



# FDA Updates

SACGHS June 16, 2010

# DTC

- Calls from many quarters including SACGHS for increased oversight of DTC genetic tests
  - Medical claims
  - Poorly established clinical value
  - Does not require intervention of healthcare provider

# Pathway/Walgreens

- Pathway to market DTC genetic test including tests pharmacogenetic tests directly to public through Walgreens
- FDA IHCTOA letter to Pathway—not an LDT
- Walgreens abandons marketing plans



# Congressional Interest

- Congressional investigation
  - Letters to DTC firms requesting information
    - Additional letter to 23andMe on recent sample mix-up
- Possible hearing this summer

# Untitled letters

- 5 untitled letters sent 6/10/10
  - 23andMe
  - Navigenics
  - Illumina
  - deCODE
  - Knome
- Request firms to work with FDA to determine which claims require oversight, how to manage submission process



# Array Based CN Public Meeting

- June 30, Bethesda
- Open to public but must register
- Can make 5 min presentation
- Intent to gather information on regulatory approach to non-targeted testing
- Panel session to address 6 questions
- Docket open for input (7/30/10)
- <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480afe30f>

# Companion Diagnostics and Codevelopment

- Companion diagnostic draft guidance
  - What is a companion diagnostic
  - When is regulation required in order to assure treatment/diagnostic safety and effectiveness
  - Publication in 2010?
- Codevelopment draft guidance
  - Informational, not directive
  - Addresses differences in regulatory strategy, review issues, etc
  - Publication in 2010?



# New Procode for LDTs

- Added product code so that MDRs can be reported for laboratory developed tests
- Have received several to date

# 510(k) Review

- FDA internal review
- IOM review
- Recommendations for changes expected this summer
- No major changes expected for OIVD, but...

# Oversight of LDTs

- FDA announces today (FDA-2010-N-0274)
  - Public meeting July 19-20, 2010
  - Intent to establish risk-based oversight framework for all tests
  - General expectations at this time
    - Registration and listing period will be needed
    - Risk-based phase in (highest risk first)
    - Avoid disruption to access
      - Low or no bar for certain tests (rare disease, etc)

# Meeting Format

- Open to public, but must register
- 5 min subject-matter presentations allowed
- 4 sessions addressing patient needs, laboratory issues, DTC, and educational issues
- Panels to discuss issues, propose approaches

# FDA Intent

- Implement oversight
- Work with stakeholders to construct framework
- Minimize disruption
- Provide access, education to labs
- Ongoing public engagement as story unfolds