CDRH's Regulatory Agenda for 2007-2008

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CDRH

FDA

Agenda Topics

- Big challenges next fiscal year
- What is the coming (compliance and) enforcement agenda
- How can you influence the (enforcement) process?
- How can you challenge agency decisions?
- [Will I have a smaller office at White Oak?]

Some Big Challenges Generally, My Humble Opinion*

- Being technologically agile and relevant; getting good products to the market
- Responding effectively to public health problems
- Maintaining public trust
- Being good stewards of available resources
- Closing the gap on benefit/risk decisions
- Facilitating a globally efficient regulatory environment – stay tuned for Larry
- Optimizing quality in process and product
- Sustaining US preeminence in health care

*not a disclaimer

Technological Agility

- **Devices are getting smaller**
  - Miniaturization, New Materials, Nanotechnology
- **Devices are getting smarter and are providing more information**
  - Intelligent Devices
  - Biotechnology Revolution
  - Personalized Medicine
  - Combination Products
  - Information-Rich Therapeutics

Technological Agility

- **Devices are becoming more convenient for the patient**
  - Home Use
  - Minimally Invasive
  - Point of Care Diagnostics
- **Devices are responding to homeland security**
  - Bioterrorism-Related Devices
- **Devices are meeting the needs for special populations**

Technological Agility and Relevance

- MDUFMA
- Having the forecasted scientific and medical skills in the right place at the right time
- Supporting laboratory operations addressing new technologies
- Applying least burdensome regulation to facilitate product development and approval
- Engaging government and industry in emerging problem identification and solutions
- Identifying and dealing with novel manufacturing issues

Responding to Problems

- Implementing CDRH Postmarket Transformation
- Acting on device nomenclature and unique product identification initiatives
- Coordinating international vigilance reporting
- Converging quality systems
- Improving risk communication to the health care community and the public in general
- Incorporating risk management

Postmarket Transformation Report

CDRH is committed to improving its medical device safety program.

CDRH's Postmarket Transformation report provides a roadmap to transform our postmarket safety program and increase our ability to identify, analyze, and act on the risks that may be posed by the thousands of devices once they are in the real world.

1. Develop a Culture of Collaboration

Create a matrix structure across CDRH's existing organizational structure to better link premarket, postmarket and enforcement efforts.

- **Establish cross-cutting product-related groups over the current functionally-based organization**
  - Foster information sharing and more effective public health promotion and protection
  - Collaboration as a part of day-to-day operations, not just in crisis situations

2. Develop World Class Data Sources and Systems

Enhanced data input, mining, analysis and tracking will help to improve the quality of care for patients by reducing medical errors, facilitating device recalls, and predicting clinical risk.

- **Pursue the development of a unique identifier system for tracking medical devices throughout their lifecycle**
- **Proposed mandatory use of electronic reporting for required adverse event reports**
- **Revise the Manufacturer and User Facility Device Experience Database (MAUDE) System**
- **Increase the use of Medical Product Safety Device Network (MedSun) programs**

3. Enhance Risk/Benefit Communication Efforts

CDRH should be a trusted, publicly identifiable source for safety information about medical devices and radiation-emitting products.

- **Perform an analysis of the communication needs of CDRH stakeholders**
- **Develop process for the development and dissemination of risk-benefit information in collaboration with clinical practitioners and professional communities**

4. Focus Improved Enforcement Strategies on Postmarket Issues

Increased collaboration among CDRH, the Office of Regulatory Affairs, and the Office of Chief Counsel.

- **Consider postmarket data and information when prioritizing inspections**
- **Include a review of recent postmarket data in inspection preparation process**
- **Leverage the audit results obtained by accredited third-party auditing bodies**
- **Update enforcement data systems.**
- **Employ all available enforcement tools, including civil money penalties**

CDRH is committed to improving its medical device safety program…

- Postmarket systems that enable constant learning and feedback not only help to support best medical practices but also spur continued innovation.
- The CDRH post-market report—and its implementation--is a major step in strengthening FDA's postmarket program for medical devices and fulfilling our public health mission.
- Postmarket Transformation will increase the agency's ability to identify, analyze and act on the risks that may be posed by the thousands of devices used by health care professionals and consumers every day.

Public Trust

- FDA must rely on public trust for long term success*
- Trust affected by opinions on government leaders, performance, and amount of power exercised**
- Public trust in FDA enhances confidence in US products
- Therefore, a strong FDA contributes, in part, to US leadership in the world market

*FDLI

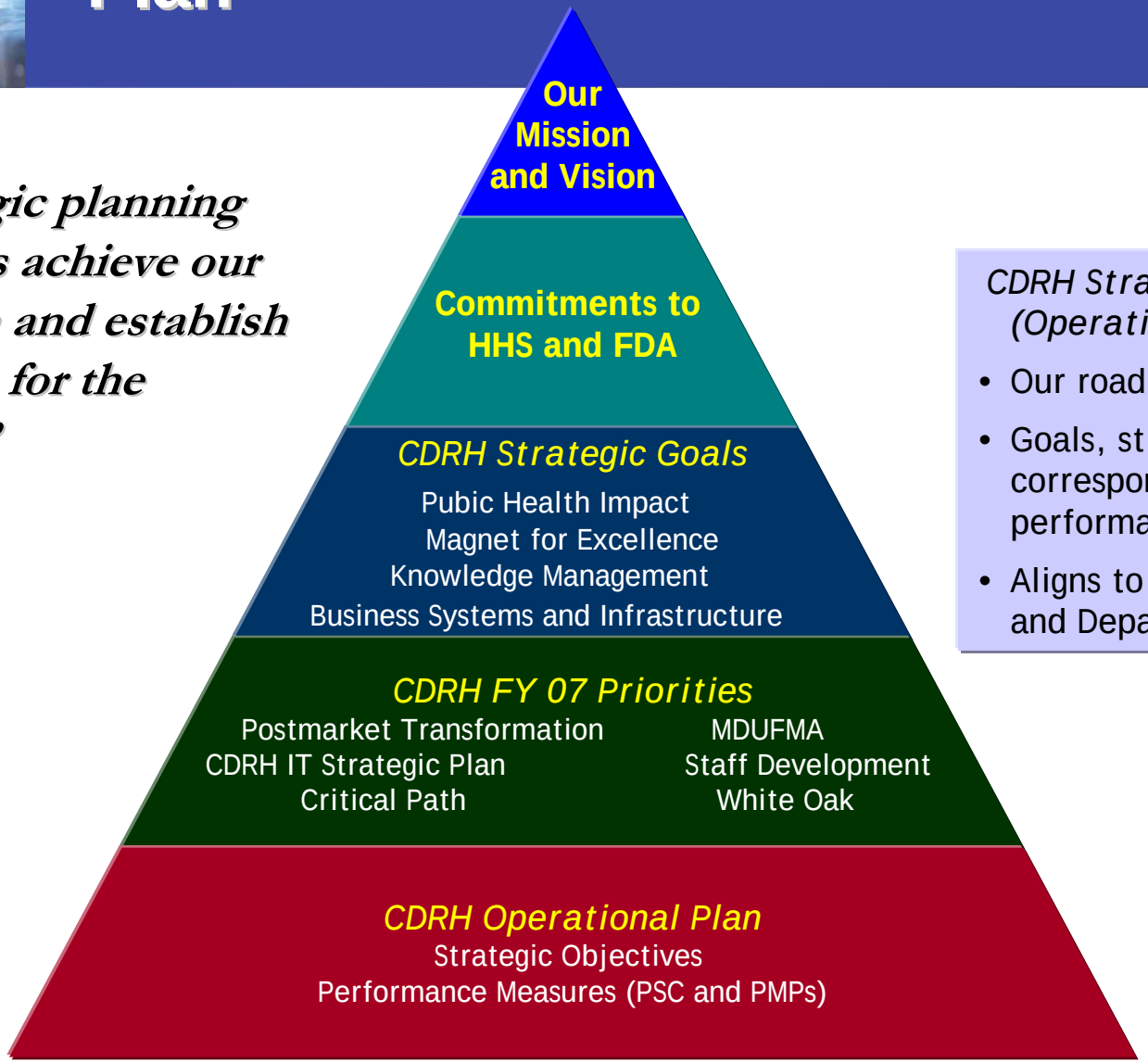
**The Brookings Institute

Ensuring Public Trust

- Competent, new leadership at the top with a clear public health vision
- Addressing perceived or real performance issues with focused strategic plan, challenging scorecards, and tireless efforts of staff to be responsive to customers and stakeholders
- Current or proposed authorities of FDA are exposed to transparent processes and public oversight.

CDRH's Strategic Action (Operational) Plan

"Strategic planning helps us achieve our mission and establish a vision for the future."



CDRH Strategic Action (Operational) Plan

- Our roadmap
- Goals, strategies, and corresponding performance measures
- Aligns to the Agency and Department goals

Good Stewards

- CDRH is people, not widgets
- Inspections staff has decreased over time
- And yet the number of registered device companies increases

THEREFORE

- Focus must be on the fewer but higher risk issues, as Commissioner has noted
- Maximize efficiency with internal quality systems

Risk Gap

- Gap in some risk assessments between government and industry
- Different variables in government vs industry decision equations
- Both concerned with risk to patients and users of devices
- Different impressions sometimes of worse case and health risk decision factors
- Leads to some differing views on activities like recalls or product approval

Global Regulation

Dr. Kessler will address

Quality

- As much a challenge for FDA as it is for industry
- Quality manuals and other documents look good on paper but do we have a quality culture in mind and deed
- Attention to Quality is one of those pay me now or pay me later scenarios; Later may end up in
  - Significant product defects
  - Loss of goodwill
  - Legal issues
- Cooperative efforts with government on Quality issues is vital

Preeminence

- US continued lead in cutting edge medical technology, innovation and creativity requires effective collaboration between industry, government, and the health care community*
- Regulatory processes must be in sync with the speed of the device lifecycle to facilitate the critical path
- FDA listens to and addresses criticisms about regulatory impediments

*Advamed

Compliance and Enforcement Agenda

- Compliance is preventive; depends on education and a commitment to quality
- Enforcement is reactive; results when message is not received or there is lack of adequate commitment to quality
- Rather than consider your risk of enforcement, honestly and thoroughly spend time evaluating your state of compliance

Compliance Education

- Educational conferences
  - FDLI
  - Advamed
  - AAMI
  - FDA
- Internal company training
- FDA Small Business office resources
- Web sites
- Working with your district
- Available for meetings and phone discussions

Enforcement Process

- Enforcement steps include identifying conditions of noncompliance (MDRs, surveillance or for cause inspections, promotion and advertising activities, trade complaints), determining violations (translating the “483” or other observations to legal cites, recommending action level (“OAI, VAI, NAI”), and formulating action based on many factors.
- Important opportunities for company to respond
- Lots of interaction between Office of Regulatory Affairs (Headquarters and/or districts), CDRH and counsel.

Enforcement Signals and Action

- Routine surveillance (FDA and third party)
- CDRH also identifies areas of concern based on available data and information and CDRH-wide participation, takes a slice of the inspection resources and directs inspections of segments of the industry
- Recent areas include external defibrillators and infusion pumps
- Resulted in several enforcement actions
- Bioresearch group also reorganized to react quickly to issues

Enforcement

Corporate Enforcement

- **Multiple signals raise concern**
- **History important**
- **What is current state of corporate compliance**
- **What is the organizational structure and responsibilities; unique or cross-cutting issue**
- **Degree of risk of the problem**
- **Responsiveness of company**

Influencing the Enforcement Process

- Better you tell us first
- As I said, minimize your exposure to enforcement action
- You must take action as the law and regulations require, e.g.:
  - Corrections and removals, recalls
  - Internal audits
  - Purchasing controls
  - Complaint handling, MDRs
- Respond when due and be as thorough as possible in your response to 483's and letters.

Influence

- Proactive response by company in the interest of the public health has a positive effect on FDA action
- FDA is ultimately interested in achieving compliance; a result that eliminates the concern, preserves the public health, and maintains the flow of good products to healthcare professionals
- We have few circumstances where the legal action will run its course

Challenging FDA Actions

- Communication with FDA office taking action
- Taking it “up the line”
- Regulatory procedures for challenges
- Ombudsman
- Other administrative and judicial due processes

- A word about internal FDA challenges to decisions
  - We have a process; there is opportunity for all opinions to be heard; ultimately a decision must be rendered; the process works

Points I Covered

- Many challenges and opportunities for collaboration
- Compliance is our goal; enforcement in few cases
- Due process allows ways to affect the outcomes of problem situations
- Yes, the Compliance Director's office will be smaller at White Oak, but may have a better view