Exchange of Scientific Information and Off-Label Promotion

Pharma, Biotech and Device Colloquium
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JOAN M. MACAULAY

Off-Label Promotion

- What is it?
- How is it done?
- Prevalence

Applicable Statutes

- Food, Drug, and Cosmetic Act
- Federal Conspiracy Statute
- False Claims Act
- State Unfair Competition Laws

Off-Label Investigations

- Federal
  - FDA/OCL
  - Department of Justice/U.S. Attorney's Offices
- State
  - State Attorneys General
  - State Medicaid Fraud Control Units

- Can be Criminal and Civil
- Can be Federal and State

Off-Label Investigations (cont'd)

- FDA
- *Qui tam* or whistleblower
- Physician/Pharmacist complaints to the government
- Competitor complaints to the government
- Lanham Act cases – unfair competition
- Products Liability Cases/class actions
- Press

Investigation Focus Points

- Significant drugs with major off-label use
- Company promotional activities
  - Consultants
  - Speakers
  - Publications
  - Educational events
  - Medical or scientific liaisons
- Is senior management mandating or directing off-label promotion?
- Is off-label promotion a systemic practice?

Legal Defenses

- Statutory
- Constitutional

Enforcement Activity

- Since 1999, the FDA has cited manufacturers nearly 70 times for off-label promotion.
- Genentech
  - Conduct at issue – off label promotion plus other issues
  - Civil and criminal enforcement – U.S. Attorney's office, N.D. California, May 7, 1999 settlement:
    - $30 million criminal
    - $20 million civil
    - $50 million total

Enforcement Activity

- Parke-Davis: Off-Label promotion plus other issues; District of Massachusetts
  - False Claims Act case
  - Companion criminal investigation
  - Settlement announced May 2004
    - $240 million criminal
    - $152 million civil
    - $38 million to state consumer protection divisions
    - $430 total

Other Disclosed Investigations

- Schering-Plough: Off-Label promotion plus other issues; District of Massachusetts
- Pfizer: Off-Label promotion plus other issues; civil action pending in California
- Johnson & Johnson Ortho-McNeil division: District of Massachusetts
- Recent DOJ investigations
- Recent Office of Personnel Management subpoenas

Publications and Exchange of Scientific Information

- Is the First Amendment a viable defense to off-label promotion?
- FDA Guidance (1996)
- WLF I (1998)
- FDAMA (effective 11/1998)
- Pearson (1999)
- WLF II (1999)
- FDA Revised Guidance (2000)
- Western States (2002)
- FDA Request for Comments (2002)

Where are we now?

- The ultimate enforcement position the FDA plans to take concerning off-label promotion is still unclear.
- The ultimate enforcement position other agencies plan to take is not clear, nor necessarily consistent with that of FDA.
- Courts have recognized that the First Amendment is alive and well and is a viable defense to the dissemination of information concerning off-label uses.

The First Amendment and The FCA

- *Parke-Davis*
- Why is this case so significant?

Company Compliance Focus

- Identify products with off-label usage.
- Conduct internal investigation.
  - Focus on substance.
  - Must be conducted under privilege.
- Ensure that problem never becomes systemic.
- Take corrective compliance actions where necessary.
- Government will credit company for an effective compliance program.

Company Compliance Focus (cont'd)

- Eliminate Risks
  - Consultants and Advisory Boards
  - Medical Liaisons
  - Grants
  - CME
- Training
- PhRMA Guidance (July 2002)
- OIG Guidance (May 2003)

JOAN M. MACAULAY

SIDLEY AUSTIN BROWN & WOOD LLP

(202) 736-8678

jmacaulay@sidley.com