CDRH: Moving Forward

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Phoenix, AZ, March 23, 2000

CDRH -- Moving forward

- Past
  - Budget
  - Performance
- Present
  - Least burdensome path to market
  - Dispute resolution and ombudsman
  - "Inreach" to CDRH
  - CDRH and HIMA
- Future

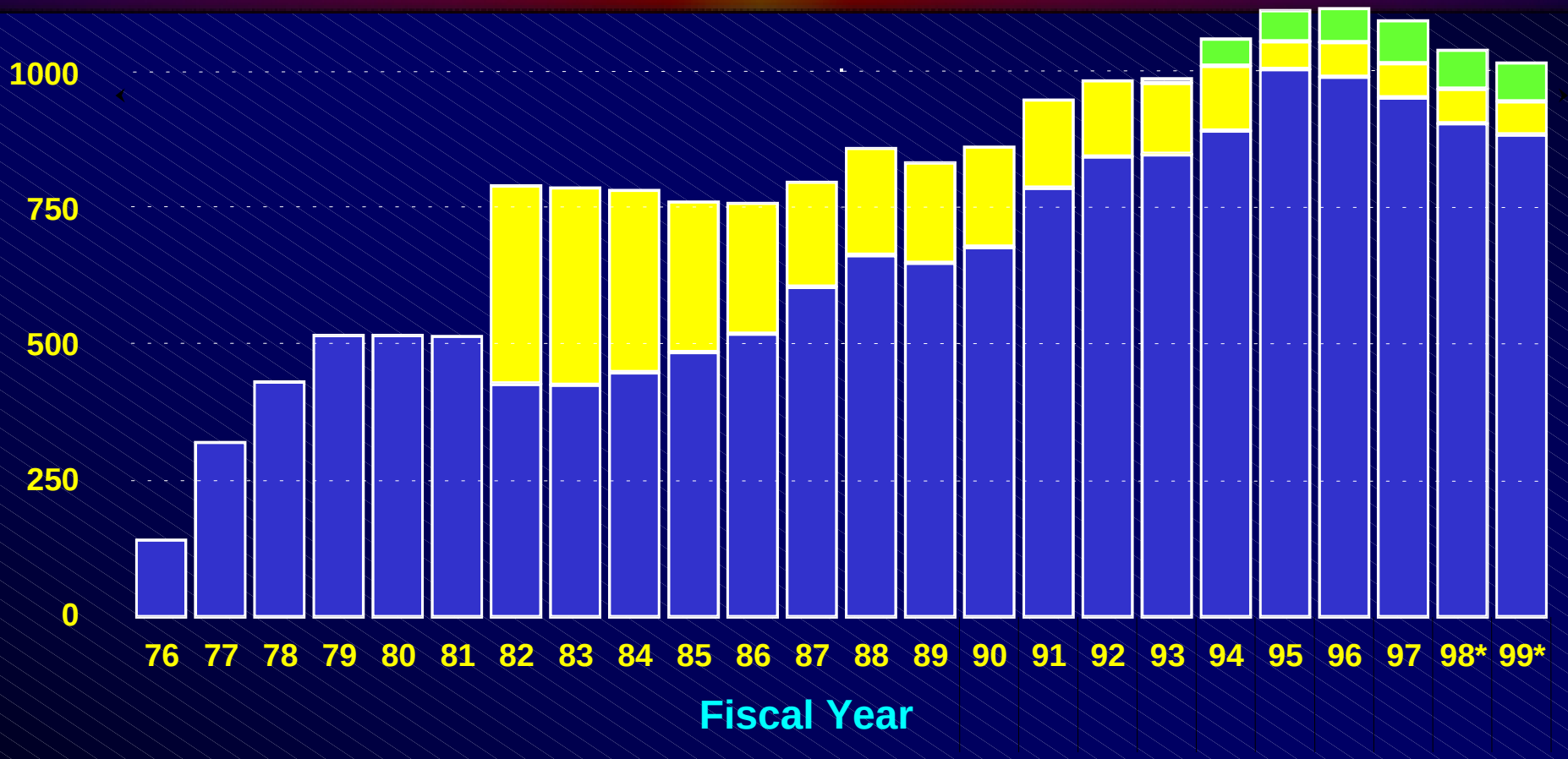
Appropriations for FY 2000

Allocates $114 to CDRH & 40 M to field for CDRH activities, mandating:

- $7.0 million increase for device review
- $3.7 million pay raise
- 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 device review to meet statutory timeframes

Device FTE History

Fiscal Years 1976 - 1999*



Performance: 510(k)s - Alternatives

	Reviews Completed FY99	Average Total Time (days)
Abbreviated	75	99
Special	361	29
Traditional	4,155	108

Disappointing review times? Abbreviated 510(k)s

- New guidance will help. See: http://www.fda.gov/cdrh/ode/guidance/1131.html
  Manufacturers may submit:
  - A declaration of conformity to a recognized standard
  - A statement that product will conform to a recognized standard when finally marketed
  - A statement that the product will conform to a non-recognized standard -- decided case-by-case
- Standards development is key

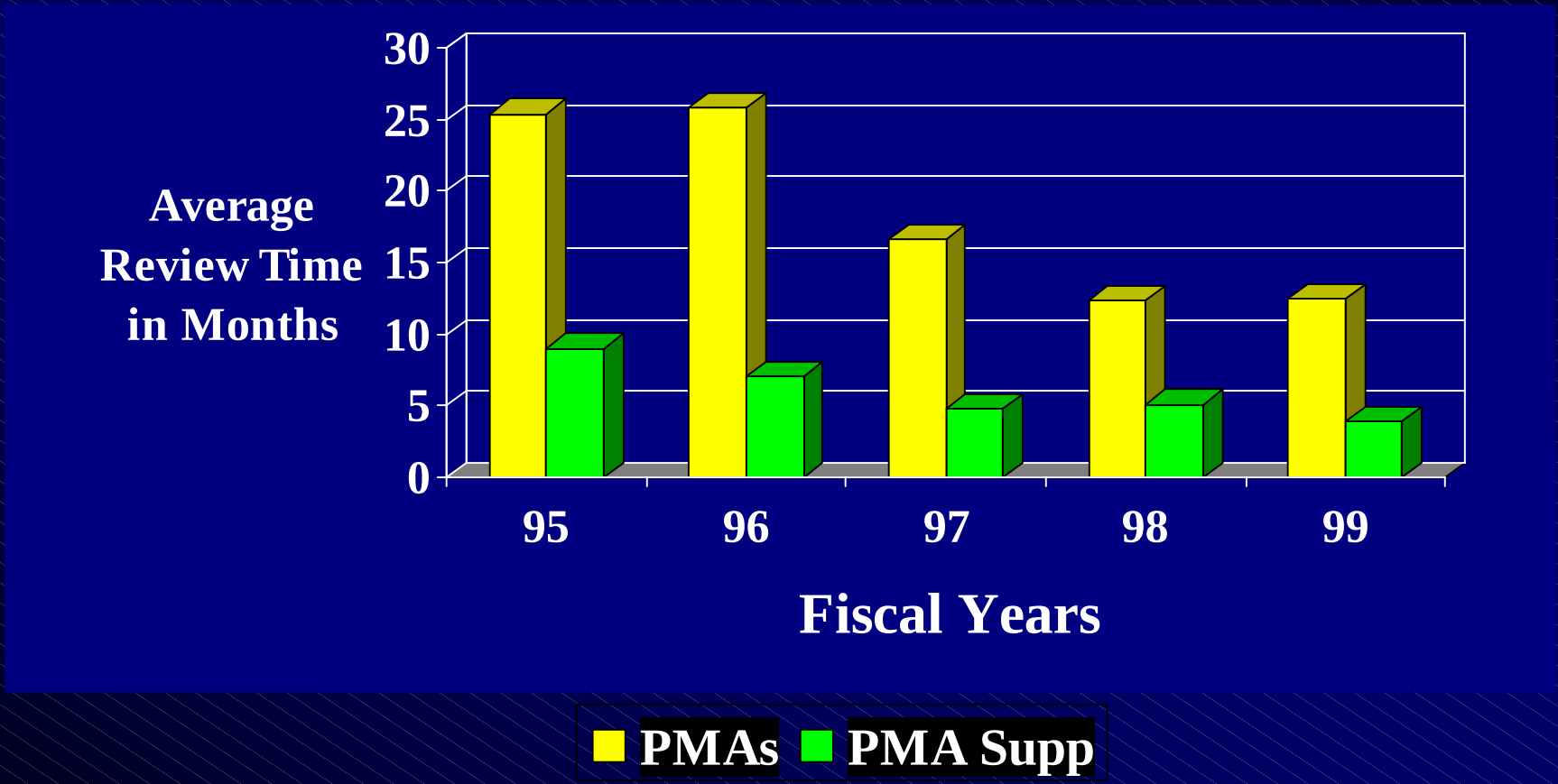
Performance: 510(k)s - Third party review

- 154 device types eligible - mostly class II
- Represents 1200 eligible 510(k)s / yr
- Only 32 submitted to 3rd parties in FY 99
- Comparison of total elapsed review time:

510(k)s with 3rd party review - 57 days
Comparable 510(k)s (all FDA review) - 105 days

- **Plans for expansion**

Performance: PMA and PMA Supplement Total Review Times

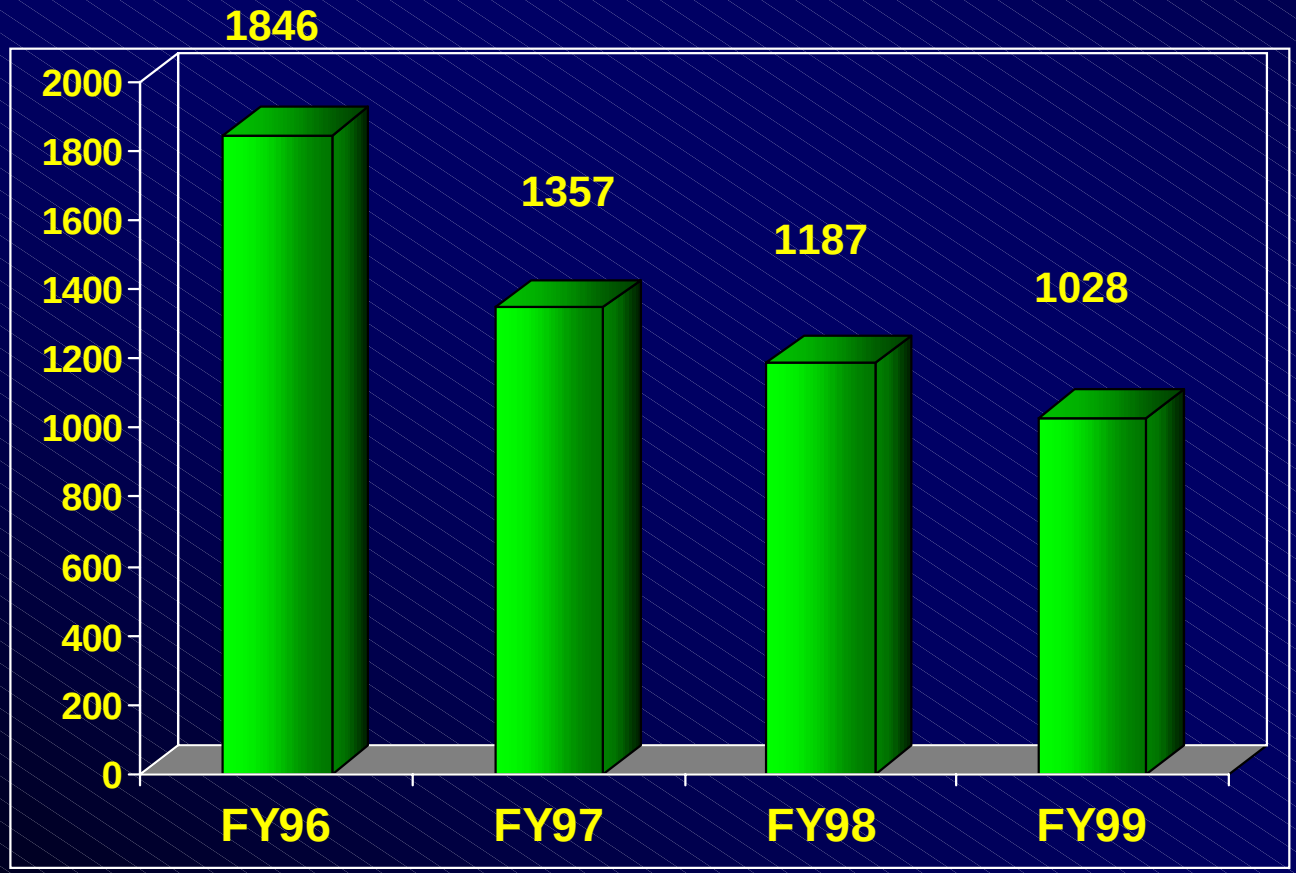


Pre-PMA & Pre-IDE Meetings

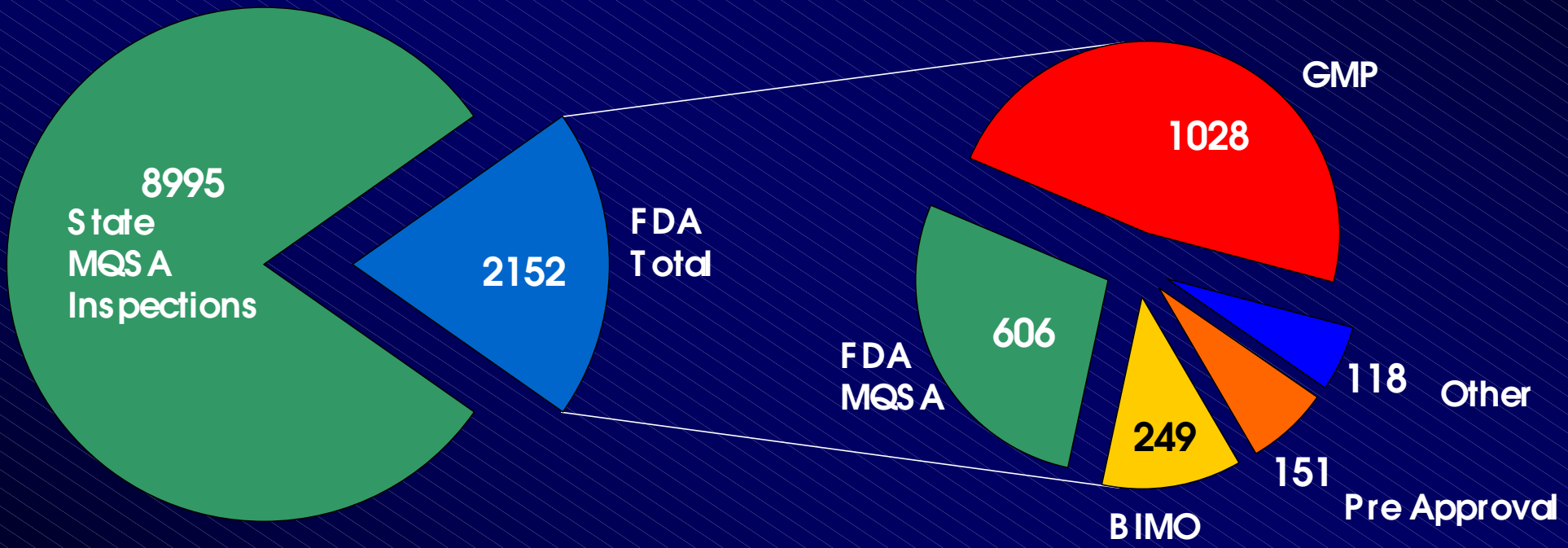
- 24 pre-IDE 12 pre-PMA 3 both
- CDRH gets very few requests
- Center policy: each firm limited to
  - **one determination meeting**
  - **one agreement meeting**
- CDRH requests that companies bring detailed, comprehensive info and allocate enough time to produce an agreement where possible

GMP Domestic Inspections FY 96 - FY 99

No. of Inspections



1999 Device Inspections



Least Burdensome Path to Market

Interpretation

- Goal: To get the right information to support submissions -- not more, not less
- Data: Needed and appropriate to product
- Process: Interactive and transparent

Least Burdensome Path to Market (cont.)

Implementation

- Public comments via Jan. 1999 meeting with stakeholders
- Proposal from LB Industry Task Force
- Comments via docket, letters, discussions
- Draft guidance released 9/1/1999
  - Focus is clinical data requirements

Least Burdensome Path to Market (cont.)

Implementation (cont.)

- Small working group of FDA & industry task force now meeting to draft:
  - Statement of concept and general principles
  - Algorithm for least burdensome approach
- LB webpage on Center's FDAMA website
  - http://www.fda.gov/cdrh/modact/leastburdensome.html
- Public meeting or teleconf. this summer

Least Burdensome Path to Market (cont.)

Implementation (cont.)

- Training classes for CDRH review staff
  - includes industry comments, videotape
- Training for advisory committee panels
- Adding language to correspondence with industry to raise least burdensome concerns

Dispute Resolution

- FDAMA - §404
- Dispute resolution panel chartered
- Announced recruitment for panel members - Nov. 99
- Hope to begin impaneling members in Spring
- CDRH's current track record :
  - Of 77 competed appeals, CDRH reversed its decision in whole or in part 40% of the time.
- Recruited ombudsman

Ombudsman

- Disputes and common problem areas
- Reports directly to the Center Director
- Outreach
- Follow-up
- Quality Systems relating to common problem areas

Ombudsman

Les Weinstein

- BA Poly Sci, MPA, JD
- HHS: Medicaid programs, HMOs
- CDRH: Regulations, FOI, International areas
- FDA (agency level): Deputy Dir., FOI Staff; Denials & Appeals Officer
- Adjunct Prof., MC; member of DC Bar

"Inreach" Using the Web

Industry and consumer feedback

- Device Advice comment line: dsma@cdrh.fda.gov
- E-mail: Director@cdrh.fda.gov
- Opportunity for direct feedback via the Web
  - "Comments"
- Commenting on proposed regulations electronically
  - Postmarket Surveillance provision (section 522)

CDRH and HIMA

Cooperation to accomplish mutual public health goals

- Least burdensome - part of small workgroup
- Ways to expand 3rd party review
- Commenting on document via Web
- Use of standards
- Device Industry/FDA Grassroots Committee

CDRH and HIMA (cont.)

- Global Harmonization Task Force
  - HIMA and FDA participating together since inception
- IVD Roundtable - Industry/FDA group focusing on
  - IVD issues and common interests for collaboration
  - Improved industry/FDA communication on IVD issues
- Postmarket surveillance of cardiovascular devices

CDRH and HIMA (cont.)

- Reengineering
- Re-marketing/servicing - in AAMI working group developing voluntary approach for self-regulation
- Blood glucose monitors - potential CRADA to support study of two technologies
- Training

Future

What's your wish list?