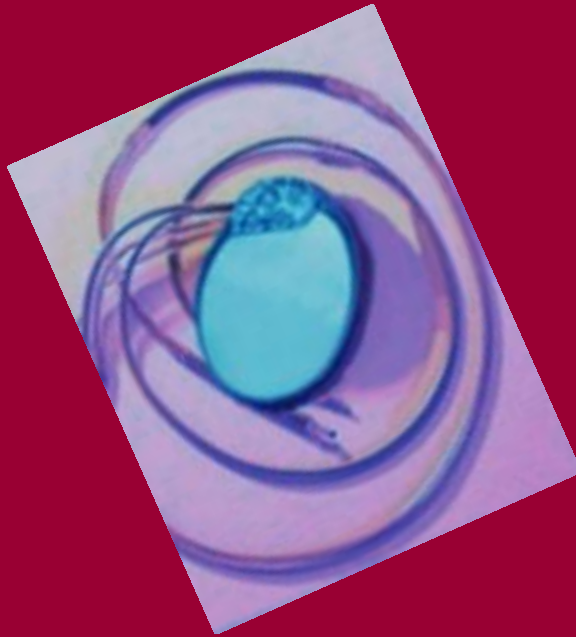


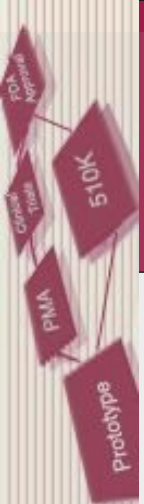
# Stanford University Biodesign

## FDA Internship and Fellowship Program



**Informational Session**

**October 20, 2011**



# Agenda:

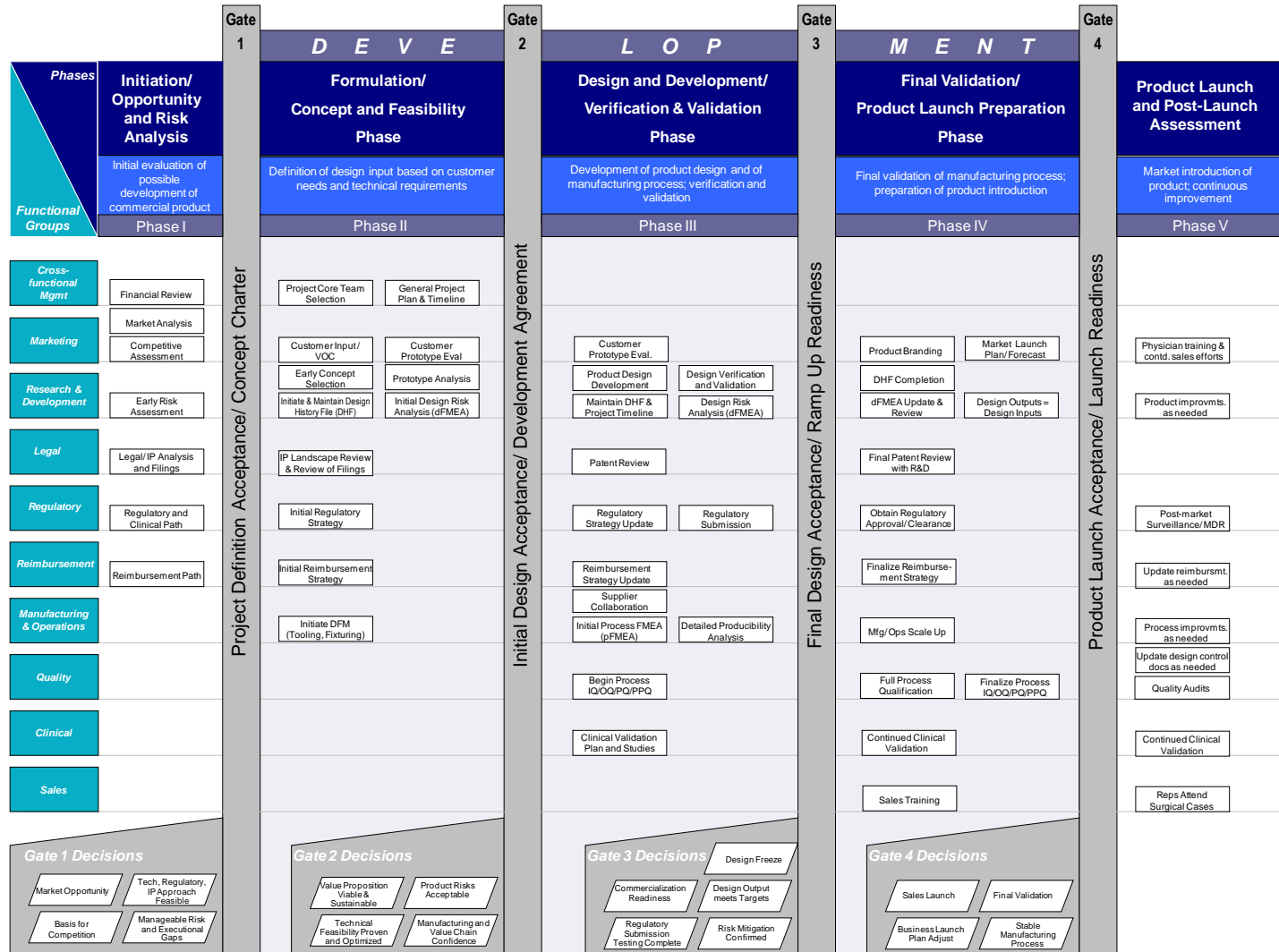
**Background on FDA and its Mission**

**Objectives of the Fellowship/Internship**

**Application Process**

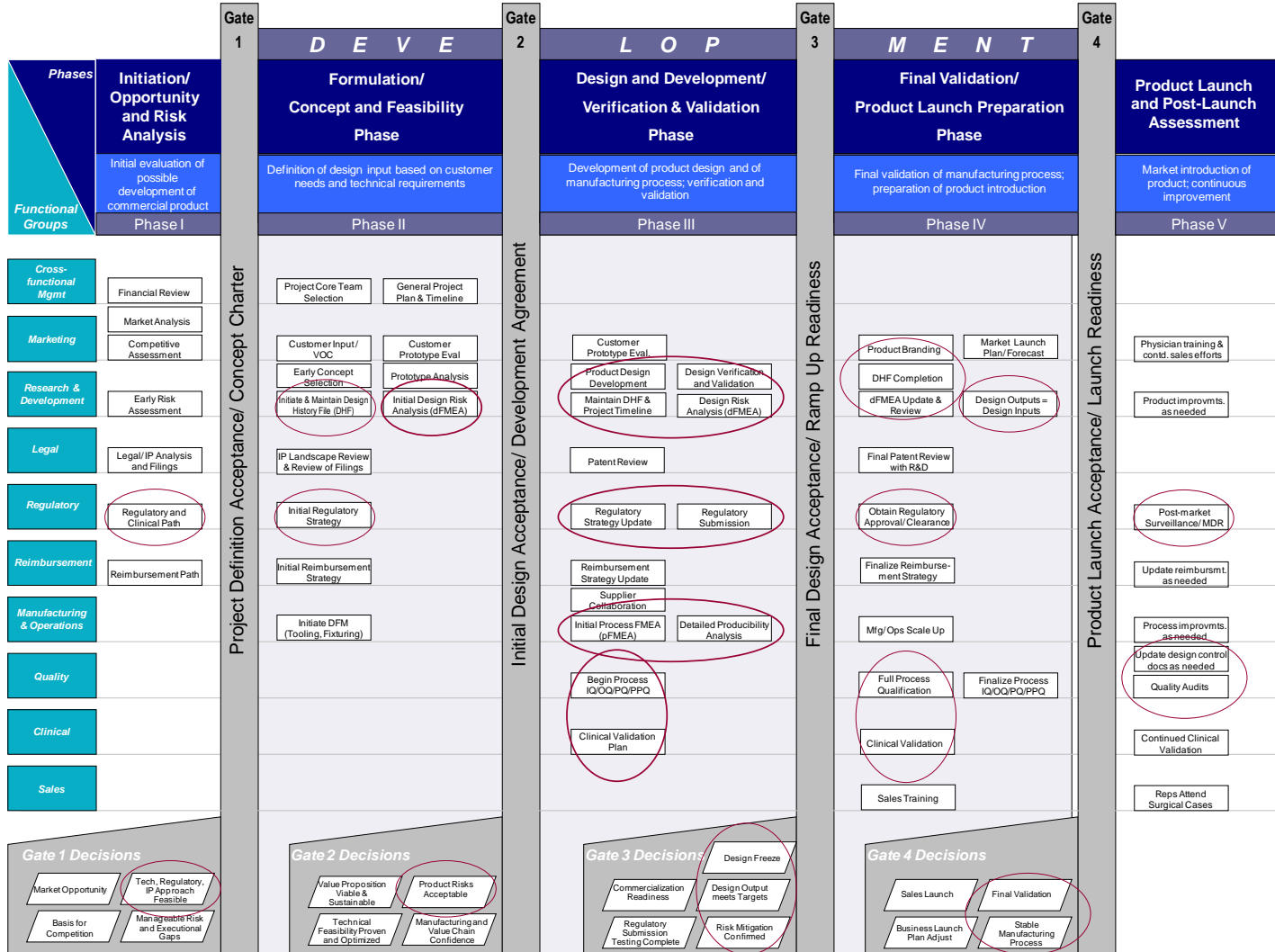
# Importance of Regulatory Requirements in the Development and Commercialization of Devices

**Medical Device Development: High-level Representation of Development Phases and of Functional Activities**



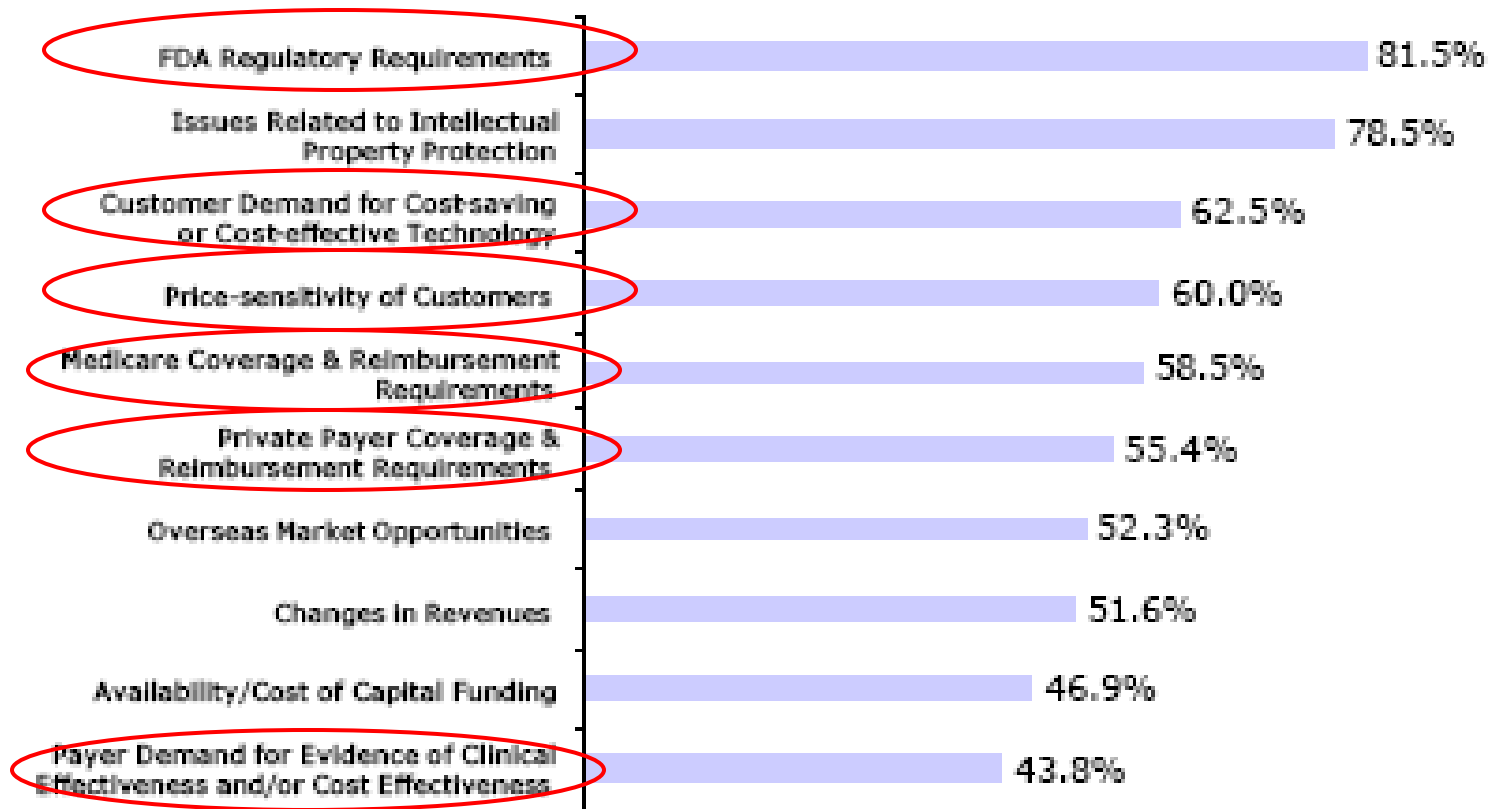
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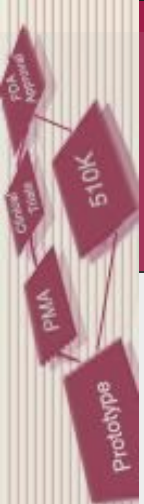
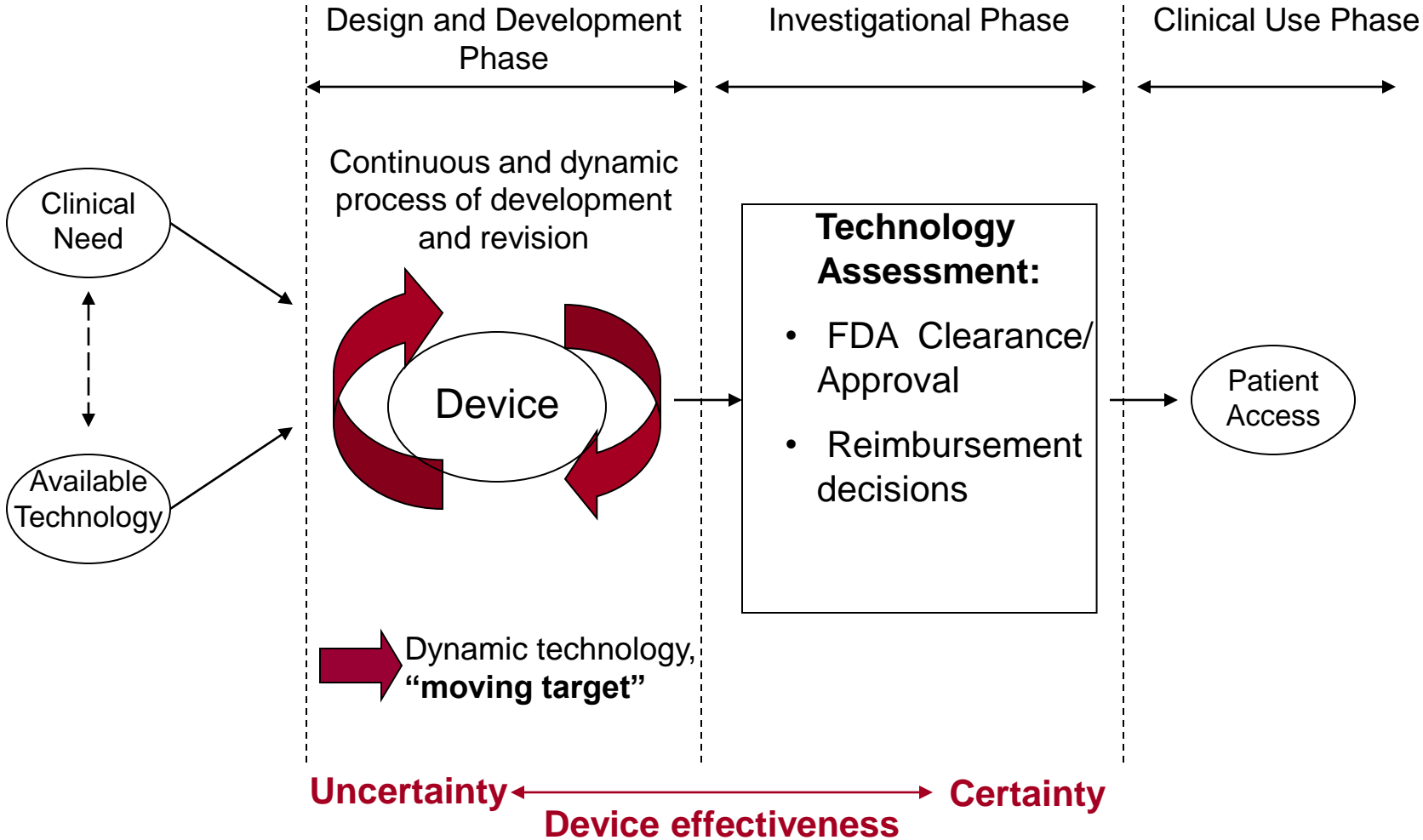
# Top Ten Factors Influencing Company's Product Development Priorities

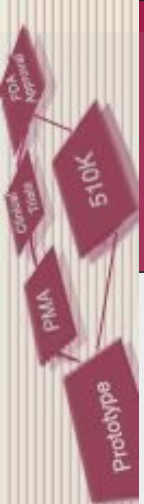
Top Ten Factors Influencing Companies' Product Development Priorities Over Past Five Years, 2003



Source: *AdvaMed Survey of Member Companies, 2003*

# Phases of Technology Innovation and Assessment





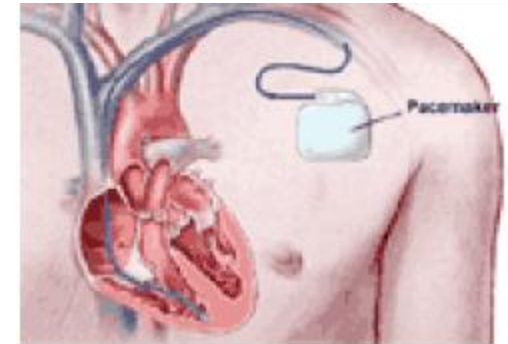
# FDA's Mission and Structure

# Some Examples of Devices Recently Approved by the FDA



CHARITÉ™ Artificial Disk

GORE TAG Endovascular Graft for Treatment of Aneurysms



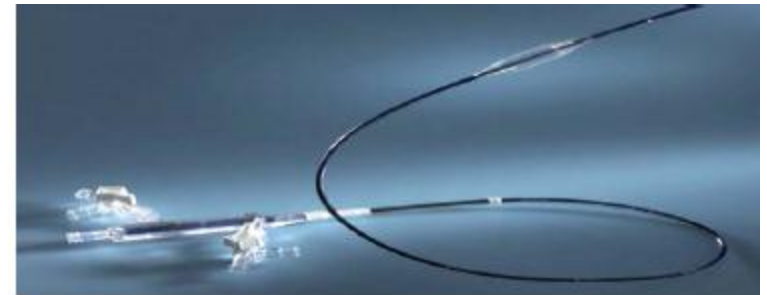
Medtronic Select Secure™ Lead Wire for Pacemakers



Implantable Defibrillator

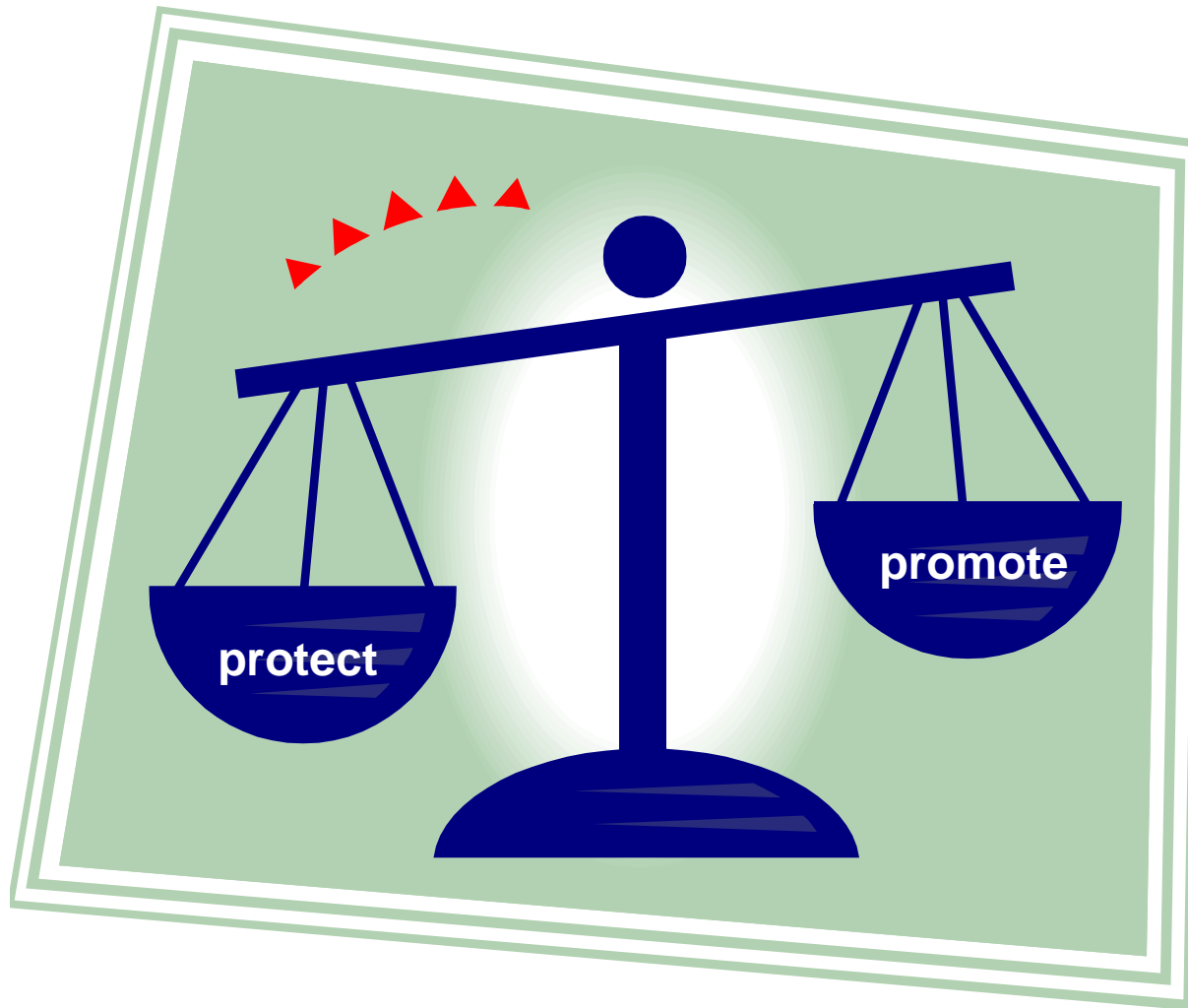


Surgical Laser



Catheter to treat Cerebral Ischemia

# FDA's Mission Today



# Two Main Players: Regulatory Agencies and Payers

## Regulators

Food and Drug  
Administration

Criterion for

*Market Clearance:*

**"SAFE AND EFFECTIVE"**

## Payers

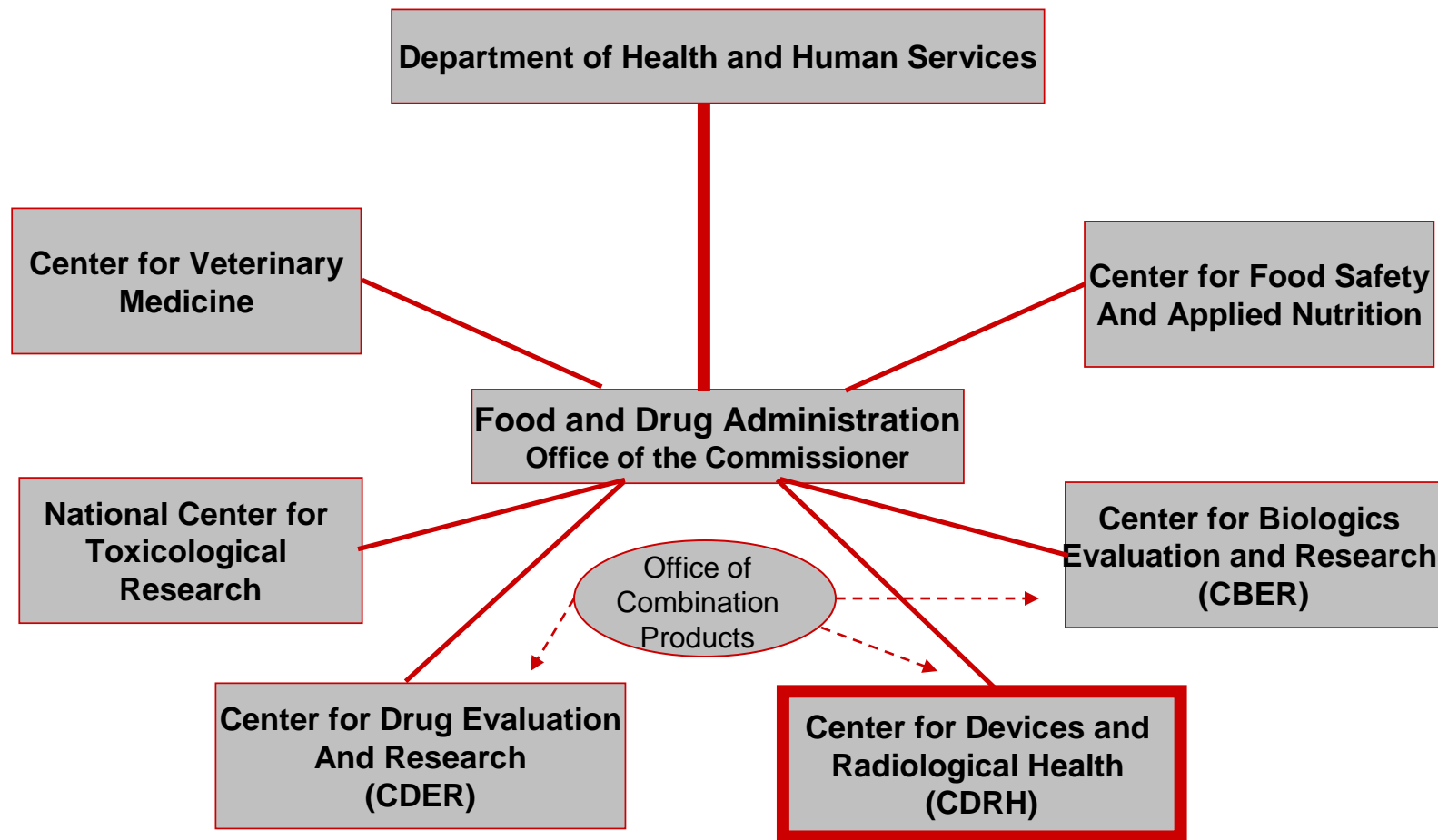
Centers for Medicare and  
Medicaid, others

Criterion for

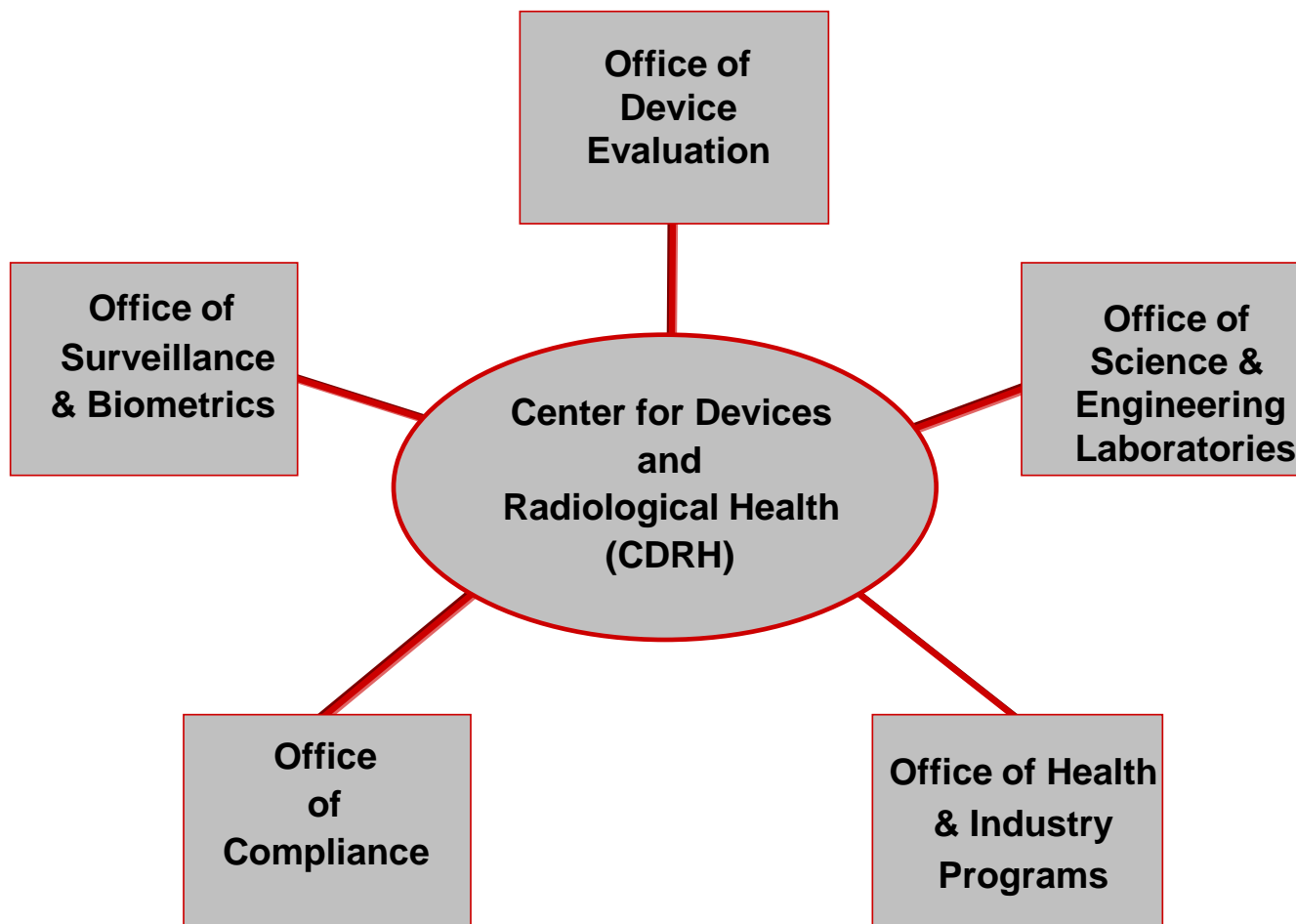
*Reimbursement:*

**"REASONABLE AND  
NECESSARY"**

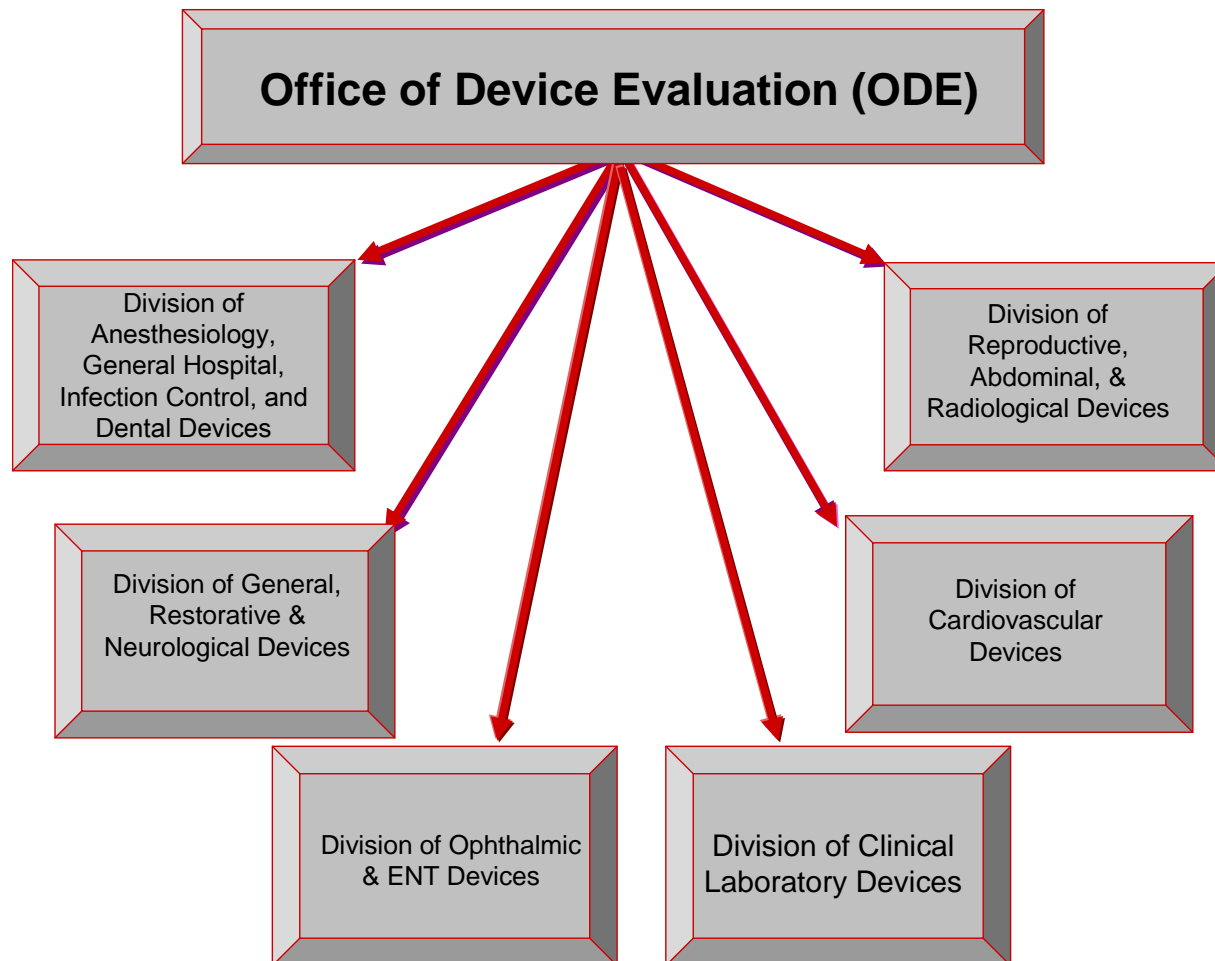
# Organizational Structure of FDA



# Organization of FDA CDRH (Center for Devices and Radiological Health)

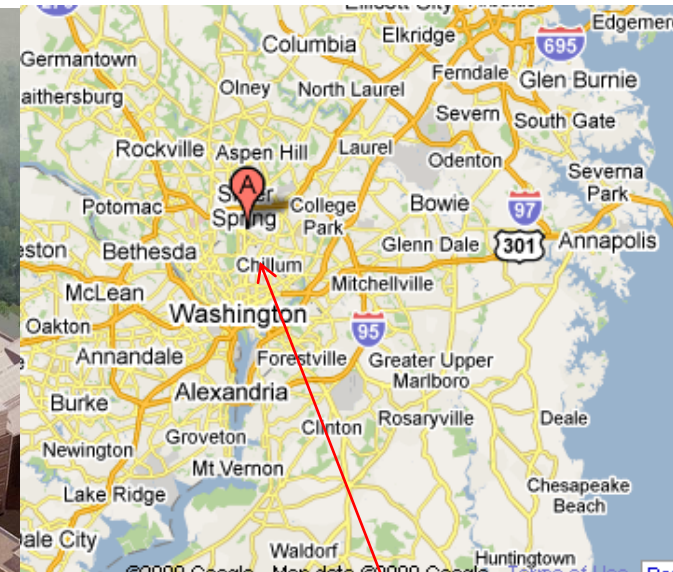


# Divisions within FDA's Office of Device Evaluation (ODE)



# FDA's Center for Devices and Radiological Health (CDRH) in White Oak/Silver Spring, MD

501K  
PMA  
Prototype



White Oak/  
Silver Spring, MD

# A New PMA Application – Submissions can be Comprehensive...

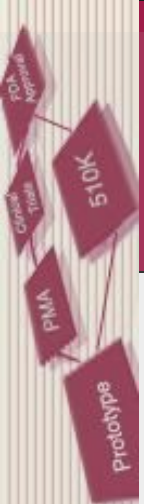


April 11, 2008

# Your Tax Dollars at Work...

(Brett Kuekan, 2006 Stanford MDFP Intern)





# The FDA/CDRH Medical Device Fellowship Program (MDFP)



# Program Objectives

- Teach students about the medical device approval process
  - Study relevant FDA regulations and legislation
  - Understand the types of applications (PMA, IDE, 510(k)) submitted for review
  - Participate in meetings with device companies
  - Participate in review/consult process
  - Develop responses to industry
  - Understand roles and responsibilities of federal advisory committees
- Give students exposure to clinical research issues from a regulatory perspective
  - Participate in developing clinical trial design with a device sponsor (company)
  - Define outcomes for a specific clinical trial design
  - Analyze completed clinical trial data
  - Participate in preparing and presenting information to advisory committees
  - Participate in approval decision process



# Program Objectives

- Teach students the concept of medical device “total product life cycle” from a regulatory perspective
  - Participate in pre-market review of device submissions.
  - Learn about adverse event reporting and post-market evaluation of devices.
  - Learn how post-market evaluation informs pre-market decisions
  - Be exposed to CDRH laboratory research and testing
  
- Provide training opportunities
  - Participation in:
    - Didactic coursework, lectures, science seminars
    - CDRH Staff College courses (writing, leadership, time management, etc.)





# Past Experiences and Projects: Stanford MDFP Fellows

- Computational Modeling for Cardiovascular Devices
  - CDRH in collaboration with Stanford, NHLBI and NSF, held a Critical Path Workshop on **Use of Computational Modeling Techniques for Cardiovascular Device Development** which introduced the current challenges for this important area of cardiovascular medical device development



# Past Experiences and Projects: Stanford MDFP Fellows

- Regulatory Process for Dental Amalgam:
  - Researching and analyzing comments from a 2002 proposed rule on dental amalgam
  - Reviewing and summarizing comments from a 2008 Federal Register Notice of final rule on dental amalgam
  - Serving as a medical device reviewer in the Dental Devices Branch



# Past Experiences and Projects: Stanford MDFP Interns

- Intern Projects:
  - Analyze adverse reports in the MAUDE database to help identify any specific issues related to the use of surgical mesh. The data will be trended to determine patterns in specific product characteristics or categories that contribute significantly to adverse events
  - Analyze adverse event data of MRI related thermal injuries, develop a scientific rationale for the occurrences, and determine suitable preventative measures
  - Evaluate partnership opportunities in FDA's EEP (External Expertise Partnership) and develop collaboration policy statements to help support public health initiatives
    - Collect and analyze data from sources associated with each area of EEP -- Critical Path, MDFP and Tech Transfer



# Application Process

- Application process  
(details see <http://biodesign.stanford.edu/bdn/career/fda.jsp>)
  - Submission of application materials by December 1, 2011
    - Cover Letter & Statement of Interest
    - Resume/ CV
    - Three letters of recommendation
  - Pre-screening of applications by Stanford Biodesign (December 2011)
  - Review and evaluation by FDA (January-February 2012)
  - Interviews with FDA (February – April 2012)



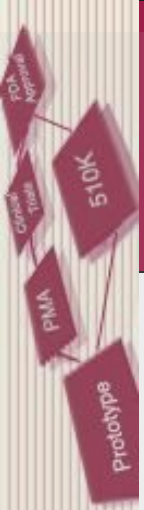
# MDFP Selection Criteria

- Selection criteria
  - Relevant academic and/or work experience
  - Demonstrated skill
  - Match between preferred medical device areas and current CDRH project activity
  - Ability to collaborate and work with others
  - Ability to communicate orally and in writing
  - Free from conflict-of-interest



## Funding and other support

- Compensation provided by FDA  
(depending on level of education and experience)
- Stanford Biodesign pays transportation to/from Washington and Stanford Cardinal health insurance during leave
- Students need to enroll for MS&E 408 during internship/fellowship period and provide summary report at end of internship/fellowship



# Q&A