PHARMACEUTICAL SUMMIT ON BUSINESS & COMPLIANCE ISSUES IN MANAGED MARKETS

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Measuring Up: Compliance and Legal Considerations in Managed Markets

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Agenda

• Panel Introductions
• What is “Managed Markets”?
• True or False: There are no federal legal/compliance risks involving Managed Markets because it involves only dealings with private payors?
  — Key policy issues
  — Potential legal issues
• Discussion of particular Managed Markets topics
• How companies address compliance risks with Managed Markets
• Lessons and Take-aways
Panel Introductions

- Timothy Ayers – Horizon Pharma
- Blake Bolinger – Bristol-Myers Squibb
- Jennifer McGee – Otsuka Pharmaceutical
- Ron Wisor – Hogan Lovells
What is Managed Markets?

• How do different companies define this concept?
• How does the government define this concept?
• What are the legal/compliance factors for defining Managed Markets?
True or False?

• There are no federal legal/compliance risks involving Managed Markets because it involves only dealings with private payors.
  — Key policy reasons why Managed Markets arrangements may raise risks:
    — Effect on prescribing decisions
    — Effect on federal health care program payments
  — What laws are potentially implicated?
    — Federal Anti-Kickback Statute
    — Federal Civil Money Penalty Statute
      — Beneficiary inducement provisions
    — HIPAA
    — State Laws
Key Managed Markets Risk Areas

- Issues that may raise legal/compliance risk:
  - Patient Assistance Programs
  - Reimbursement Support/Co-Pay Cards and Coupons
  - Contracting Arrangements/Service Requirements
  - Pricing Issues
    - Rebates
    - Value-Based Pricing
How Do Companies Address Managed Markets Compliance Risks?

• What are the internal definitions of Managed Markets and specific risk areas?

• What internal resources focus on Managed Markets?

• What external resources are regularly used, if any?
Lessons Learned
Lessons/Considerations

• Today’s Compliance Departments must expand their purview and focus
  — Look beyond HCPs and federal health care programs
  — Monitor more than just policies and transactions
    — Must seek insights into what is really going on (i.e., intent)
• Monitor All Trends and Developments
  — Focus on case law, including from the pharma and provider industries
  — Lookout for new DOJ and OIG guidance
  — Take note of all new CIA terms and developments
• Use outside resources for evaluation and benchmarking
Questions?