What Pharmaceutical Companies Should Do About Drug Safety Governance: A Legal Perspective

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Scott Bass
Sidley, Austin, Brown & Wood LLP
Washington, D.C. and New York
sbass@sidley.com

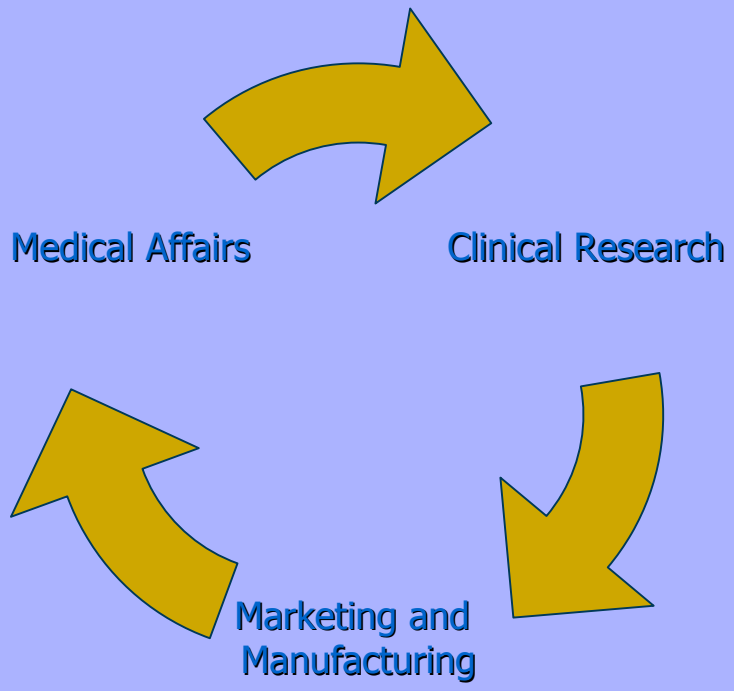
What Pharmaceutical Companies Should Do About Drug Safety Governance

I. Understand All Potential Exposure As Interrelated

II. View Marketing,Medical Affairs, and Quality Operations/Exposure From An Integrated Perspective

III. Adopt a Meaningful Approach -- Globally -- to Policies, Training and Audits

View Operations / Exposure from an Integrated Perspective



Legal Overlay

Safety Implications: FFDCA, Fraud and Abuse,Product, Consumer Fraud
Kickback/FCA Issues
Securities/ Sarbanes Umbrella Concerns
EU/Japan Regulatory Conflicts

Revise Policies to Address the New Integrated Reality

- Ensure That Existing Policies are Brought Together
  - Companies Often Do Not Know That There Are Overarching Or Global Policies That Conflict or Are Outdated
  - Ensure That Different Product Groups Read From The Same Bible
- Start With an Integrated Outline Instead of Trying First To Harmonize Existing Policies
- Document Training and Do it Often

Make Risk Assessment Part of Every Function

- Train On Consequences Up, Down and Across the Line
  - e.g., GMP can mean safety/criminal/FCA
- Take a Principled Company Position on Gray Area Issues -- *e.g.* Medical Affairs Line Drawing
  - Medical Liaisons
  - Clinical Research Grants
- Establish Strong Rules on Document/Email Communications

Audit Compliance

- Establish Audit Master Plan on Global Basis with Meaningful Test Area
- Include Co-Marketing or Licensing Partners
- Ensure Careful Review of Draft Audit Reports to Ensure That They Remain Factual and Within The Competence of the Auditor

- Key to Government Investigations
- Isolate Conduct and Can Reduce Vulnerability Of Otherwise Compliant Senior Officer
- Provides Opportunity in Some Cases to Have Privilege Protection