Current Issues for Medical Devices

David W. Feigal, Jr., M.D., M.P.H.

Director

Center for Devices and Radiological Health

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Overview

- FDAMA
- Regulations
- Reengineering
- Alternatives in 510(k)s, MDRs
- Resources
- Harmonization
- Hot Topics

Themes of FDA Modernization Act

- Interactive process for product review
- Decisive action
- Patient access
- Codifies reengineering
- Agency discretion, not mandatory requirements
- FDA review accountability/timeliness

FDAMA Accomplishments

- Completed
  - 24 guidance documents and
  - 6 final rules
- Recognized
  - >400 consensus standards
- Exempted
  - more than 60 Class II devices
- Approved
  - 13 third parties for 510(k) reviews
- Designated
  - >150 device types for 3rd party review

FDAMA Accomplishments

- Piloted
  - Sentinel postmarket reporting
- Instituted
  - interactive "determination" and "agreement" meetings with sponsors
- Rescinded
  - 55 tracking orders
- Chartering
  - advisory panel for scientific disputes
- Expanded
  - stakeholder participation through open meetings nationwide

Regulations Published in '99

62 regulations published in CY '99 so far

- 7 final rules
- 3 Direct to Final Rules
- 11 Proposed Rules
- 38 Notices
- 3 Advanced Notice of Public Rule Making (ANPR)

Reengineering

Examples of Reengineered Process

- New 510(k) paradigm
- Regulations development
- Recalls
- GMP inspections
- Products development protocol (PDP)
- Modular PMA review
- Standards

Reengineering

New Projects

- Postmarket process
- Registration and listing
- QSIT and HACCP
- Class I recalls
- Radiological health
- Bioresearch monitoring

Reengineering Implementation In 1999

Phase I

GMP-HACCP-OC

BIMO-OC

Rad Health-OC

Postmarket-OSB

Phase II

Registration and Listing - OC

Hazard Benefit

Information Dissemination

Phase III

510(k) - ODE

IDE/PMA - ODE

PDP Process - ODE

515(b) - ODE

Standards - OST

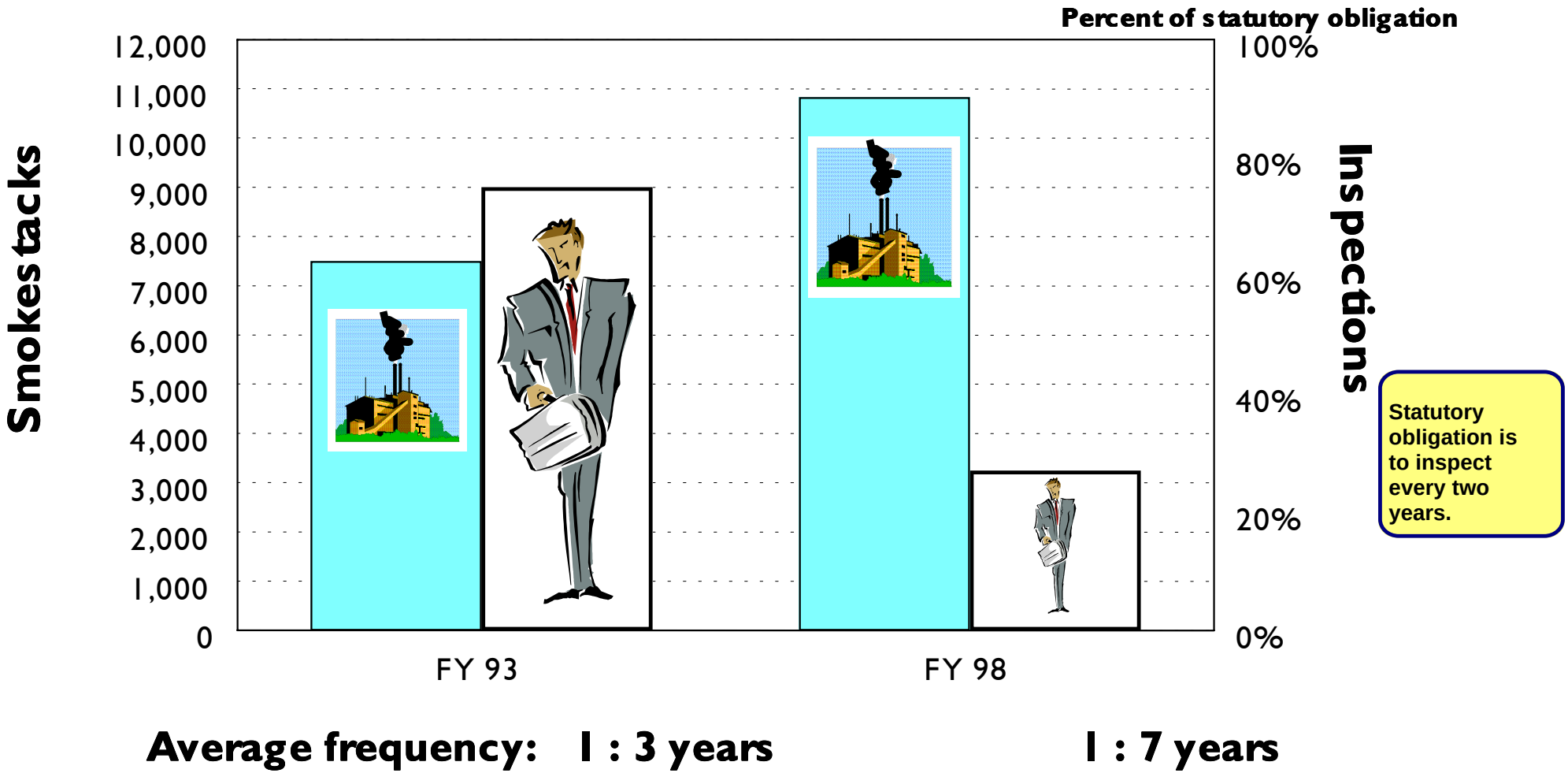
Regulations - OHIP

Recall - OC

GMP - QSIT - OC

MDR - OSB

Device GMP Inspections
FY 93 - FY 98



Average frequency: 1 : 3 years **1 : 7 years**

Inspections: How to get more from decreasing $$$?

Changes are allowing Field to prioritize and optimize use of its time and resources in device inspections:

- "Grassroots" changes
- Reengineering changes
  - QSIT: Quality System Inspection Technique
  - HAACP: Hazard Analysis and Critical Control Points

Inspections: "Grassroots" Changes

- Pre-announced inspections
- Annotation of 483's
  - Company corrections
- Post-inspection letters to all
  vs. only Warning Letters
- Warning Letters
  - 15 days to respond to 483's
  - Untitled letter if response satisfactory

QSIT:
Quality System Inspection Technique

- Paradigm shift: looking at systems rather than at product problems
- Inspection focuses on four subsystems
  - Management controls
  - Design controls
  - Corrective and preventive action (CAPA)
  - Production and process controls

HACCP: Hazard Analysis and Critical Control Points

- Goal: to prevent production problems
- Inspectional approach: mfrs. determine their critical control points, control them
- Investigators and auditors focus on critical control points

510(k)s - Alternatives

	Applications Received (4-98 to 9-99)	Review Complete	Average Review Time
Abbreviated	105	82	91
Special	458	411	28
Traditional	6147	6453	**110**

510(k)s - Third party review

- 154 device types eligible
  - mostly class II
- same device types = 1200 510(k)s / yr
- only 32 510(k)s submitted to 3rd parties so far this fiscal year
- Average total review time for comparable 510(k)s -- same product code & fiscal year:

  3rd party - 57 days

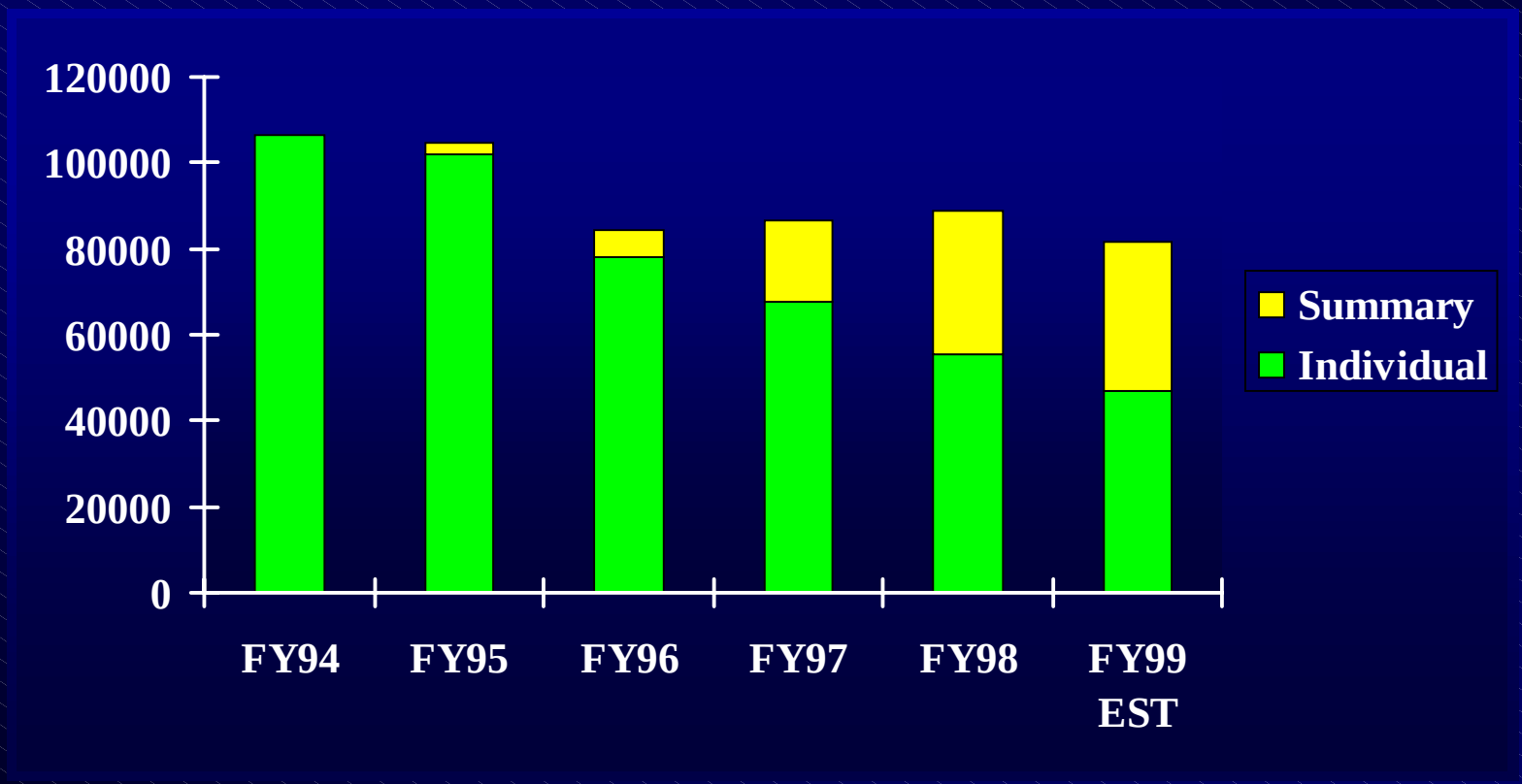
  All FDA review - 105 days

Summary Reporting of MDRs

Goal: Reduce "noise" in the MDR system, improve the signal to noise ratio

- Allow periodic submission of well-known, repetitive reports in line item format
- Expect 38,000 summary reports in FY '99
- 45 manufacturers participating
- 52 exemptions
- New system in place for January 2000

Manufacturer Reports
(Includes Summary Reporting)



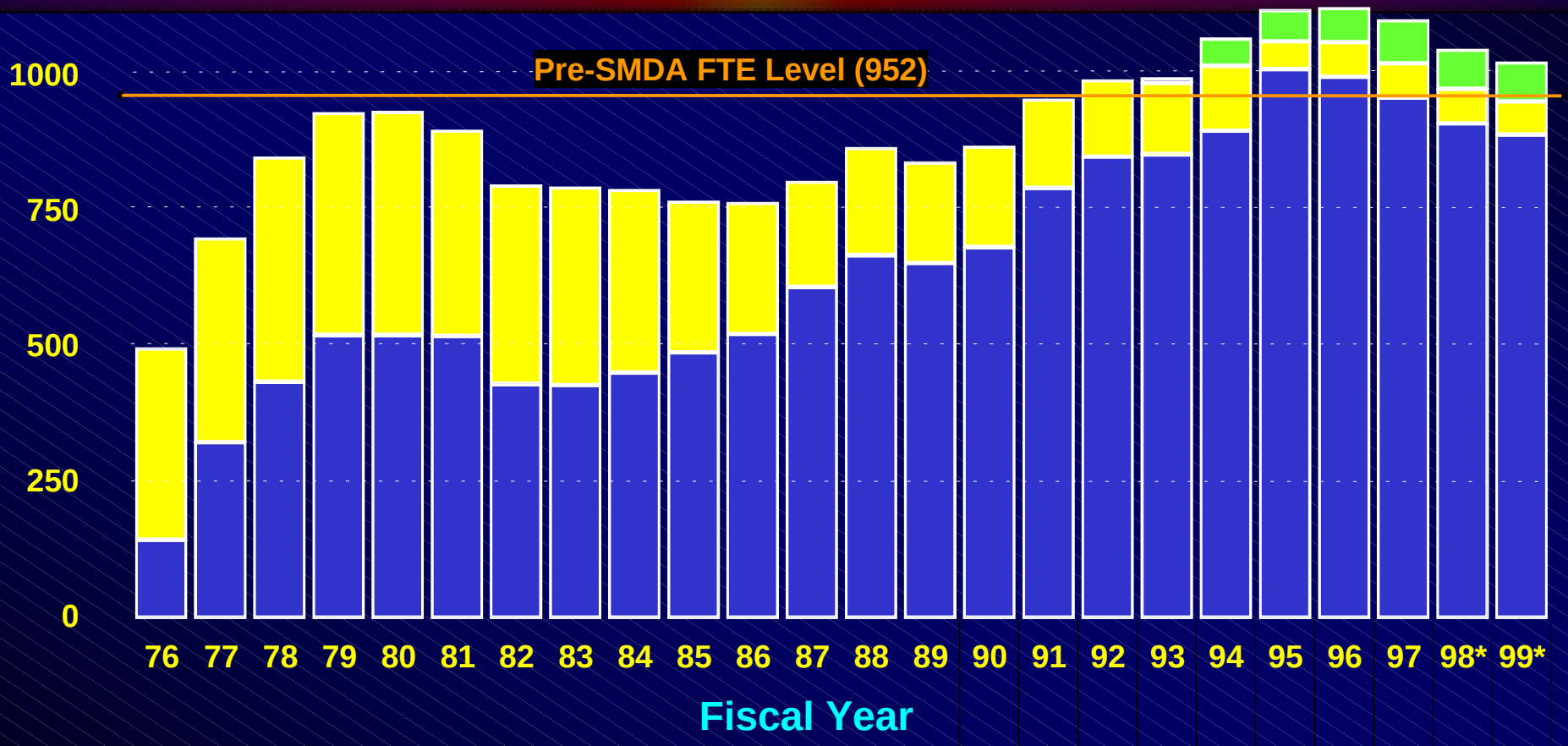
Resources

What's Driving CDRH to Reengineer its Program Processes and Financial Management Practices?

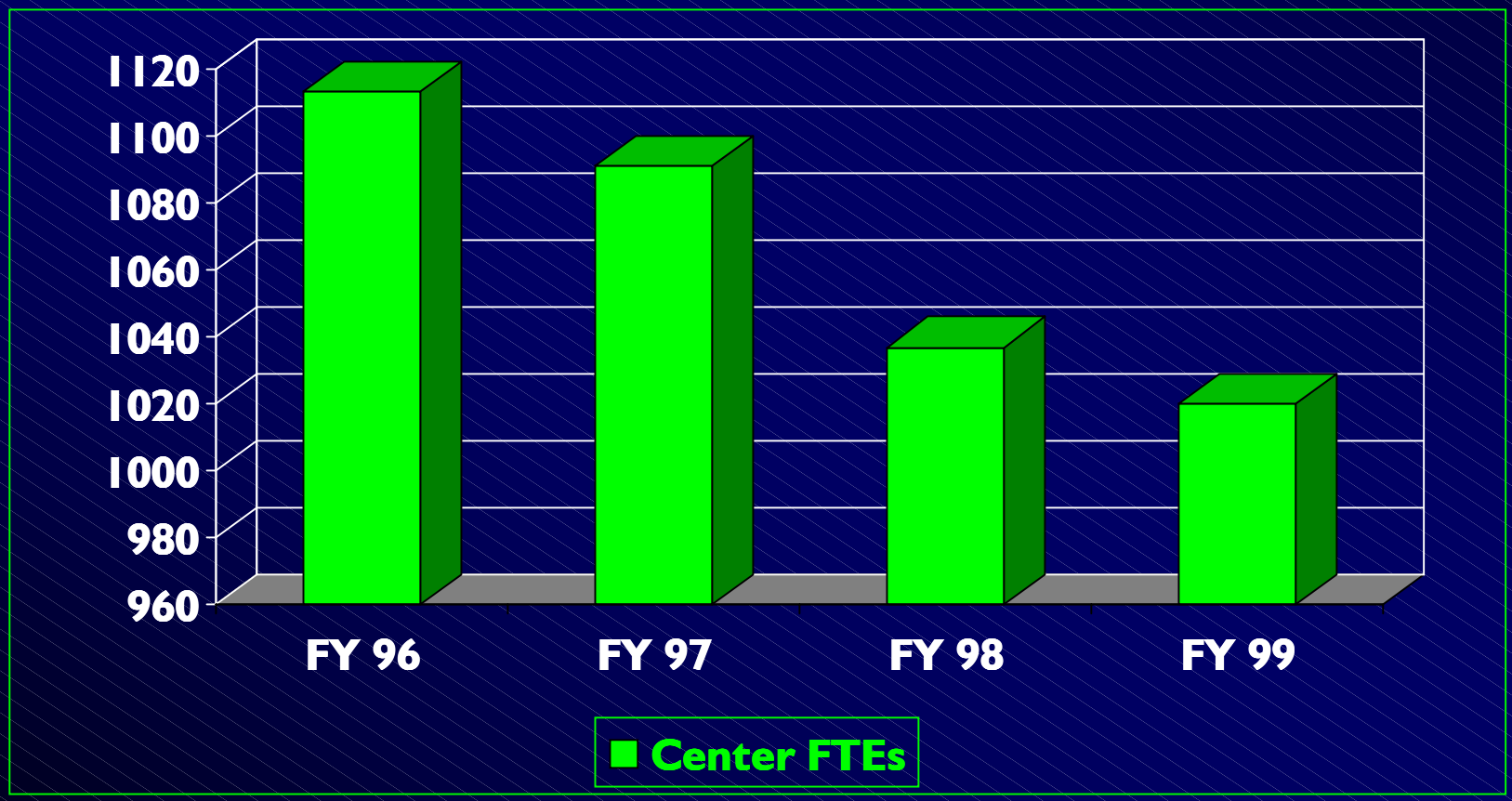
- Resource erosion from 4 years of flat dollar budgets
- Performance improvements in device review bought at the expense of other programs
- Resource demands of FDAMA implementation
- Rising payroll costs make operating budget below acceptable minimum

CDRH FTE History

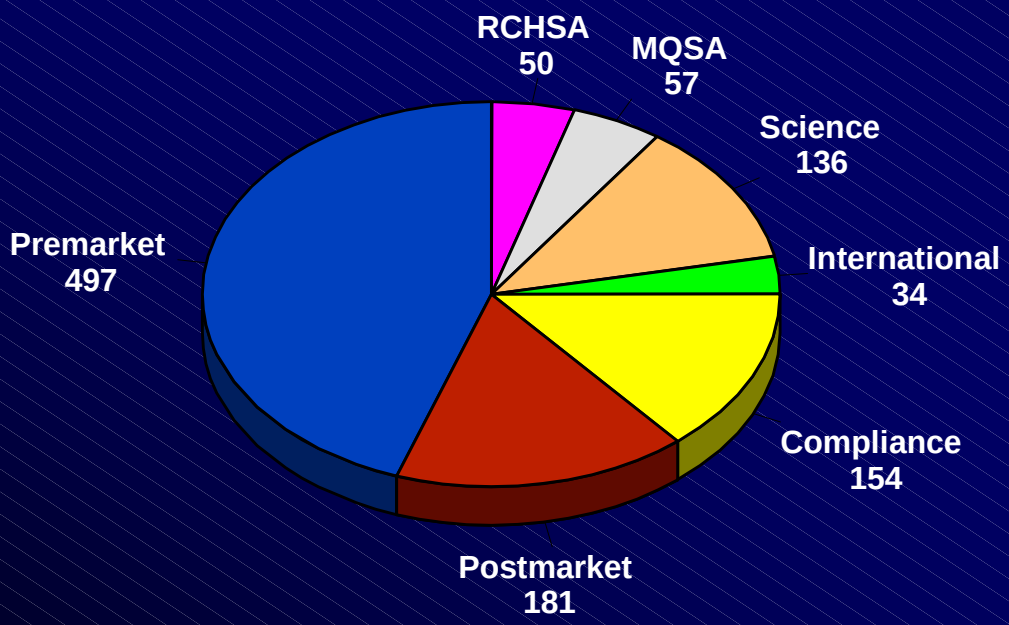
Fiscal Years 1976 - 1999*



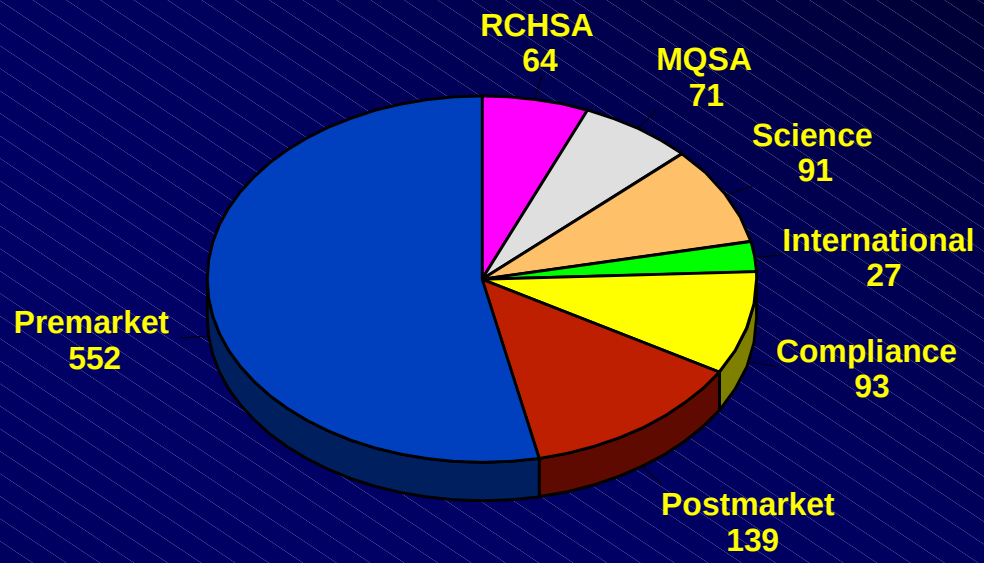
Flat Budget = Declining Staff



CDRH FTE Distribution



FY95
N=1,109



FY98
N=1,037

Appropriations for FY 2000

- Bill signed Oct. 22, 1999
- Allocates $114 M to CDRH & $40 M to field for CDRH activities, mandating:
  - Use of $1 million for reprocessed devices -- premarket review, enforcement, oversight
  - Allocation of no less than $55.5 million and 522 FTEs by whole agency for premarket review to meet statutory timeframes
  - Reauthorization of mammography user fees

Impact of FY 2000 Appropriations

- Center and Field must absorb 4.8% pay raise and other inflationary costs
- $7M increase for device review results in reductions in other areas due to absorbing inflationary costs
- $1M mandate on reuse of devices must come from base resources; not funded

Harmonization

Global Harmonization

Four study groups:

- Regulatory Requirements / Premarket Review
- Device Vigilance / Post-Market Surveillance
- Quality System Requirements and Guidance
- Auditing

Global Harmonization

8th meeting in September 2000

Hosted by Canada

Http://www.ghtf.org/default.htm

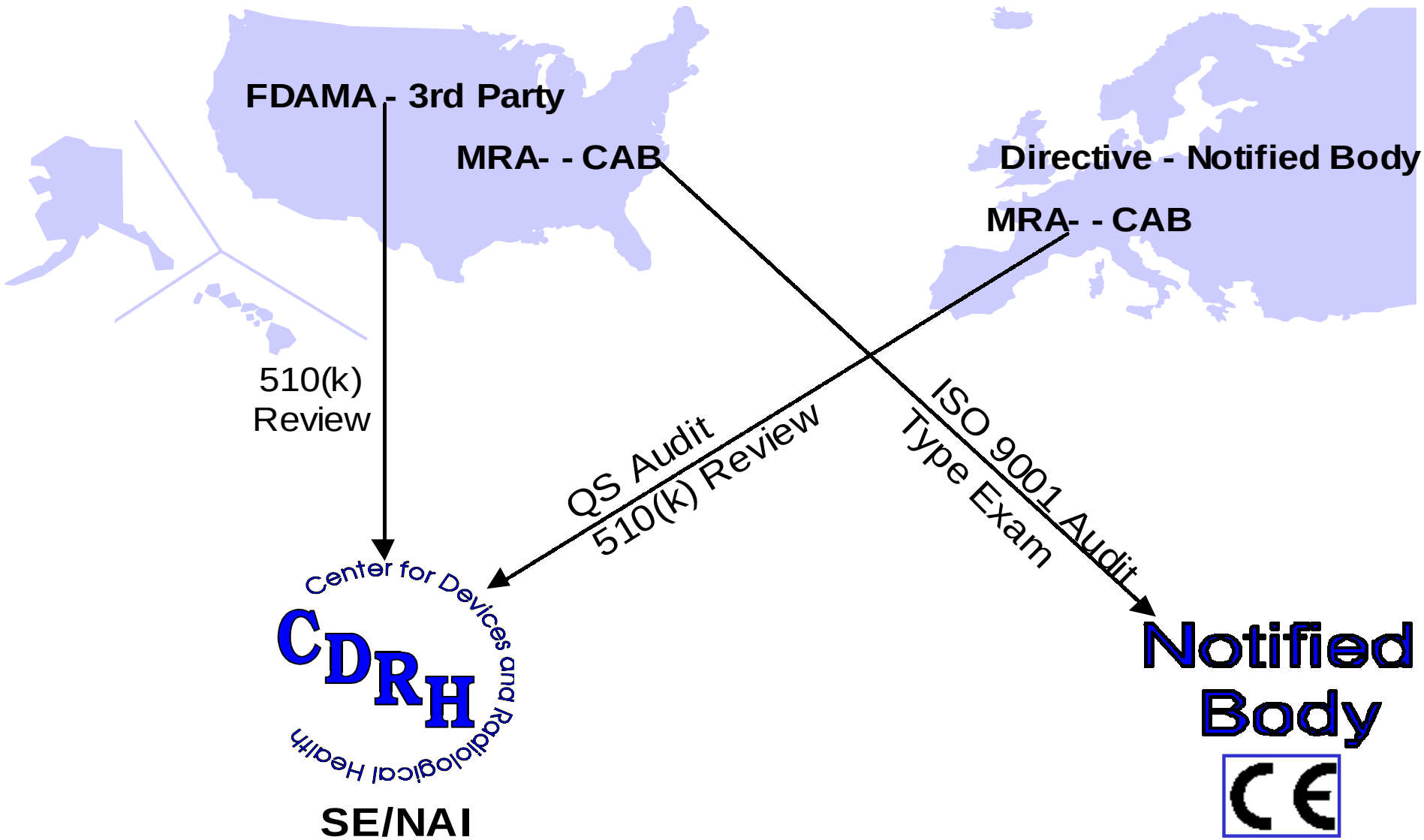
U.S./EU MRA

What it is:

- Surrogate Inspector and Reviewer
- EU must learn U.S. system and implement it like U.S.
- U.S. must learn EU system and implement it like EU

What it is not:

- Not acceptance of CE mark
- Not harmonization
- Not equivalence of U.S. and EU systems


FDAMA - 3rd Party
MRA- - CAB
Directive - Notified Body
MRA- - CAB
510(k)
Review
QS Audit
510(k) Review
ISO 9001 Audit
Type Exam
Center for Devices and Radiological Health
CDRH
SE/NAI
Notified
Body
CE

Hot Topics

Reuse

FDA's policy is changing because:

- Types of single-use devices being reprocessed
- FDA laboratory findings
- Widespread practice but little data on safety or effectiveness
- Single-use labels not clearly meaningful
- Single-use labels don't identify vulnerabilities
- Patients are not informed -- experimentation?

Tissue-based Products

Concern about transmissible spongiform encephalopathies (TSE)

- Dura mater and Creutzfeltd-Jakob Disease
  - 1987 cases of transmission of CJD to donor
  - FDA requirements for processing human dura mater
- FDA meetings to address issues, increase knowledge
- International Workshop on Clearance of TSE Agents from Blood Products and Implanted Tissues

Fetal Ultrasound Monitors

"Keepsake" videos of the fetus.

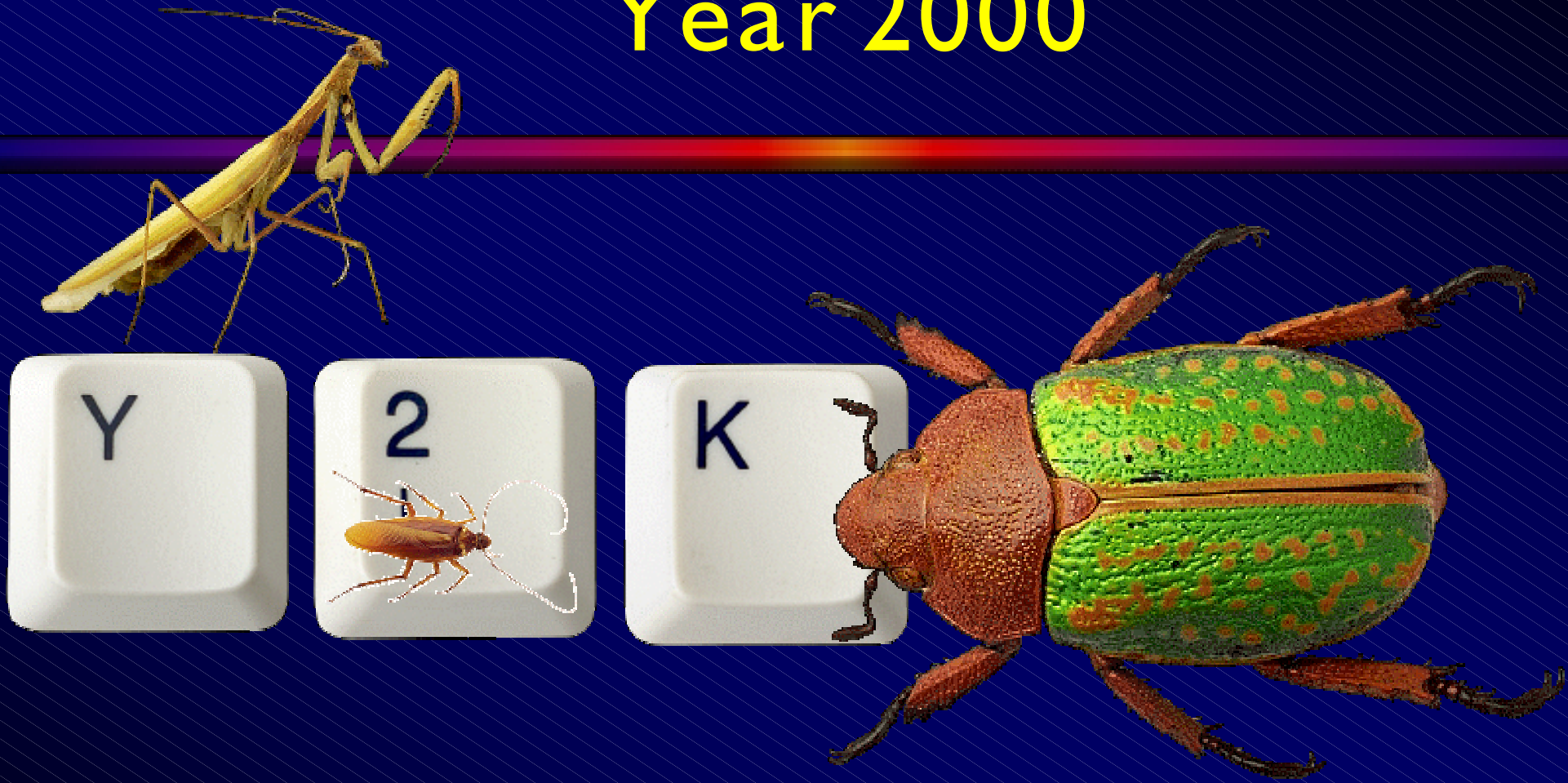
- Ultrasound is a Class II prescription medical device.
- A letter to manufacturers in 1994 explained that fetal ultrasound for souvenir purposes is not approved and is an unnecessary exposure to radiation.
- FDA is aware of about 10 locations per year where keepsake ultrasound videotaping occurs.
- One seizure occurred in 1997.
- This is a cottage industry involving registered sonographers and becomes a practice of medicine issue.

People Scanners

People scanners are not medical devices but are handled strictly as radiological products.

- These products screen people for contraband and weapons and are used primarily in prisons and some international airports.
- The issue of exposure to ionizing radiation for nonmedical purposes is monitored by CDRH.
- At the annual meeting of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) recently, recommendations made there in 1998 were further discussed.

Year 2000



http://www.fda.gov/cdrh/yr2000/year2000.html

CDRH: The Future

- Transparent
- Adequately Resourced
- Re-engineered
- FDAMA-ed
- Science Based
- Partners
- Credibility

Center for Devices and Radiological Health

CDRH