Medical Device Amendments of 1976

- Registration and Listing
- Premarket Control
- Production following GMPs
- Obligation for postmarket reporting

Work Functions

- Office of Device Evaluation
- Office of Compliance
- Office of Surveillance and Biometrics

CDRH Strategic Plan

- Total Product Life Cycle
- Knowledge Management

Office of In Vitro Diagnostics

- Consolidated functions
- All regulatory activity from common technical base
- Laboratory for innovative programming
- Charge to actualize TPLC
- Not unique but geographically advantaged

Intellectual Appeal

- Weak grounding for premarket review
- Underlying artifice to premarket review

Intellectual Appeal

- Quality system regulations are robust
- Quality system regulations are under-tapped
- Postmarket tools measure where it counts

History of OIVD

- November 2002 -- premarket and compliance
- September 2003 -- transfer of postmarket surveillance
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Recalls (Corrections and Removals)

- 21 CFR 806.10
- Written reports
- Device problems cause risk to health

Recalls -- Corrections and Removals

- Formal review process
- Health hazard evaluation
- Formal classification system

Rich Source of Information

- 130 first year
- Three for waived devices (PT meter, pregnancy test, and glucose test)
- Corrective actions taken

OIVD

- Recalls are a learning tool
- Recalls may be a sign of good corrective action systems
- Worry more about firms without recalls then with well addressed recalls

Medical Device Reporting

- 803.50
- Required reporting
- MedWatch system
- May have caused death or serious injury
- Likely to cause death or serious injury

Medical Device Reporting

- Manufacturers responsibility
- User fee responsibility
- Voluntary as well as mandatory reporting

Past -- part time analyst with part time expertise

- Analysis is now embedded in Office
- Analogous to reporters in Iraq
- First quarter -- 2616 reports
- Highest volume glucose meters
- No signals of import to waived tests

MedWatch

- Imperfect system
- Different reporting systems and thresholds
- Lack of denominator data
- Difficulty analyzing signals

MedSun Pilot

- OSB -- 3 years ago
- Recruitment of active participants
- Directed reporting
- Feedback
- 160 sites

LabSun Pilot

- Laboratorians rich source of information
- Laboratorians not reluctant to share information
- Nine lab pilot
- First quarter -- 20 signals

LabSun

- Larger labs
- If pilot is expanded it could focus to include waived cadre
- If pilot is expanded it could focus to include high complexity labs using waived tests in the lab network

Miscellaneous Signals

- Field inspections and observations -- multiple
- Direct consumer inquiries or complaints -- 14
- Trade complaints -- 2 (low number)
- Government agencies -- 2
- Foreign governments -- none

Miscellaneous Signals

- Literature
- Professional meetings
- Round tables
- Internet -- list serves

Miscellaneous Signals

- 2 waived test issues identified
- Both under review

Postmarket Regulatory Tools

- Strong legal basis
- Underutilized
- OIVD has a commitment to correct this oversight
- Outcomes unclear -- likely to be more holistic and polished approach