First Things First

- My Bias: The Manufacturer's Perspective
- Discounts, Rebates, and Admin Fees
- Relationships in Search of a Safe Harbor
- The Options: GPO, Discount, and Personal Services Safe Harbors
- Imperfect Options and the Effort to "Come Close"
  - The Complication of Trying to Figure out if the Government Will See the Outcome as Positive or Negative?
  - Is "Switching" Good or Bad?
  - In the Eye of the Beholder
- Should Manufacturers Even Ask for Clarification?
- The Old Debate Revisited: Can the Statute Be Trumped by a Safe Harbor?

Transparency: A Complicated Issue

- Enforcement Really Has Shaped the Policy Debate Here.
- There Are Some Strong Transparency Arguments to Be Made.
  - What Is the Value of a Rebate If It Does Not, in Fact, Translate to Reduce Costs?
  - That Begs the Question, of Course, about What Actually Happens to Those Rebates.
- Interestingly, at Least from the Legal Perspective, Manufacturers' Counsel Can Find Themselves Somewhat Aligned with the Pro-Transparency Forces of the World.
  - Making the Discount Safe Harbor Make Some Sense.
- But Is Transparency the Unqualified Good that Some in Enforcement Believe It to Be?

Some Concerns about Transparency

- Will Manufacturers Resist Making Concessions?
  - What Does the BP Experience Tell Us?
- Will Transparency Undermine the PBMs' Position in the Market Place?
- Is the Enforcement Push for Transparency at Odds with Congressional Policy?
  - Clearly Elements of Transparency in DIMA
  - But Clearly Transparency Was Not Seen as an Absolute Good, Either.
    - Let's Think about Both the Discount Drug Card and the Part B Competitive Acquisition Program
- Which Begs the Question: Should Policy Be Driven by Enforcement?

A Few Quick Words about the Supervision Issues

- First, There Is Nothing New under the Sun.
- Second, the State Laws Are Not Always a Model of Clarity.
  - What Level of Supervision Is Required?
- Third, Not So Clear What the Tie to a False Claim Is.
  - True, Sometimes There is a Contractual Hook.
  - But Not Always.
  - The Implied Warranty Theory as the "Answer"
  - But What about the Concept of Materiality?
  - Coulds and Maybes

The Next Shoe to Drop

- PBMs: Whither Will They Go in the Post-DIMA World?
  - Primary Player or Subcontractor?
  - Interesting Business Call
- Are There Really Adequate Protections for Patients and Manufacturers in DIMA?
- There Is Good There.
  - Some Examples
- But There Are Some Clear Vulnerabilities
  - A Skewed Version of Cost Effectiveness?

Some Specific Concerns

- Decisions Must Be Made by a Pharmaceutical and Therapeutic Committee
  - Limited Protection There, However
    - Only One Member of the Committee Must Be a Practicing Physician and One a Practicing Pharmacist Who are "Independent and Free from Conflict."
    - Majority of Members Must Be Physicians or Pharmacists
- Committee Standards Are Such as to Facilitate Formulary Restrictions
  - Clinical Decisions to Be Based on the "Strength of the Scientific Evidence and Standards of Practice"
  - Statute Points to "Peer-Reviewed Medical Literature"
    - Which Term Refers, in Turn, to "Randomized Clinical Trials, Pharmaeconomic Studies, Outcomes Research Data, and Such Other Information the Committee Determine[s to Be] Appropriate"
      - Allows the P&T to Assert a Very High Standard
  - Committee Must Also "Take into Account" Whether a Particular Drug Has "Therapeutic Advantages in Terms of Safety and Efficacy."

The Class and Category Powers of Plans

- Basic Rule Is that 2, But Only 2, Drugs Must Be Selected for Each "Class" of Drugs.
  - Implication: Class Determinations Will Further Support the Restriction Powers of the Plans.
- CMS Will Seek, in Essence, a Safe Harbor on Class Determinations from the United States Pharmacopeia
  - Consultation Requirement, But Pharmaceutical Companies Not Listed
  - Common Problem
    - Implication: Pharmaceutical Companies Will Need to Develop Relationships with Those Who Have a Voice and Supportive Materials
  - But Plan Not Bound by That Safe Harbor
- Some Countering Provisions Present Here
  - Plans Cannot Change Classes During Plan Year, Except in the Case of "New Therapeutic Uses and Newly Approved Covered Drugs"

Implications of the Formulary Standards

1. Standards Should Be a Major Aid to Plans that Want to Restrict Formularies, Particularly for Off-Label Uses
2. Tremendous Increase in the Relative Need for Research and, Particularly, for Pharmaeconomic Research
    1. Note the Restrictive Focus of Pharmaeconomic Issue — Reflection of Plans' Interests
3. Comparative Research Made More Important and Will Be Essential in Some Cases
4. Remember the Limited Time Available to Affect Initial Determinations — Pharmaceutical Companies Will Need to Manage Resources in This Period Carefully
5. Litigation Likely
6. Will the Manufacturers Seek Help from the Enforcers?