

# Office of In Vitro Diagnostics

- Update
- Survey of hot topics

# OIVD -- History Recapped

- CDRH unveiled strategic plan -- 2001
- Central thesis was regulation through Total Product Life Cycle (TPLC)
- Connection between disparate programs in premarket review, compliance, and postmarket surveillance

# OIVD -- History Recapped

- TPLC global enterprise
- Mid 2003 -- decision to launch IVD pilot
- Allow laboratory for program development
- Allow geographic consolidation of unique product line with common themes

# OIVD

- Launched in November 2003
- Represented combination of three organizations (IVD division in Office of Device Evaluation, IVD branch in the Office of Compliance, and a member of the Office of Systems Management )

# OIVD

- Charged with one stop shopping for IVDs
- Underfed until user fees brought in management and program resources
- Nothing if not an instrument for change

# Premarket Review

- Technical core (50 scientists) directed at premarket review
- Work focused on determining if an old product is substantially equivalent to a predicate or if new products are safe and effective

# Compliance

- Small cadre (5 scientists) directed at compliance work
- Cross coverage in areas of case management, QSRs, and promotion and advertising

# Compliance

- Work focused on
- Supporting the field inspection programs in ensuring company conformance to GMPs
- Addressing issues identified related to violations in test production, promotion, or labeling
- Handling of problem cases

# Postmarket Surveillance

- Transfer deferred
- One FTE (part-time) devoted to post-market surveillance with appropriate non-dedicated support staff for vigilance.
- Work directed at monitoring reports of device failures, identifying problems, and taking corrective actions. production, promotion

# Intellectual Appeal

- Allowed FDA to parallel operations in regulated industry
- Allowed change in focus
- From premarket regulation -- artificial and weak
- To postmarket regulation -- real world, relevant, has strong but untapped regulatory tools

# Evolution of program

- Continued focus on standardizing reviews
- Continued focus on implementing “least burdensome” reviews
- Expanded use of new regulatory tools – particularly de novo classifications

# Evolution of program

- Compliance transfer complete in December 2003; continued but decreased cross-reference and use of resources
- Business as usual including warning letters, import alerts, inspection planning, special compliance actions as appropriate
- First seizure (PerkinElmer)

# Evolution of program

- OIVD assumed responsibility for all MDRs in October 2003; work is done by review staff in a manner which parallels the use of embedded reporters during the Iraq war
- OIVD with OSB launched MedSun

# New Initiatives -- OIVD Web Page

- Comprehensive overview of programs
- News
- Safety tips
- Relevant data bases

# New Initiatives -- Data Template

- Introduced data template for completing review
- Posting these on web page

# Data Template -- current

- Standardize work
- Focus work
- Ensure transparency of work

# Data Template -- future

- Streamline work, plan for electronic submission akin to Turbo Tax or Tax Cut for IVDs
- More complicated than seems
- Compromise -- paper template
- Current pilot launched
- Electronic version mid-spring

# Compliance Corner

- Posting relevant communications
- Clarify FDA position on important actions

# Background of Dazzling Technology

- West Nile
- Anthrax
- SARs
- HPV in screening

# Background of Dazzling Technology

- First timed automated cytology studies
- Real time PCR genetic tests for Factors V and II

# Background of Dazzling Technology

- First closed loop between glucose meter and a pump
- Continued modifications and interest in minimally invasive glucose methodologies

# CLIA

- Work with CDC and CMS to develop guidance
- CLIA is high priority program
- Chemistry division is heavily involved

# Hot Buttons -- Analyte Specific Reagents

- Aggressive over the edge marketing
- Outstanding regulatory issue of adequacy of current oversight of high risk tests

# Analyte Specific Reagents

- Plan for proposed rule making
- Problem in risk based evaluation
- SACGT
- FDA
- Professional Societies

# Analyte Specific Reagents

- New twists
- Identification of prevailing requirements
- Statute -- 510(1)
- Regulations -- 864.0

# Analyte Specific Reagents

- FDA issued Roche AmpliChip letter
- General and specific policy under internal discussion
- Future direction uncertain

# Hot Buttons -- IVAT Proposal

- Reviews based on analytical data only
- Not inconsistent with current practice for established tests
- Is inconsistent with current practice for unestablished tests
- Ongoing consideration; tension with public health mission

# Hot Buttons -- Informed Consent

- FDA statute considers sample equivalent to a subject
- Legally investigations for device submissions require IRB and informed consent
- Inconsistent with Common Rule

# Hot Button Items -- Informed Consent

- Issue under review in OCC
- Interim -- IRB, business risk

# Hot Button Item -- Drugs of Abuse

- FDA in limelight in mid 90's for interest in regulating OTC tests for drugs of abuse
- Issue is what is appropriate jurisdiction and how do you defined medical problem versus condition
- Particularly interesting with regard to workplace testing

# Hot Button Item -- Drugs of Abuse

- Guidances in 2000 expressed interest in jurisdiction and premarket review
- Incited a letter writing campaign by NOTA
- Re-issue of guidance last year
- Flexible guidance but does require premarket review

# Hot Button Item -- Pharmacogenomics

- With or without ASR rule, these devices are in line for commercialization
- Chips raise unique analytical issues in terms of standardization
- Information generated raise unique clinical issues in terms of interpretation

# Hot Button Item -- Pharmacogenomics

- OIVD issued multiplex guidance in February 2003 to deal with new technologies and uses
- CDER issued Pharmacogenomic Data guidance in November 2003 to deal with regulatory requirements and voluntary options for submitting this data to FDA in the context of drug trials

# OIVD

- Work in progress
- Creative entity
- Looking for opportunities to leverage
- Looking for synchrony with  
Commissioner's Strategic Plan – risk based  
smart regulation emphasizing consumerism

Good Science