# FDA Legislation

It’s Never Over

# An Agency Congress Hates to Love

- Multiple bills; multiple components of every bill
- Multiple investigations, inquiries, document requests
- Multiple hearings, demands for testimony
- Thousands of letters

# Over FDA's History
# The Theme Remains the Same

- Failures, mistakes, "scandals" about products lead to legislative "solutions"
  - '38, elixir sulfanilamide,107 deaths
  - '62, thalidomide
  - '76, unsafe devices, 731 deaths, 10,000 hurt
  - '80, infant formula
  - '90, nutrition labeling
  - '94, '06, dietary supplements
- More responsibilities, more tasks, more reports, more opportunities for scrutiny

# Recent Comprehensive Legislation

- FDAAA 2007
- BPCA, MDUFMA, BPRA(PDUFA) 2002
- FDAMA 1997

# FDAAA
# >85 New Tasks (about 2/3 completed)

- A broad range, across processes and regulated products
  - Clinical trials registration expansion and results reporting
  - REMS
  - Risk communication
  - Encourage pediatric medical devices
  - Deal with advisory committee conflicts
  - Establish food registry, improve recall processes, promulgate rule for ingredient standards
  - Report on aquaculture, genetically engineered seafood, pesticide residue monitoring
  - Develop and publish processes for review, clearance of scientific articles
- Advertising-specific
  - Standards to determine if ads are “clear, conspicuous, and neutral” as regards side effects and contraindications
  - Establish DTC user fee program (killed by Congress not appropriating funds)

# Currently Pending Legislation

- 8 bills related to product safety
- 4 bills related to Rx importation
- 4 bills related to biosimilars
- 4 bills related to brand-generic settlements
- 11 bills related to other assorted issues

# A Few Specifics

- Regulate tobacco products (enacted)
- Food Safety Enhancement Act (passed House)
- Prohibit approving biologics that are or contain a “select agent or toxin” made by an entity that has sold products to Iran
- Require FDA to determine if standardized benefit-risk summaries in labeling and ads would improve decision making; require comparative clinical effectiveness information in labels
- Prohibit marketing of authorized generics

- Safe baby products
- Safe seafood
- Safe vaccines
- Safe food, safe seafood
- Prohibit bisphenol A in children’s product containers
- Finalize 2007 proposed sunscreen rule

# And for This Particular Panel

- H.R. 2175, Families for ED Advertising Decency Act
  - FCC must revise  interpretation and enforcement of its regulations on indecent material that may not be broadcast between 6 AM and 10 PM to include as indecent any ad for a medication to treat erectile dysfunction or for “male enhancement” – not to include a product placement or name mention
    - ** In fairness, this bill doesn’t directly affect FDA except that it could relate to approved products, but It’s topical

# Appropriations
# A Catch-All

- ~$2.3 b for 2010 (~300 m ↑ over 2009)
- Emphasis on safety – these funds will "help reform how FDA ensures safety" and "significantly improve food and medical product safety"
  - 1150 more inspections
  - 20K more examinations of imported food
  - 3300 more examinations of imported drugs
  - 4400 more examinations of imported devices

# Funding-Related "Instructions" Some Examples

- Prioritize review of new therapies and treatment protocols for Stage IV neuroblastoma
- Respond to Citizen Petition regarding standard of identity for honey; remind honey manufacturers about adulteration and misbranding
- Don't close or re-locate St. Louis laboratory
- Discretionary study on similarities between food addiction and drug addiction

- Discretionary new review groups to study prevention, diagnosis, and treatment of rare diseases and of developing world neglected diseases
- Issue sunscreen final rule by 12/09
- No funds from FDA for Reagan-Udall Foundation
- No less than $51.5 m for OGD

# Health Care Reform – FDA Does Not Escape

- Biosimilars/Follow-On Biologics Legislation included in both House and Senate Committee-reported bills
- “Sunshine” act provisions included in both House and Senate Committee bills
- Comparative Effectiveness requirements included in both House and Senate bills
  - Largely reimbursement-oriented, but dependent on FDA-reviewed data/information
- Comparative Effectiveness Data on Product Label as potential amendment

# How Does FDA Respond?

- Focusing on Congress' apparently highest priority issue, product safety, new FDA leadership committed to change
- Political environments change people's view of "acceptable"
  - A Democratic Congress may be more patient with a Democratic Administration – but not forever

- Recognize it’s never over
- Recognize it won’t change because you want it to
- Deal with it