



# Environmental and Structural Factors Influencing the Politics of Pharmaceuticals in 2005-2006

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How Public Opinion, New  
Leadership, the SOTU and  
Governance Primacy Drive Change



# Environmental Factors

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Most Important Issues Identified by  
Voters on November 2<sup>nd</sup>:

1. Economy/Jobs
2. War in Iraq
3. Campaign Against Terrorism
- 4. Health Care/Medicare/Rx Drugs**
5. Education
6. Social Security



# Environmental Factors

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- Rx Out of Pocket Expenses Focuses Attention on Cost Not Value
- Cross Border Pricing Differential Unsustainable Politically
- High Stakes of Getting Part D “Right” in 2006 Election Cycle
- Impact of Other Political Imperatives (Deficits/Judges/Iraq/Social Security)



# Structural Factors

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## Impact of New Leadership in Bush Administration

- Attorney General
- HHS Secretary
  - FDA Commissioner
  - CMS Administrator
  - OIG



# Structural Factors

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## Changes in Congress Affecting Direction

- Republican Gain in the Senate
  - Strengthens Leader & Committee Chairs
  - Weakens Influence of Moderates
  - Committee Ratios & Budgets Shift



# Structural Factors

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## Changes in Congress Affecting Direction

- Shifting Chairs in the Senate
  - Budget Committee
  - HELP Committee
  - Judiciary Committee
- House Legislative Outlook Stable



# Environmental Factors

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## Impact of the President's SOTU

- Third Most Important Address by President
- Placement in SOTU = Ranking in Priorities
- New Initiatives vs. Implementing Programs
- Strength of Conviction = Allocation of Budget Resources + Political Capital



# Structural Factors

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## Success or Failure of “Governance Primacy” Advocates in Health Policy

- Frist & Hastert Most Knowledgeable Leaders on Health Care Issues in a Generation
- Dingell & Kennedy Most Credible Architects of Democratic Health Care Policies
- Where Can They Agree?





# Structural Factors

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## What Will Congress See in 2005?

- Expanding Health Insurance Coverage
  - Frist/Kerry Proposal for “HealthyMae”
  - HSAs/AHPs
- Resolving the Importation Debate
  - “if [foreign drugs] are safe, they’re coming.” President Bush in final Presidential debate



# Structural Factors

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## What Will Congress See in 2005?

- Maintaining Confidence in Drug Safety
  - Greater Oversight of Drug Approval Process and Phase IV Studies
- Continued Oversight of Health Care Fraud
  - OIG 2005 Work Plan
  - Actions of State AGs



# Structural Factors

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## What Will Congress See in 2005?

- Medicare Part D Implementation Issues
- Follow-On Biologics
- Medical Malpractice Reform
- Vaccine Issues
- DTC