

Enforcement Climate

- Congressional Oversight
- U.S. Attorney's Offices
- State AG, Inspector Generals
 - quotas on fraud recoveries
 - state False Claims Act
 - Consumer Protection
- Off label enforcement will continue
- Whistleblowers
 - to government
 - competitive practices

Target v. Witness

- Counsel familiar with prosecutor
 - status of investigation/target/witness/custodian
- Advice to Employees
 - the right not to talk to government agents
- Preserve documents
 - have pre-existing retention policy
 - issue litigation hold
 - e-files
- Deal with disgruntled employees
- If something is wrong, cure it

Inquiries by Governmental Agents

- How do you answer these questions:
 - With whom do you have contact?
 - Marketing/Sales or Medical Education/Medical Clinical affairs
 - Who writes the checks for CME?
 - Who attends the meetings to develop CME?
 - What is the nature of discussions regarding content of CME?
 - Who from CME provider is there to discuss content?
 - What was the nature of back and forth over content?
 - Is there an agreement to have CME provider do something that company can't do on its own?

Best Practices

- Is the FDA involved?
 - Bring FDA program on your side
 - create a record
 - disclosure
 - good compliance
 - training
 - education
 - public health
- Risk Continuum:
 - Real Firewalls; separate key people
 - audits
 - Compliance Officer
 - to whom does CO report?
 - Marketing Plans
 - Sales Staff
 - Legitimate purpose of information exchange
 - CME
 - Disclosure of payments to speaker
 - List the pre-eminent faculty
 - Content: science v. promotion