



What to Expect from the New Congress and New Administration

March 5, 2009
Washington, DC

John P. Ford

Getting Started

- New administration takes time to get up and running
- Key personnel have yet to be named
 - Their priorities
 - President Obama's priorities
 - Changes in circumstance
 - Emergencies (peanut butter)
 - Budget (shortfalls, directives)
 - Congress, legislation and oversight
 - Stakeholders and media
- HHS Secretary and FDA Commissioner require Senate confirmation
- Daschle departure slowed process
- Economic stimulus and health care reform are major priorities, affect on other priorities

Same Party, Different Jobs

- Congress and the Administration
 - Two sides of the same policy coin
 - Congress acts, the agency reacts (FDAAA)
 - The agency acts, congress reacts (DTC, Reprint Guidance, preemption)
- Congressional majorities and Administration of same political party reshape congressional oversight compared to recent years
- Key administration personnel will have ties to key congressional offices
 - Fewer disputes
 - Disputes resolved quietly more often
- Institutional perspectives shape day to day relationship between an agency and congress
 - Tension between Administration and congress
 - Tension between House and Senate
 - Partisan and intra-party tensions

The Administration

- Key personnel need to be named, confirmed or appointed, and adjust to new jobs
- Obama FY 2010 budget will provide early detailed look at priorities
- Obama versus Bush enforcement “scorecard”
- Philosophical shift between Bush administration and Obama administration, existing policies will be reviewed
 - DTC advertising
 - Reprint Guidance
 - Preemption

Congress

- Interest in oversight remains strong
- “Oversight is as important as legislation....Sometimes just focusing attention on an issue helps us to resolve it.”
 - Rep. Henry Waxman, Chairman, House Committee on Energy and Commerce
- Guidance on Good Reprint Practices
 - A “parting gift” to industry.
 - Rep. Waxman

DTC Advertising

- DTC Advertising
 - Moratorium
 - Disclaimers and other restrictions
 - Unknown risks
 - FDAAA studies, risk communication
 - User fee

Financial Transparency

- Physician Payment Sunshine Act
 - Disclosure, \$100 annual exclusion
 - Preemption, additional requirements not preempted
 - CMPs for non compliance
 - Delayed reporting
 - Date of approval, or
 - Two years after payment

Financial Versus Other Conflicts

- Continued oversight of financial interests
 - Clinical trials
 - Ethics, informed consent
 - Validity of results
 - Advisory committees
 - FDAAA
 - Vacancies
 - Financial versus philosophical conflicts

Reprint Guidance

- Guidance on Good Reprint Practices
 - A “parting gift” to industry.
 - Rep. Waxman

Tobacco

- Tobacco
 - New standards and program requirements
 - Adequacy of resources
 - Personnel requirements
 - Deadlines
 - Unknown, but possibly significant effects on FDA's existing programs

Information Collection, Characterization, and Dissemination

- FDAAA and Information
 - Collection
 - Characterization
 - Dissemination
- Pharmacovigilance, product life cycle (pre and post market)
 - Risk Identification
 - Risk Evaluation
 - Risk Minimization

(continued)

Data Collection, Characterization, and Dissemination (continued)

- Continued implementation of FDAAA
 - Risk communication, studies and reports
 - Expansion of clinical trials database
 - Emphasis on product life cycle
 - Post market safety, REMS
 - Active surveillance