CDRH Update

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Overview

- Review performance
- Science emphasis
- Leveraging
- Communication
  - Least burdensome path to market
  - Dispute resolution
  - Using the Web
- Challenges

Review Performance: 510(k)s

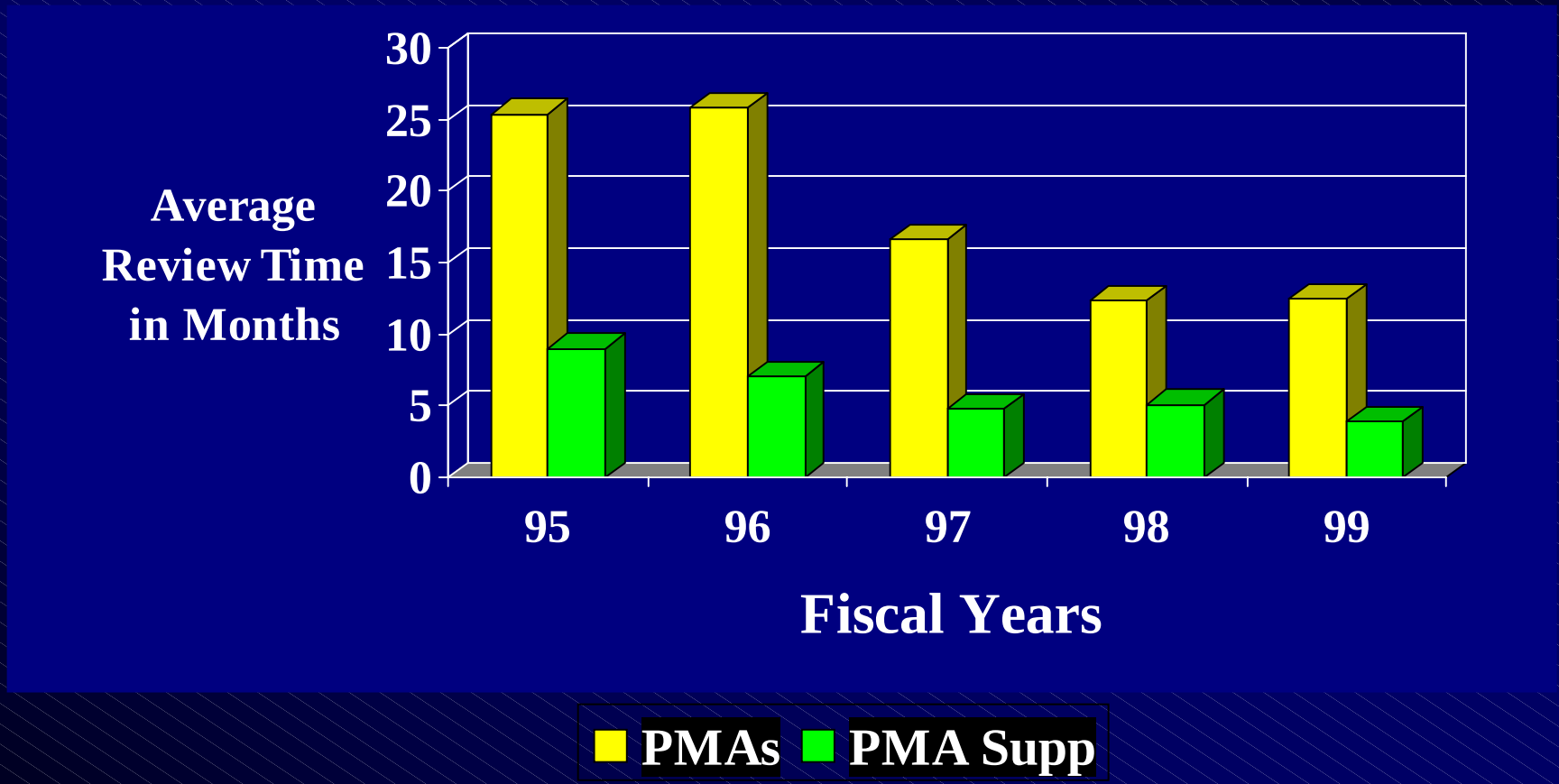
	Applications Received (4-98 to 9-99)	Review Complete	Average Review Time
Abbreviated	105	82	91
Special	458	411	28
Traditional	6147	6453	110

Review Performance: 510(k)s - Third party review (FY'99)

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

3rd party -	57 days
All FDA review -	105 days

Performance: PMA and PMA Supplement Total Review Times



Science Emphasis

Scientific review

- Looking at science across the center
- Quality & relevance to CDRH
- First topic - electromagnetic stimulation devices

Leveraging

Cooperation with outside groups to accomplish mutual public health goals

- Training
- Teleconferences
- CRADA under development with CTIA
- MOU with NIDCR
- Workshops

Communication: Least Burdensome

Interpretation

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

Communication (cont'd): Least burdensome

Implementation

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- Draft guidance released 9/1/1999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

Communication (cont'd): Dispute Resolution

- Goal: To resolve scientific disputes expeditiously
- Draft guidance published in April
- Final guidance pending, will address industry comments
- Panel chartered; "recruitment announcement" in November
- Ombudsman vacancy announcement closed November 26

Communication (cont'd.): Using the Web

Registration and Listing

- Goal: To streamline in-house system, make system more efficient for manufacturers, register and list electronically
- Register and list on-line
- Grassroots meetings
- Industry feedback
- Preparing proposed rule
- Pilot with nine firms to begin in early 2000

Communication (cont'd): Using the Web

Industry and consumer feedback

- Current
  - Device Advice: dsma@cdrh.fda.gov
  - E-mail: Director@cdrh.fda.gov
- In the works
  - Direct feedback via the Web
  - Commenting on proposed regulations electronically

Challenges Are Many

- Appropriations/budget
- Postmarket vigilance/surveillance
- Enforcement
- Use of standards, standards development
- International activities (MRA, GHTF)
- Review issues, including 3rd party review
- Rad Health
- Y2K
- Etc.

Challenges: Appropriations for FY 2000

- Bill signed Oct. 22, 1999
- Allocates $114 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 device review to meet statutory timeframes
  - $7 million increase for device review

CDRH: The Future

- Transparent
- Adequately resourced
- Re-engineered
- FDAMA'ed
- Science-based
- Partnering
- Credible