medicare Modernization Act
  - New products/pipeline/future blockbusters
- Performance overview
- Future outlook

# Critical issues affecting generic markets over the next 10 years

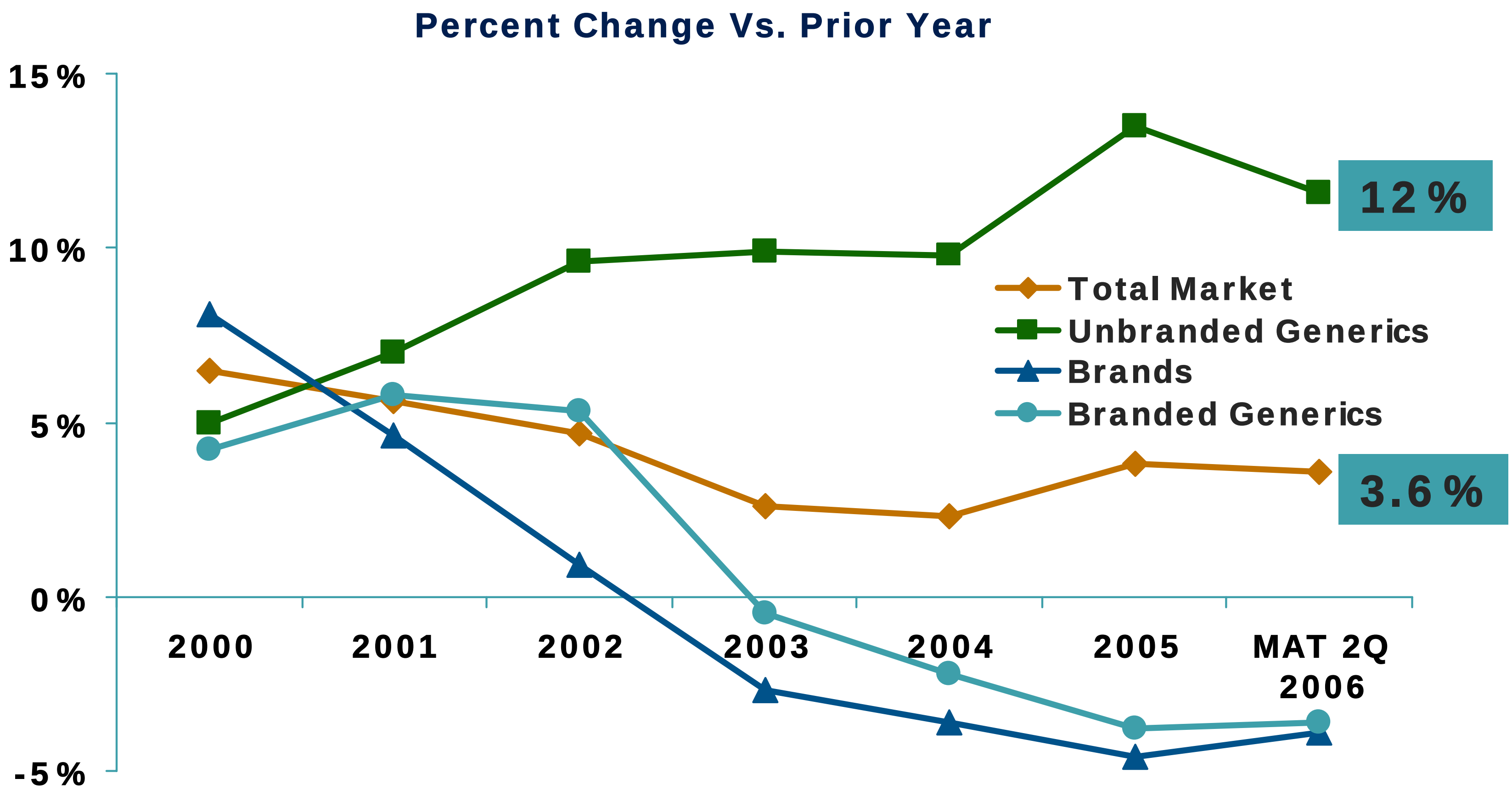
- Medicare Part D increases access
- Blockbusters increasingly seen in specialist-driven markets, which lead market growth
- Generic biotechs protocols, acceptability and competitiveness
- Weak primary care launches
- Price pressure encouraging consolidation
- ‘Chindia’

# Generics continue to gain traction, while brands hold dollars



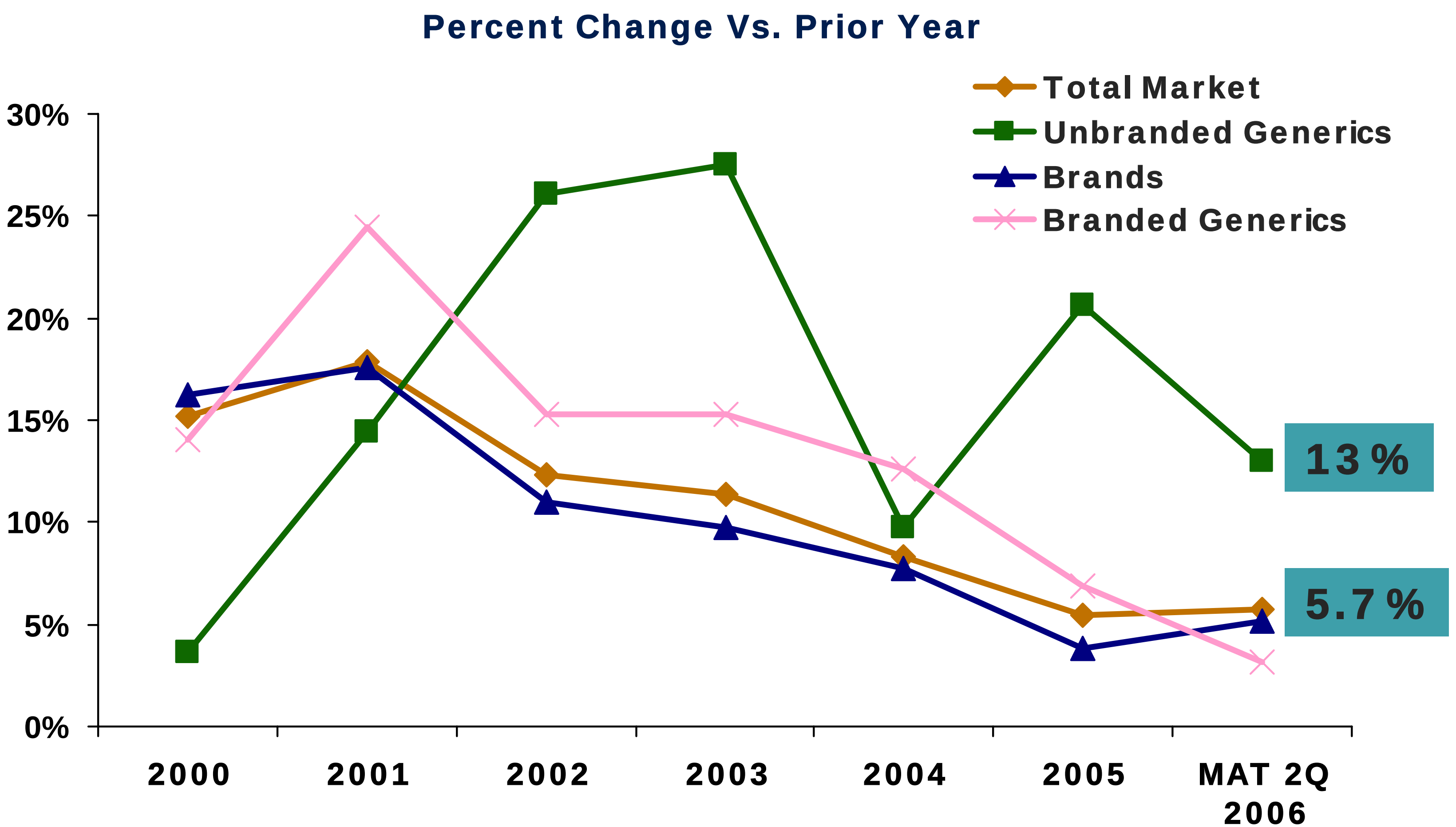

Source: IMS NPA™ Plus, IMS National Sales Perspectives™, August 2006

# Generics driving total market recovery in Rx growth




Source: IMS National Prescription Audit ™ Plus, August 2006

# Growth of generic sales is volatile but above brands now for four years




Source: IMS National Sales Perspective, August 2006

# Together, Teva and Ivax create a generics giant controlling almost a fifth of the generics business

| Sales of unbranded generics by leading corporations | | Twelve months to 2Q 2006 US $ Mil | % Share | % Change |
|---|---|---|---|---|
| | US Industry | 23,294 | 100% | 13.0% |
| 1. | Teva (incl Ivax) | 4,477 | 19.2 | 23% |
| 2. | Novartis (incl Sandoz) | 2,645 | 11.4 | 10% |
| 3. | Mylan | 1,981 | 8.5 | 9% |
| 4. | Watson | 1,504 | 6.5 | 9% |
| 5. | Par | 1,055 | 4.5 | -6% |
| 6. | Pfizer (incl Greenstone) | 921 | 4.0 | 76% |
| 7. | Boehringer Ingelheim | 791 | 3.4 | 30% |
| 8. | Actavis | 660 | 2.8 | -13% |
| 9. | Hospira | 648 | 2.8 | 16% |
| 10. | Baxter | 534 | 2.3 | -22% |
| | Top 10 | 15,216 | 65.3 | 12.6% |

Source: IMS National Sales Perspective, August 2006

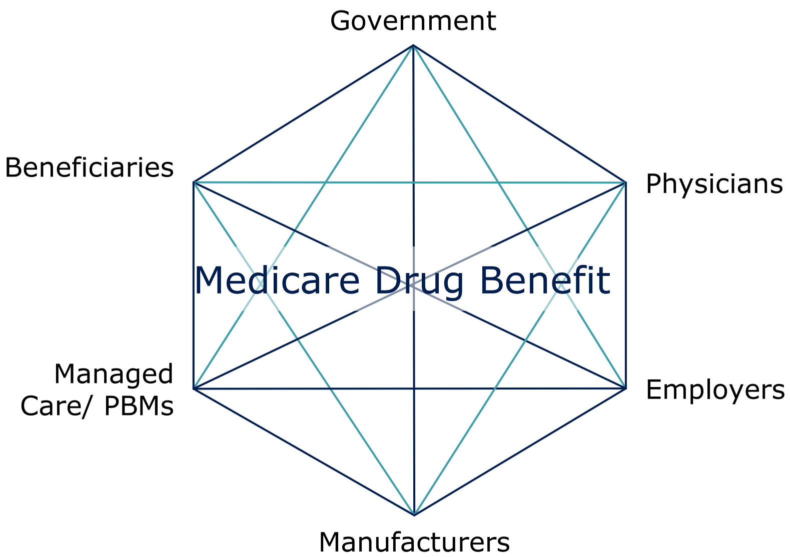
# Mallinckrodt and Endo show strong growth

| Sales of unbranded generics by leading corporations | | Twelve months to 2Q 2006 | | |
|---|---|---|---|---|
| | | US $ Mil | % Share | % Change |
| 11. | Apotex | 598 | 2.6% | 11% |
| 12. | Barr | 573 | 2.5% | 19% |
| 13. | Mallinckrodt | 564 | 2.4% | 32% |
| 14. | Ranbaxy | 402 | 1.7% | 0% |
| 15. | American Bioscience | 387 | 1.7% | -1% |
| 16. | Taro | 308 | 1.3% | -4% |
| 17. | Andrx | 238 | 1.0% | -22% |
| 18. | URL/Mutual | 295 | 1.3% | 4% |
| 19. | Pliva | 301 | 1.3% | 16% |
| 20. | Endo | 320 | 1.4% | 154% |
| | Top 20 | 19,201 | 82.4% | 12.6% |

Source: IMS National Sales Perspective, August 2006

# The Medicare drug benefit is reshaping the Rx marketplace

## Medicare drug benefit stakeholders and system dynamics




**Progress**:

- Enrollment
- Managed care clamors for a piece of the pie
  - PDPs – 80 orgs, 2000 plans
  - MA – 168 orgs, 1000 plans
- Medicare Part D Uptake
- Potential future scenarios

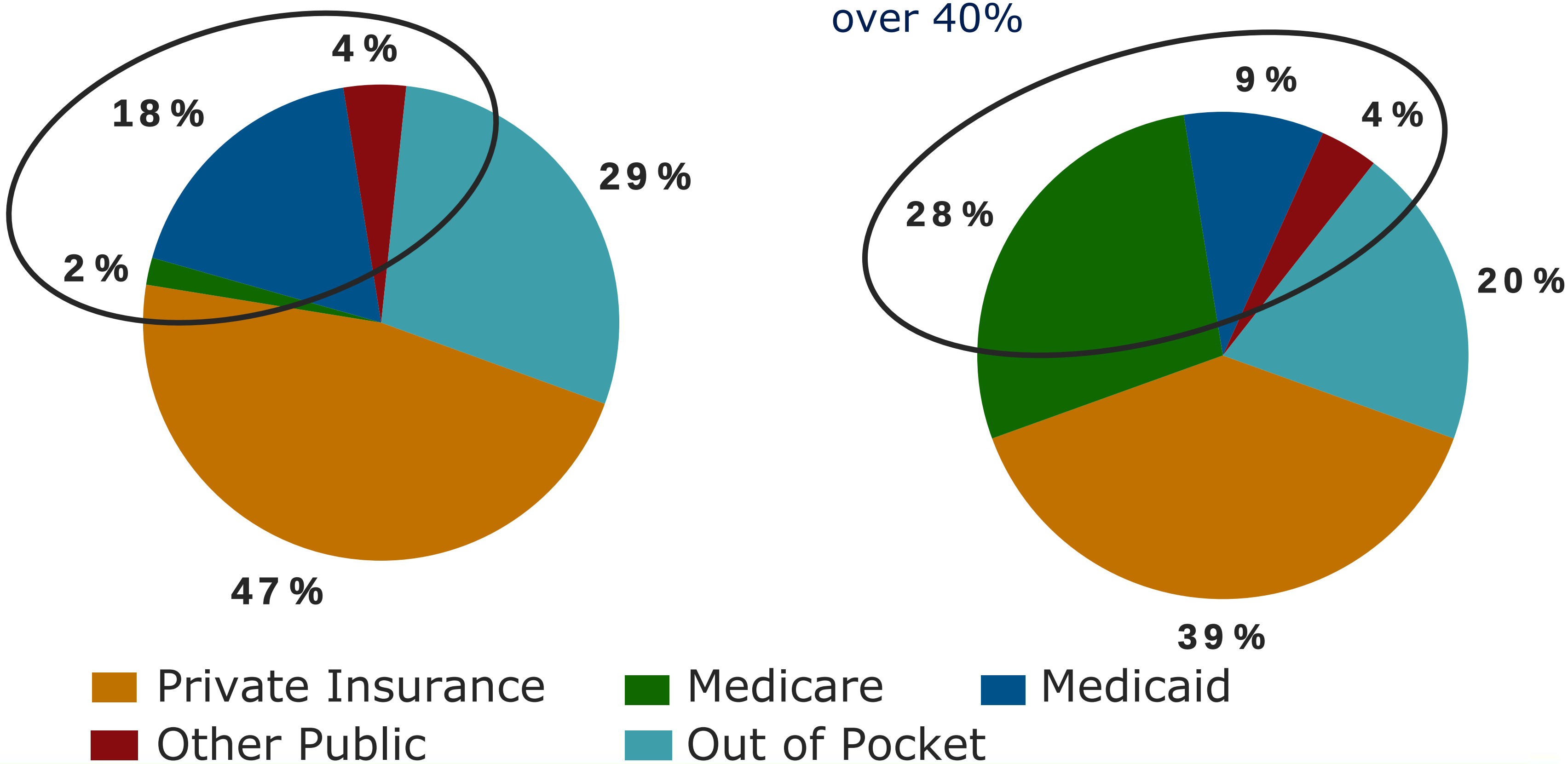
# Part D turns the government into the largest purchaser of prescription drugs

**Source of Rx Spend, 2005**

Today, the government accounts for less than 25% of Rx spending

**Source of Rx Spend, 2006**

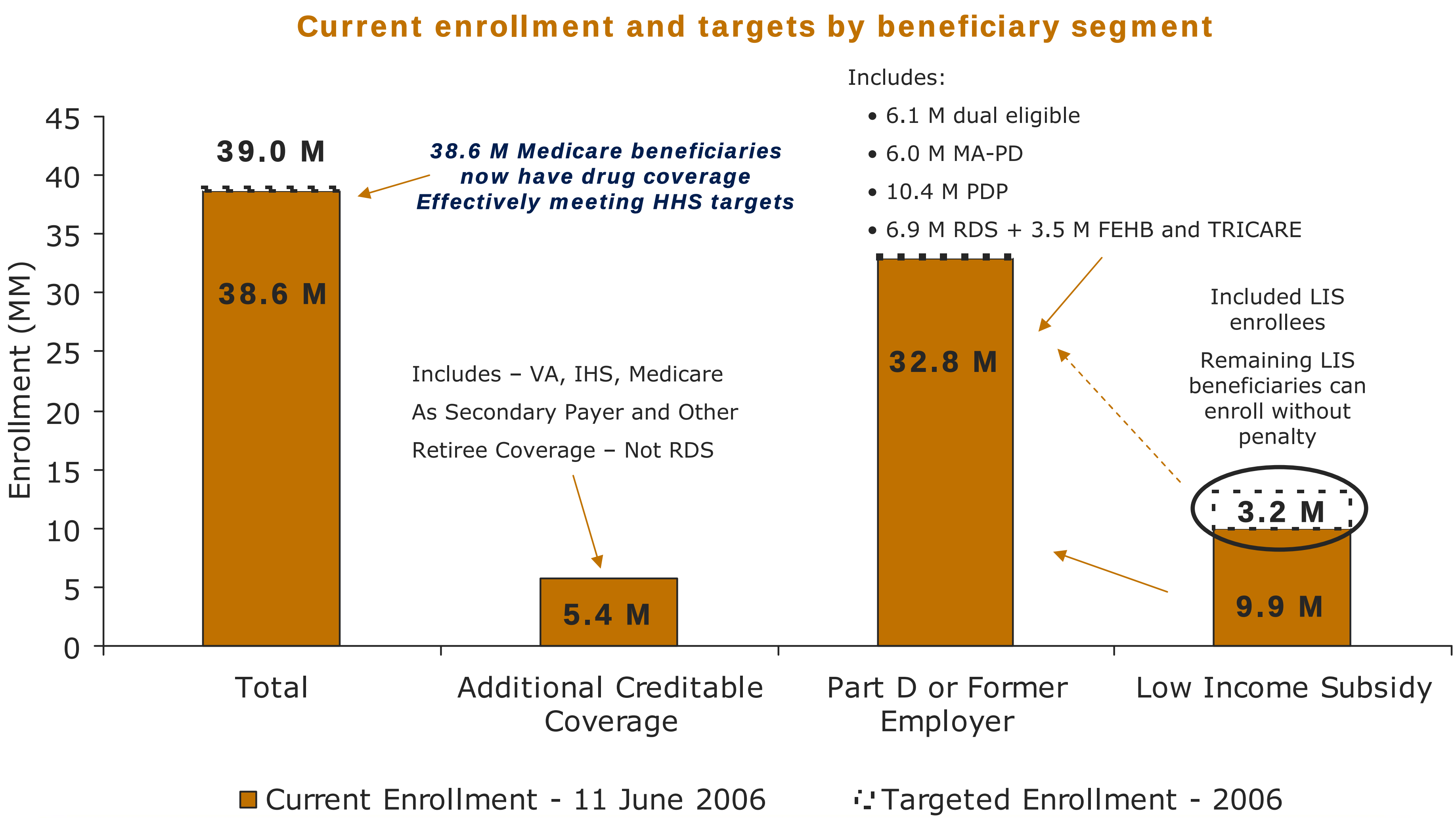
In six months, the government proportion of Rx spend grows to over 40%




Source: Center for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, 2005

# Enrollment close to CMS estimates as of June 11

## Who's new and how sick, still unknown




Source: CMS – data as of June 11



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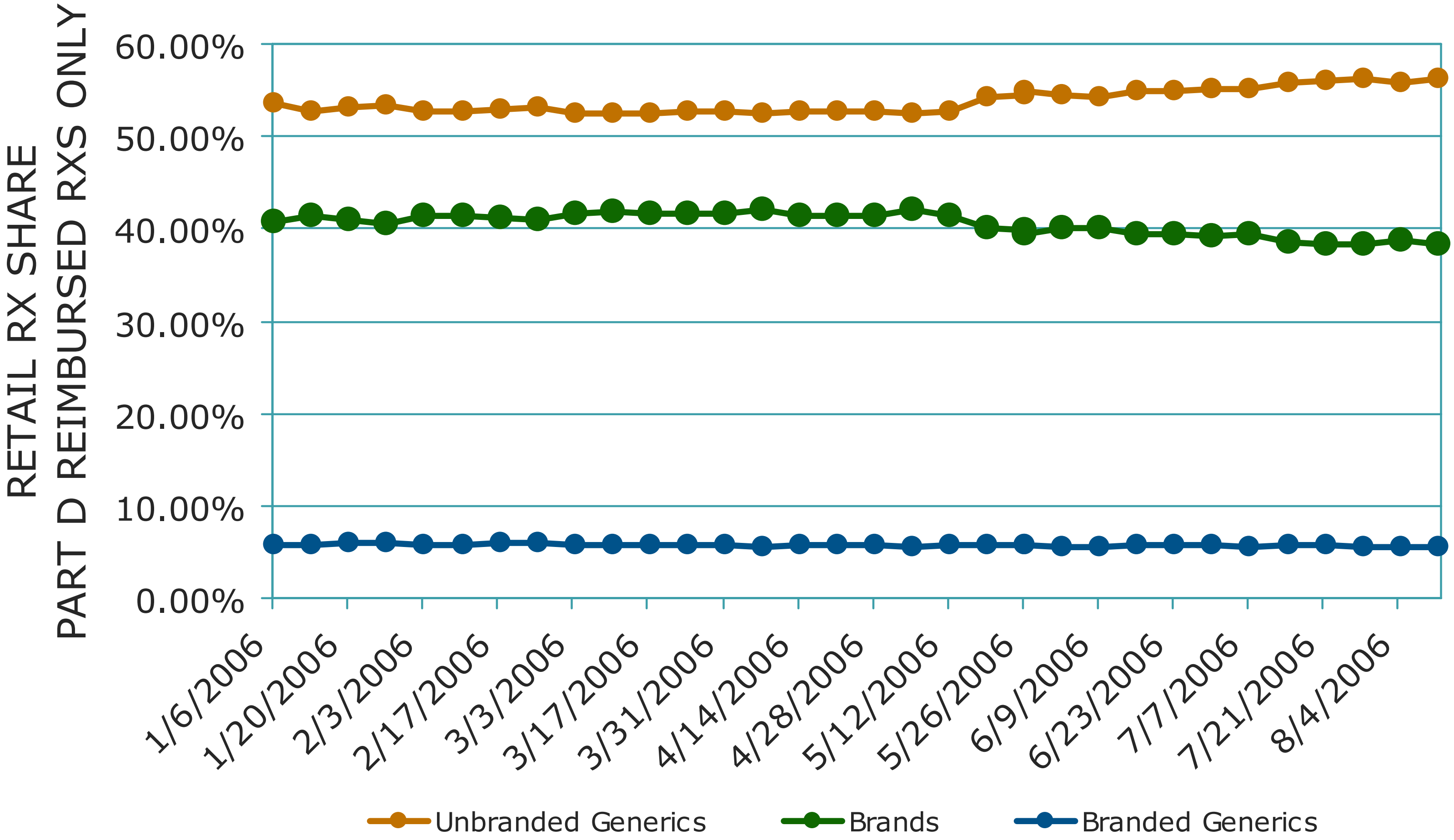
# Unbranded generics share of Part D Rxs is increasing

## Generic pravastatin introduced in May and simvastatin in June




Source: IMS Weekly Medicare Part D Uptake Report, August 17, 2006



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# Medicare Part D

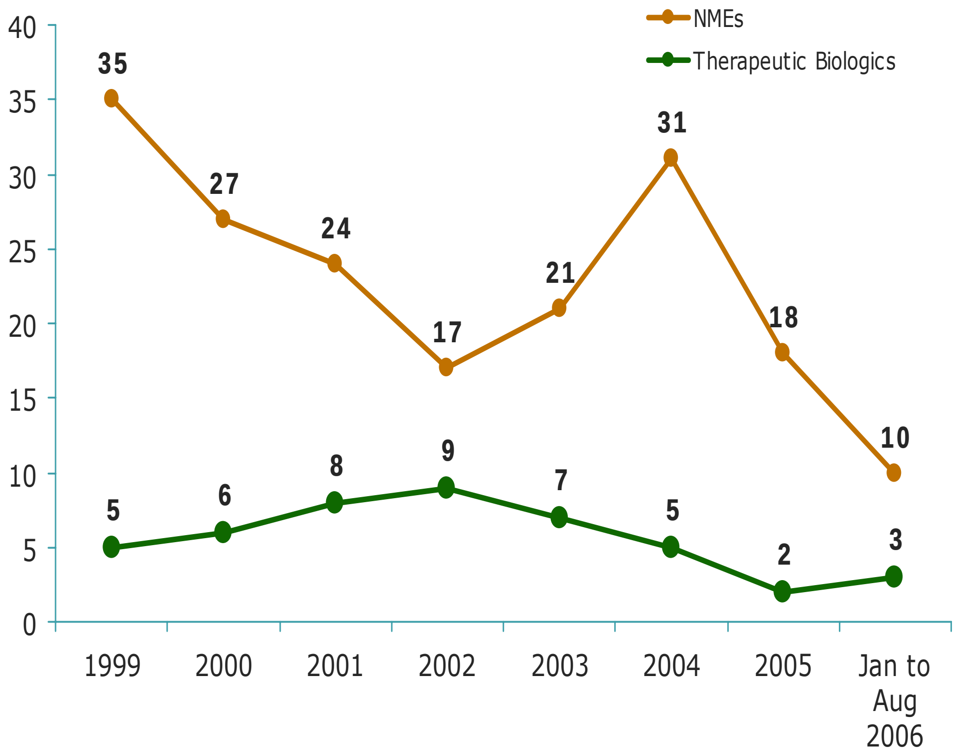
## Looking Forward to 2010

- ***What We See***

- **Costs exceed administration estimates**
- **Providers consolidate**
- **Plans simplify**
- **Patients fight the donut hole**
- **Physicians will opt to prescribe for the "dominant" plan**
- **Part D and Part B increasingly overlap**
- **Retirees migrate – Not by choice**
- **Surviving plans are happy, but what about consumers?**

# Searching for growth…pipeline…new products…blockbuster performances

# FDA approvals to August 2006 beat pace of 2005




- As of August 31, 2006 there were 10 new molecular entities and 3 novel biologics approved
- These 13 novel agents surpass the 11 approvals for 1st nine months of 2005; but lag behind 2004 (20 NMES cleared in 1st 3 quarters)
- NME approvals include 1 for a new OTC product, L'Oreal's sunscreen (Anthelios SX)
- 3 NMEs for oncology; 2 NMEs for nervous disorders
- So far, Pfizer leads with 3 approvals
- Note: FDA does not consider Exubera, Gardasil or Symbicort new molecular entities

Source: The Pink Sheet Daily, Sept 15, 2006; Market Insights Analysis

# Top launches in 2006: four of the top 10 by monthly sales are brands

| | Product | Mfr | Month | Avg Mthly Sls 2006 $(M) to May |
|---|---|---|---|---|
| 1. | Pravastatin sod | Teva | Apr-06 | 29.7 |
| 2. | Fluticasone prop | Par | Feb-06 | 27.5 |
| 3. | Pravastatin sod | Watson | Apr-06 | 20 |
| 4. | Fluticasone prop | Roxane | Mar-06 | 16.3 |
| 5. | Ultram ER | J&J | Feb-06 | 6.8 |
| 6. | Avandaryl | GSK | Jan-06 | 4.1 |
| 7. | Orencia | BMS | Feb-06 | 3.4 |
| 8. | Amitiza | Takeda | Mar-06 | 2.6 |
| 9. | Desmopressin Ace | Teva | Feb-06 | 2.5 |
| 10. | Lisinopril | Lupin | Feb-06 | 1.8 |

Source: IMS Health, National Sales Perspective, July 2006

# Performance overview

# Agenda

- Industry Overview
- Key Trends and Issues
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- Future Outlook

# Amgen continues to move up, and Roche enters the top 10

| | Leading Corporations | Twelve months to 2Q 2006 | | |
|---|---|---|---|---|
| | | US $ Mil | % Share | % Change |
| | US Industry | 261,368 | 100.0 | 5.7% |
| 1 | Pfizer | 26,871 | 10.3 | -9% |
| 2 | GlaxoSmithKline | 20,847 | 8.0 | 8% |
| 3 | Merck | 16,713 | 6.4 | 12% |
| 4 | Johnson & Johnson | 15,744 | 6.0 | -5% |
| 5 | AstraZeneca | 13,796 | 5.3 | 10% |
| 6 | Amgen | 13,140 | 5.0 | 20% |
| 7 | Novartis (incl Sandoz) | 12,837 | 4.9 | 7% |
| 8 | Sanofi-Aventis | 10,675 | 4.1 | -2% |
| 9 | Lilly | 8,841 | 3.4 | 4% |
| 10 | Roche (incl. Genentech) | 8,502 | 3.3 | 24% |
| | Top 10 | 147,967 | 56.7 | 4.2% |

Source: IMS National Sales Perspective, June 2006



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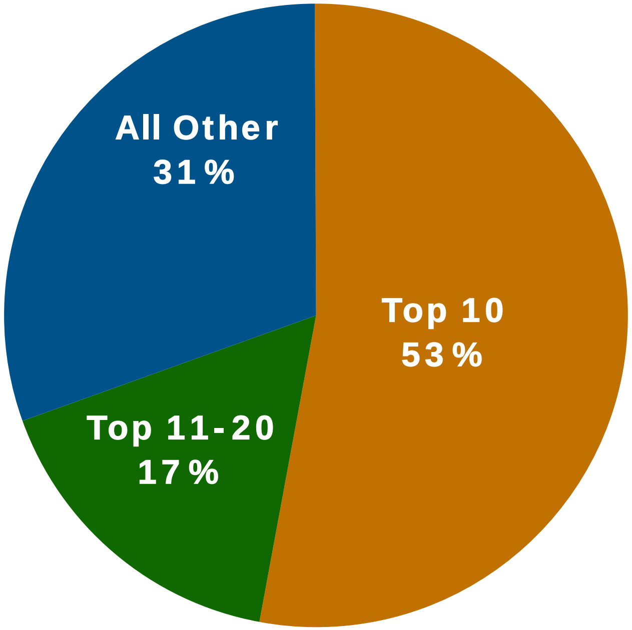
# Roche/Genentech join the top 10 & leading players account for 43% of growth

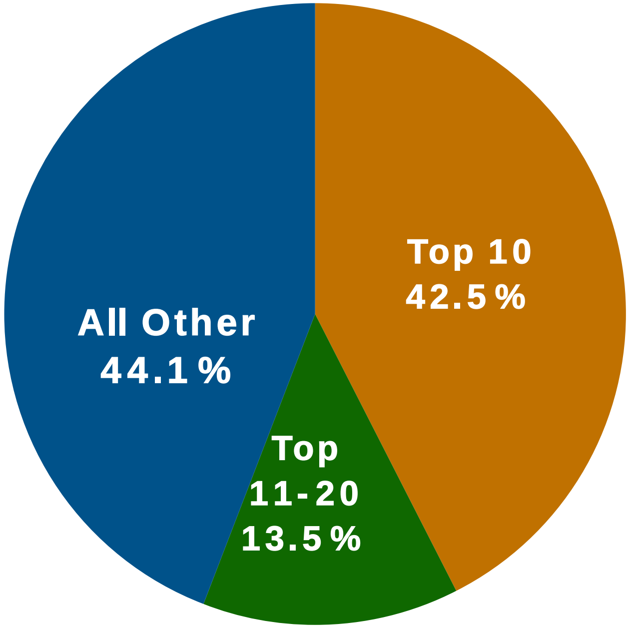
## Mid-sized and smaller companies gain with 44%

**Contribution to Growth**
**Percentage of Absolute Change**

**2002**




**MAT 2Q 2006**




Source: IMS National Sales Perspective, June 2006

# Generic manufacturers dominate the top 10 on a total prescription basis through MAT June 2006

| Leading Corporations | 12 Months ending June 2006 | | |
|---|---|---|---|
| | TRxs (Mil) | % Share | % Change |
| US Industry | 3,724 | 100.0 | 3.6 % |
| 1. Teva (incl. Ivax) | 393 | 10.6 | 17% |
| 2. Pfizer | 314 | 8.4 | - 9 % |
| 3. Novartis (incl. Sandoz) | 292 | 7.8 | 8 % |
| 4. Mylan | 239 | 6.4 | 8 % |
| 5. Watson | 195 | 5.2 | 8 % |
| 6. Merck | 138 | 3.7 | 10 % |
| 7. GlaxoSmithKline | 129 | 3.5 | - 3 % |
| 8. AstraZeneca | 115 | 3.1 | 8 % |
| 9. Mallinckrodt | 104 | 2.8 | 24 % |
| 10. Actavis | 89 | 2.4 | -1 % |
| Top 10 | 2,008 | 53.9 | 6.2 % |

Source: IMS National Prescription Audit Plus, July 2006; Novartis includes Sandoz and Eon

# Lipids are still the leading class while cancer therapies and insulin show strong growth

| | Leading Classes | Twelve months to 2Q 2006 US $ Mil | % Share | % Growth |
|---|---|---|---|---|
| | US Industry | 261,368 | 100% | 5.7% |
| 1 | Cholesterol Reducers | 19,555 | 7.5 | 10% |
| 2 | Proton Pump Inhibitors | 13,264 | 5.1 | 2% |
| 3 | Anti-psychotics | 10,964 | 4.2 | 9% |
| 4 | Anti-depressants | 10,474 | 4 | -1% |
| 5 | Erythropoietins | 9,329 | 3.6 | 10% |
| 6 | Seizure Disorders | 8,272 | 3.2 | -1% |
| 7 | Angiotensin II Antagonists | 5,380 | 2.1 | 12% |
| 8 | Monoclonal Antibodies | 5,029 | 1.9 | 59% |
| 9 | Calcium Blockers | 4,650 | 1.8 | 1% |
| 10 | Insulin Sensitizers | 4,531 | 1.7 | 21% |
| | Top 10 | 91,448 | 35.0% | 8.3% |

Source: IMS National Sales Perspective, June 2006

# Lipitor® continues on top; Nexium®, Advair Diskus®, Plavix®, and Aranesp® moving up

| | Products | Company | Twelve months to 2Q 2006 | | |
|---|---|---|---|---|---|
| | | | US $ Mil | % Share | % Growth |
| | US Industry | | 261,368 | 100% | 5.7% |
| 1 | Lipitor® | Pfizer | 8,572 | 3.3 | 5% |
| 2 | Nexium® | AstraZeneca | 4,776 | 1.8 | 16% |
| 3 | Zocor® | Merck | 4,730 | 1.8 | 4% |
| 4 | Advair Diskus® | GSK | 3,782 | 1.4 | 14% |
| 5 | Plavix® | BMS | 3,774 | 1.4 | 14% |
| 6 | Prevacid® | TAP | 3,707 | 1.4 | -4% |
| 7 | Aranesp® | Amgen | 3,344 | 1.3 | 42% |
| 8 | Zoloft® | Pfizer | 3,103 | 1.2 | -1% |
| 9 | Epogen® | Amgen | 3,070 | 1.2 | 2% |
| 10 | Enbrel® | Amgen | 2,918 | 1.1 | 19% |
| | Top 10 | | 41,776 | 16.0% | 9.2% |

Source: IMS National Sales Perspective, June 2006



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# Agenda

- Industry overview
- Key trends and issues
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- Future outlook
  - Pivotal Events in 2006
  - Five Year Outlook

# Future Outlook

# Biosimilars expected to enter strategic markets in 2008-2010:

## Humatrope launches in Australia at 25% discount

BIOGENERICS

FOLLOW-ON BIOLOGICS

BIOSIMILARS

COMPARABLE BIOLOGICS

- Recent FDA approval of Omnitrope provides small opening for US market
- Biogenerics already being marketed in China, E. Europe, India and S. America
- Generic Procrit approved in Croatia, EU states may follow
- Pfizer eyes market potential, looks for partners

- Key players include
  - BioPartners
  - Cangene
  - GeneMedix
  - LG Chemicals
  - Pliva
  - Rein Biotech
  - Roemmers
  - Sandoz
  - SciGen
  - Stada
  - Teva

# …But biologics brands may fare better than pharmacologicals

- High cost of materials and production will limit discounting, and hence brand share erosion
- More scope to leverage survival strategies
  - Extend exclusivity period through law ?
  - Improve manufacturing efficiency
  - Create differentiation
  - Control manufacturing capacity
  - Play the quality and safety card

**No longer *if* biogenerics approved, but *when*…**

**2008 - 2010?**

# US market five year outlook 2006-2010: opportunities and challenges

- **Future NCEs, active pipeline of specialty products, biologics, and vaccines**
- **Medicare drug benefit**
- **Strong demand fueled by aging population**

- **Future patent expirations/generics**
- **Weaker than expected performance of NCEs in 2005**
- **Safety concerns**
- **Decline of detailing**
- **Therapeutic substitution**

**CAGR 5-8%**

# *Thank you!*

Diana Conmy, Corporate Director, Market Insights

IMS Health