Off-label Promotion: Managing the Regulatory Risks

Pharma Congress 2003

National Audio conference

October 2, 2003

Michael Misocky, R.Ph., J.D.

Off-label Promotion

What is it?

- *Know it when you see it!*
- *Inconsistent with or contrary to approved product labeling (includes but not limited to indications for use, dosing, special patient populations)*

Off-label Promotion

When is it not "promotion"?

- ***Scientific Exchange*** *(see 21 CFR 312.7) (could include press releases, scientific reprints, and medical education)*
- ***Unsolicited requests***
- ***Safe harbors*** *(Independence Criteria for CME and FDAMA Section 401 or 21 CFR Part 99)*

Off-Label Promotion

What are the regulatory and other risks?

- ***FDA Warning or Untitled Letters*** *(could warrant corrective campaign)*
- ***Mandatory preclearance*** *(of all promotional materials)*
- ***Dept of Justice Civil or Criminal Proceedings*** *(for misbranding)*
- ***Class Action Lawsuits***
- ***False Claims Act*** *(Medicaid Fraud)*

Off-label Promotion

Managing the risks

- *Get a handle on "all" activities (concerted campaign)*
- *Review training materials (similar rigor and scrutiny as promotional materials)*
- *Find a safe harbor and dock there*
- *First amendment protection for scientific reprint dissemination*
- *Mandatory promotional compliance training program*