Stakeholders Meeting

April 28, 1999

Today's Presentation

- Response to Stakeholder Input
- Regulatory Challenges
- Limited Resources
- Current Initiatives
- Need Public Advice on Meeting FD&C Act Requirements

Stakeholder Concerns

- Have better and more communication between stakeholders and CDRH
- Make greater use of third parties
- Recognize and use concensus standards
- Stress science-based regulation
- Increase consumer involvement in Agency decision-making

The Law Says
CDRH's Job is To:

- Meet All Statutory Performance Objectives
- Get Safe and Effective Medical Devices to Users in a Timely Fashion: 510(k), IDE, PDP, PMA, & HDE
- Ensure Radiation-Emitting Electronic Products are Safe
- Conduct Science-Based Reviews of New Emerging Technologies
- Inspect Mammography Facilities
- Conduct Biennial Inspections of Device Manufacturers (II/III)
- Review Adverse Event Reports to Identify Safety Problems

The Medical Device Industry

Growth in Size and Complexity

- 10,828 Manufacturing Establishments
- 93% of Firms Have Fewer Than 100 Employees
- Value of Shipments About $ 72.5 Billion
- Increasing Diversity and Complexity

Increasing Workload

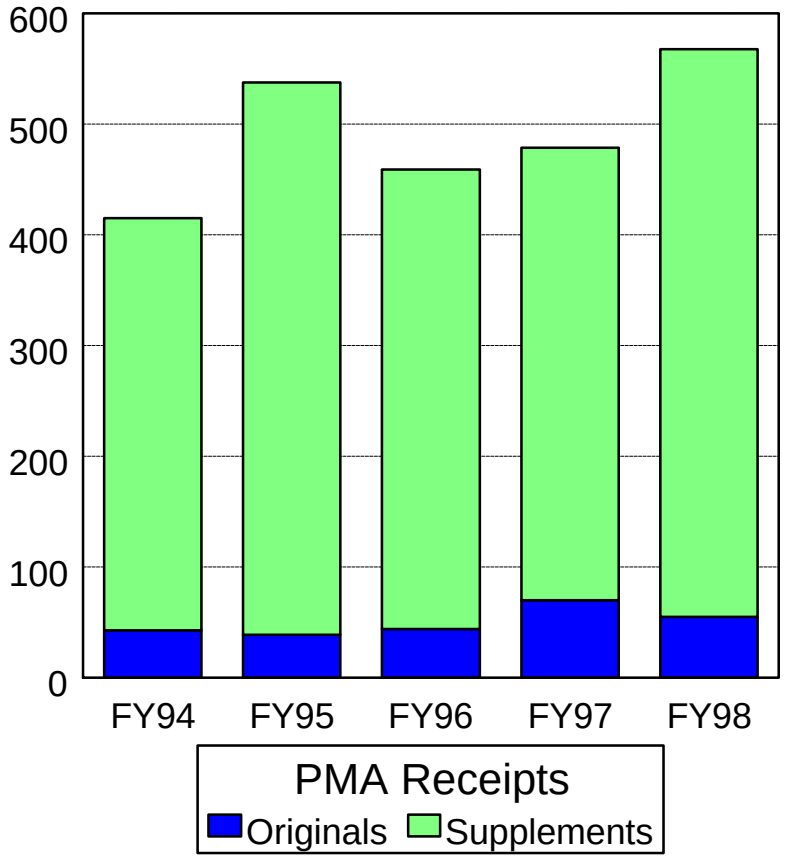
- Ongoing Activities
  - 17,861 PMA/IDE/510(k) Submissions
  - 70,000 - 80,000 Medical Device Reports
  - 10,800 Establishments Subject to GMP Inspection
  - 10,000 Mammography Facilities Subject to Annual Inspection

- Emerging Areas
  - Implementing FDAMA
  - Mutual Recognition Agreements
  - Y2K Preparedness
  - Building a Stronger Science Base

PMA/HDE Workload Demonstrates Industry Innovation

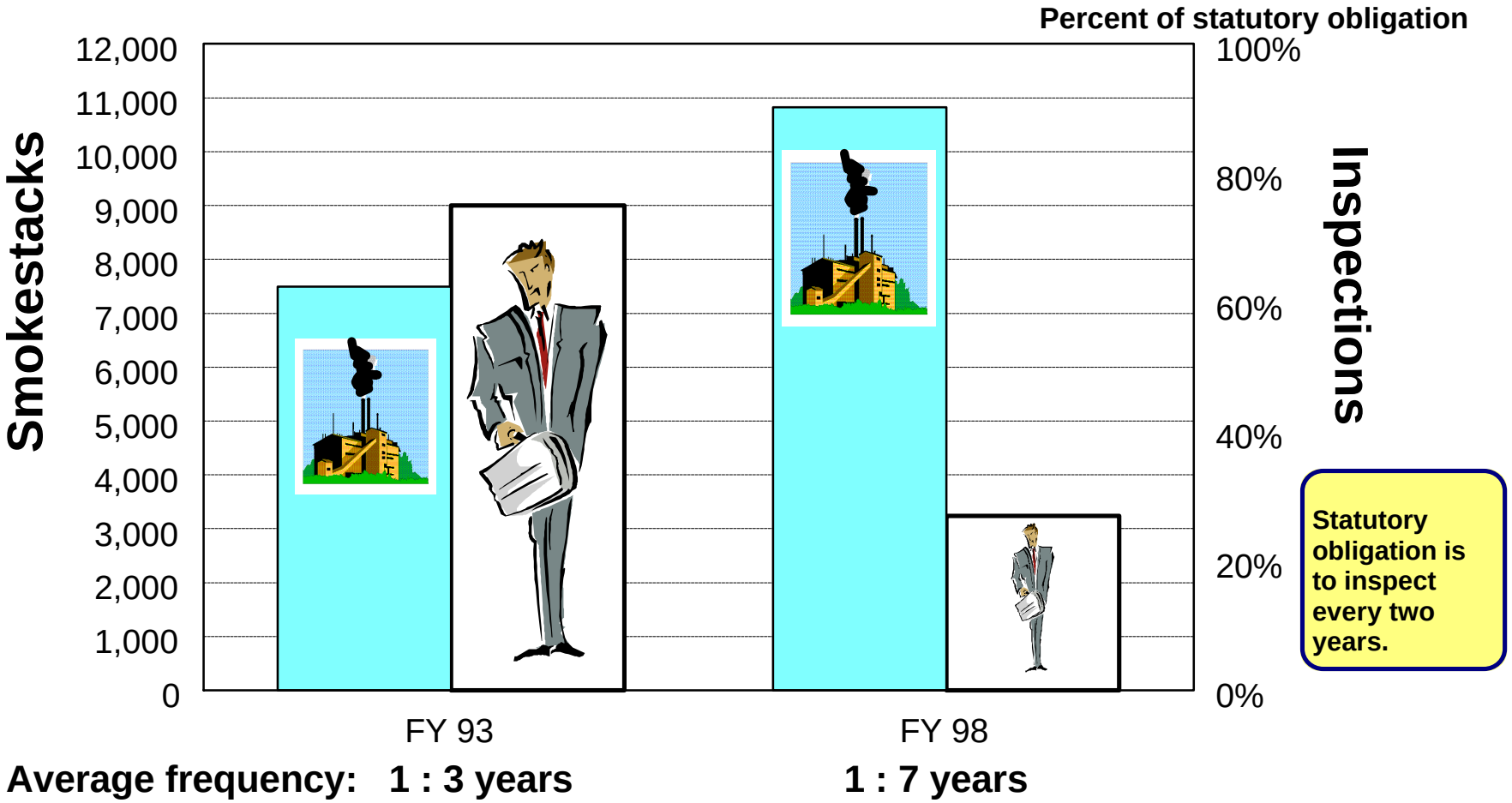
Examples of Medical Device Breakthroughs FY98

1. Device to detect free PSA, an antigen associated with prostate cancer
2. Bladder stimulator for children with neurogenic bladder disorders as a result of spina bifida
3. Synthetic coronary bypass graft for people who do not have enough vessels suitable for use as grafts
4. Finger joint replacement for people whose previous implant has failed
5. Ultrasound devices to evaluate bone density and assist physicians in predicting fracture risk
6. Device to treat patients with disabling angina who cannot have angioplasty or bypass or stents



Device GMP Inspections

FY 93 vs FY 98



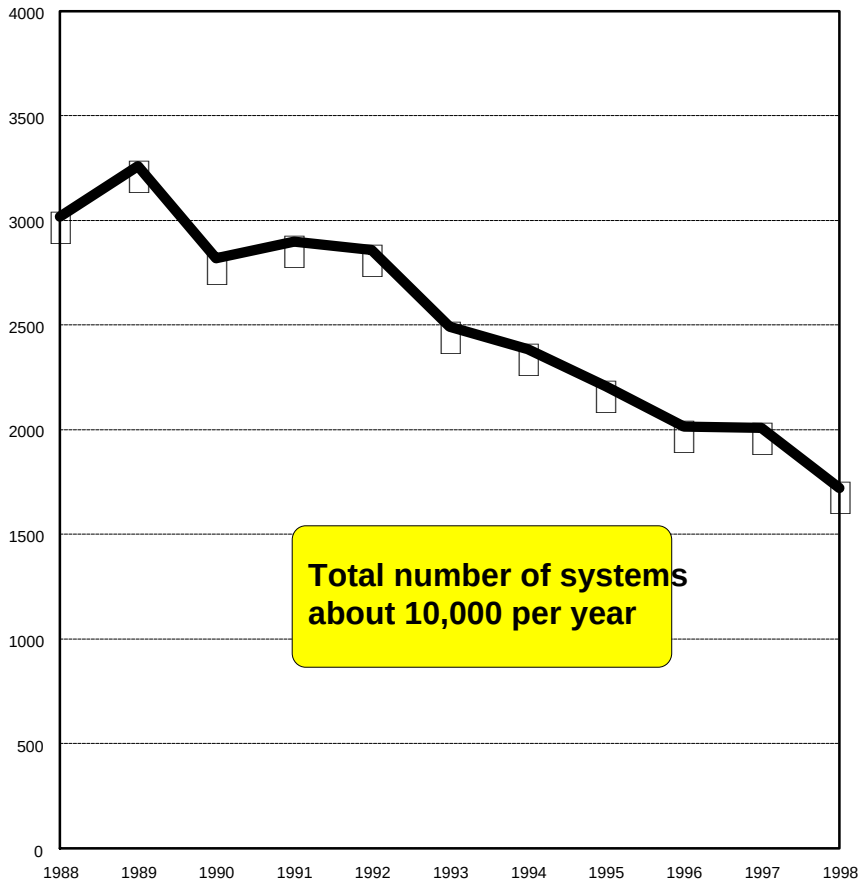
Average frequency: 1 : 3 years **1 : 7 years**

Radiological Health Workload and Current Issues

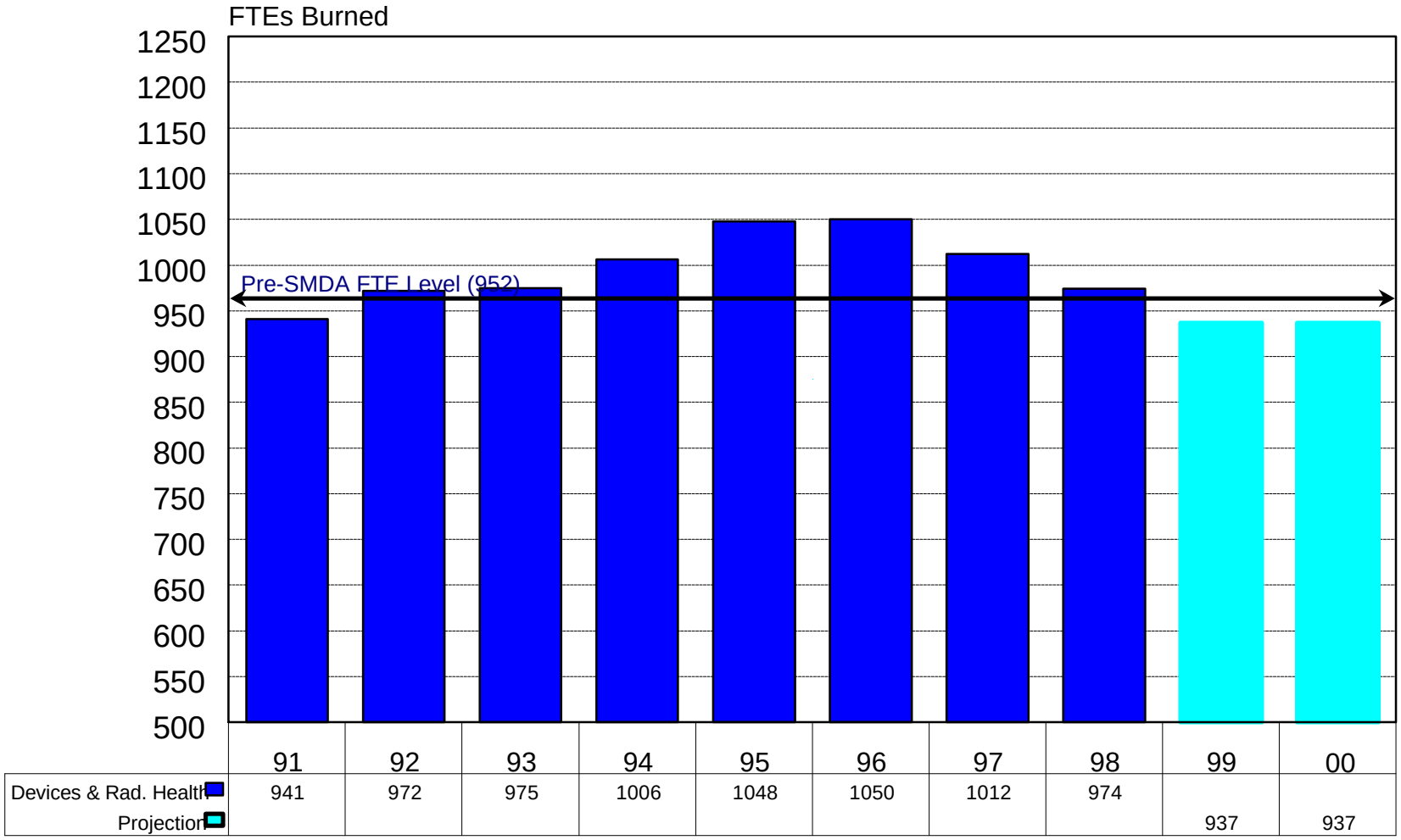
Examples of Radiological Health Issues in FY 98

1. **EAS device Interactions**
2. **Digital Broadcast Device Interactions**
3. **Fluroscopy Burns**

Number of X-Ray Systems Tested by Year Excludes MQSA



Center for Devices and Radiological Health FTE History

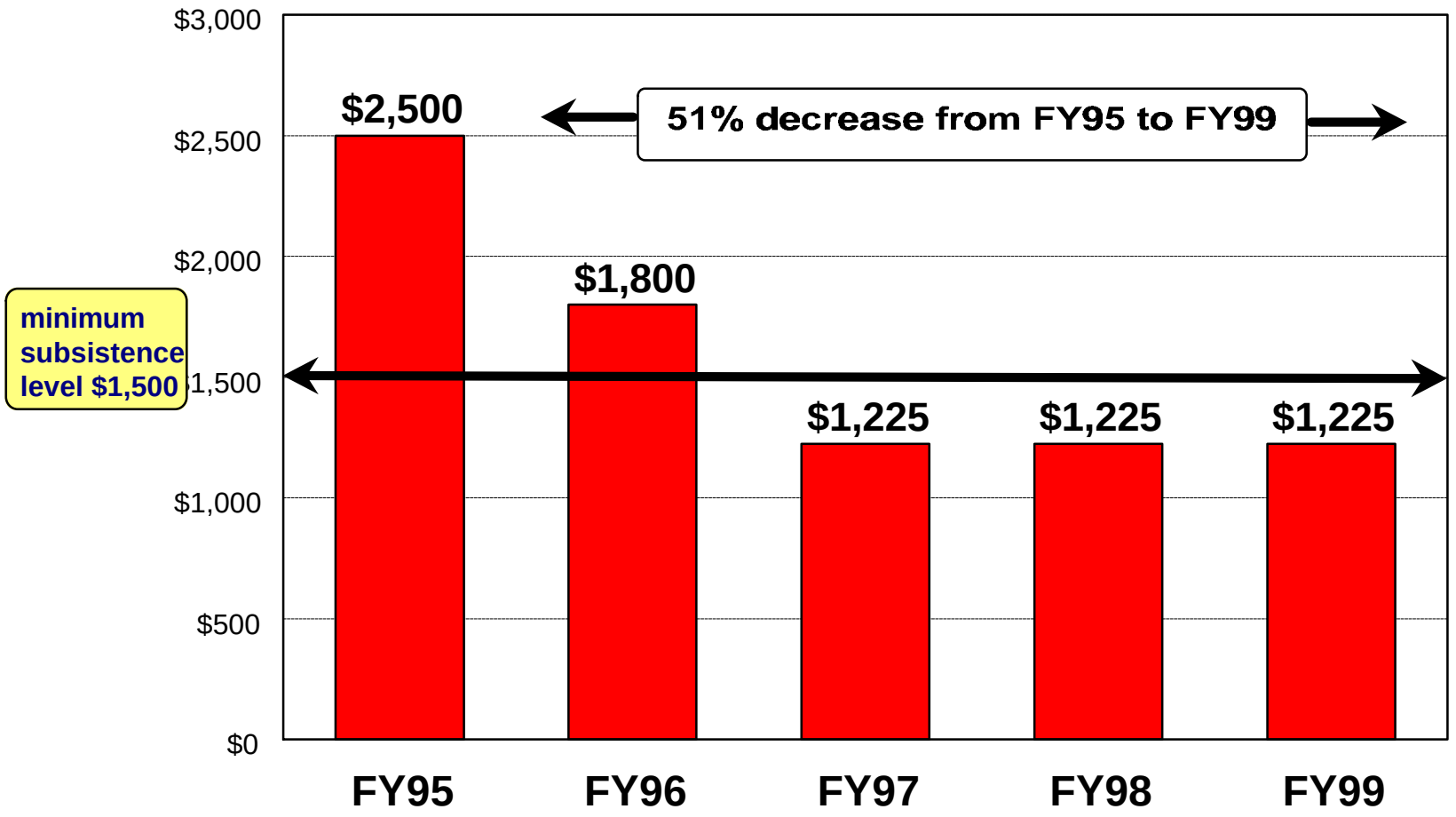


	91	92	93	94	95	96	97	98	99	00
Devices & Rad. Health	941	972	975	1006	1048	1050	1012	974		
Projection									937	937

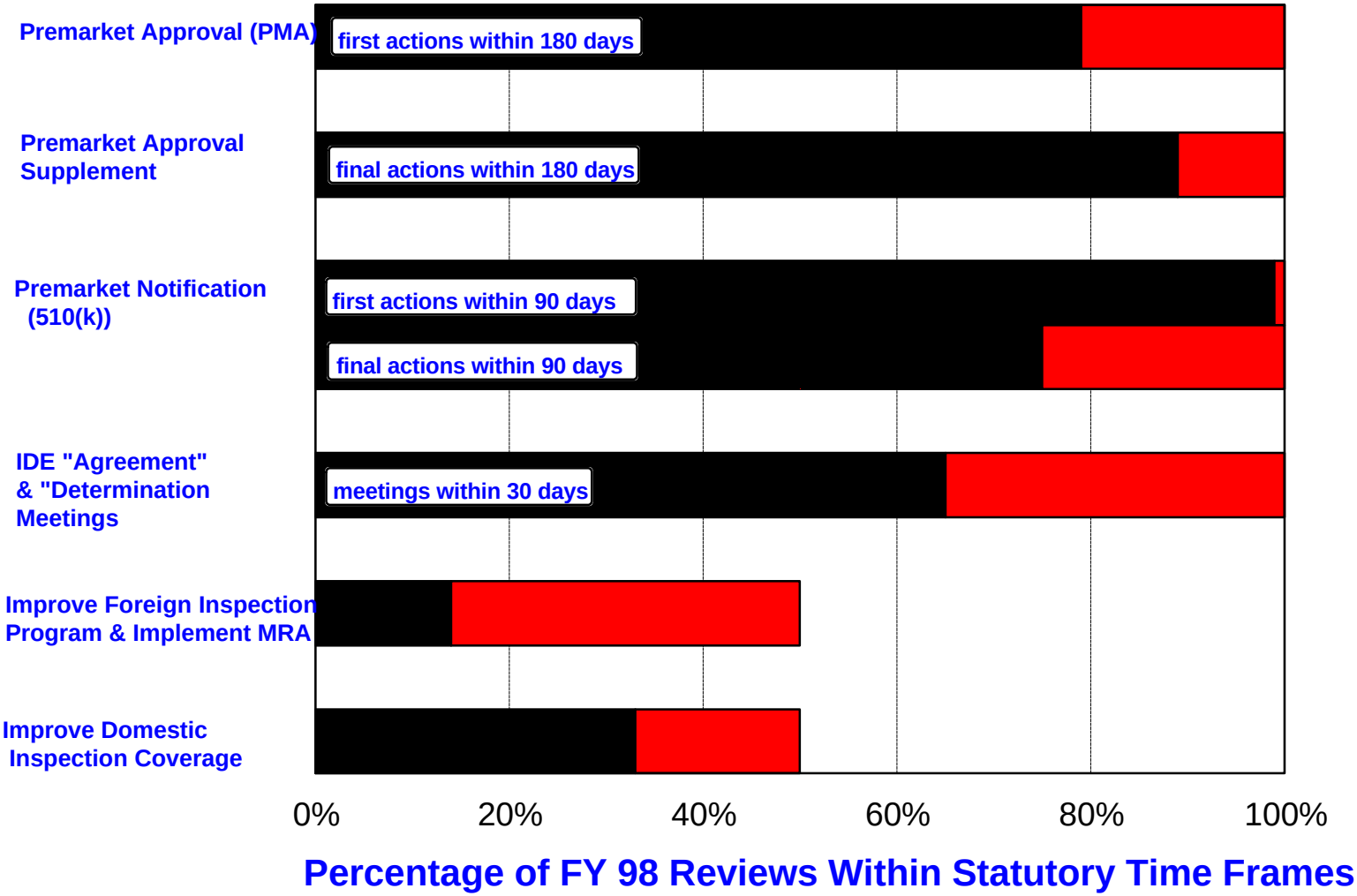
Fiscal Year

Note: MQSA resources are excluded

CDRH Has Reduced Its Operating Support for Office FTEs by 51% FY95-FY99



Statutory Requirements vs Current Status



Reengineering

- Examples of Reengineered Processes

  New 510(k) paradigm
  Regulations development
  Recalls
  GMP Inspections
  Product 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

Building A Stronger Science Base

Sound Science Ultimately Costs Less

- Improve soundness and timeliness of decisions
- Revitalize scientific expertise of Center's workforce
- Upgrade laboratory facilities and equipment
- More scientific partnerships
- Prepare for emerging technologies
  - Miniaturization
  - Tissue Engineering
  - Molecular Medicine
  - Reduced Invasiveness

Implementing FDAMA

- Completed 22 guidance documents and 6 final rules
- Available list of about 400 recognized consensus standards
- Expanded number of devices eligible for third party review
- Accredited 13 third parties for 510(k) review
- Earlier interactions with stakeholders during application review process
- Information available on CDRH website
  http://www.fda.gov/cdrh
- and Y2K page
  http://www.fda.gov/cdrh/yr2000/year2000.html
- Expanded stakeholder participation
- Piloted Sentinel postmarket reporting

We Need Your Comments

1. Are there any changes we've made through reengineering or in implementing FDAMA that you particularly support? Are there some changes you are concerned about? Are there other changes we should be making?

We Need Your Comments

2. How can industry and FDA work together to communicate the status of Y2K readiness of the industry to their stakeholders?

We Need Your Comments

3. What kinds of things should FDA do to encourage international harmonization in device regulation? What strategies can industry and government use to address the growing costs of international harmonization?