

FDA Update

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New Faces

- Acting Center Deputy Director – Kate Cook
- Associate Director for Policy and Operations – Don St. Pierre

New Mandates

- User fee submission deadlines
- IVD specific agreement

IVD Goals

- Guidances – most product specific; migration guidance for platform changes
- Waiver pilot – parallel reviews for FDA and CLIA
- Re-visit exemption list; redeploy resources
- Evaluate pre-IDE program

IVD Goals

- Least burdensome regulatory model
- Based on tier-triage
- Thrown into IVDMIA and Laboratory Developed Test mix

Two Controversial Guidances

- ASR – questions and answers
- Not intended to infringe on legitimate laboratory developed test practices
- Is intended to prevent ASRs from being sold in kit form without premarket review
- Finalized last fall
- Not new but clarifying

Two Controversial Guidances

- IVDMA's – tests that integrate multiple signals into single risk scores
- First identified in 2004
- Subject of compliance letters
- Subject of guidance
- Under review
- Not new authority but new application
- Presaged in ASR rule preamble

Background

- Three alternative regulatory proposals for IVDMIAs
- 21st Century Medicine Alliance – registry with comment but without regulation
- ACLA -- registry through CMS; cross-consultation with FDA
- AdvaMed Least Burdensome model (independent initiative but good timing)

Background

- Secretary's Advisory Committee on Genomics Health and Society (SACGHS)
- Gaps in clinical validity
- Gaps in clinical utility
- Opportunities for public private partnerships

Caveat

- If credible this will be a day job

OIVD

- Now 5 years old
- Well established infrastructure
- New additions – patient safety committee, recall committee, LabNet initiative

New Products

- Respiratory virus panels
- Rapid test for MRSA
- Top 2A assay
- Plague and Tularemia
- Warfarin markers

New Guidances -- done

- IVD studies
- Waiver guidance
- Interactive review guidance

New Guidances -- pending

- Respiratory viral panel special controls
- Enteroviral special controls

Outreach

- 11th 510(k) submissions workshop
- 2nd audio conference (critical path)
- 1st best practices workshop on molecular diagnostics

Critical Path Initiatives

- Genomics (biomarker) internal working group
- Artificial pancreas working group
- Nanotechnology working group

Leveraging -- NCI

- NCI-FDA-Industry Co-Development White Paper (PACCT program)
- Proteomics group
- Early detection research network
- SPORE
- PACCT
- Interagency oncology task force

Leveraging – Outside Groups

- American Association of Cancer Research (AACR)
- Drug Information Association (DIA) – fourth pharmacogenomic workshop
- IVD-PhARMA-BIO Round Table

Compliance Actions

- 150 recalls/year
- Counterfeit glucose strips only class 1
- Troponin working group
- LabNet signals – active surveillance
- Recall committee
- Patient safety committee

Programmatic Cross Roads

- Core mission same: promote and protect public health
- Core tool same: good science
- Knowledge base: broadened

In the Desert

I saw a creature,
Who, squatting upon the ground,
Held his heart in his hands,
And ate of it.

I said, "Is it good friend?"
"It is bitter-bitter," he answered,
"But I like it
Because it is bitter,
And because it is my heart."