

Medical Technology Leadership Forum

School of Public Health

Special Program
*A Leadership Dialogue for Stakeholders
and Policy Leaders from Japan and the
United States*

FDA Update

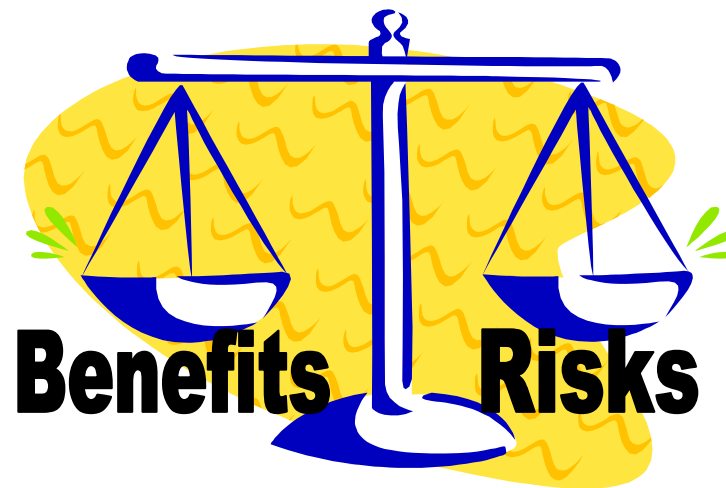
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Chief Quality and Regulatory Officer
Medtronic

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CDRH Mission

Getting safe and effective devices to market as quickly as possible...



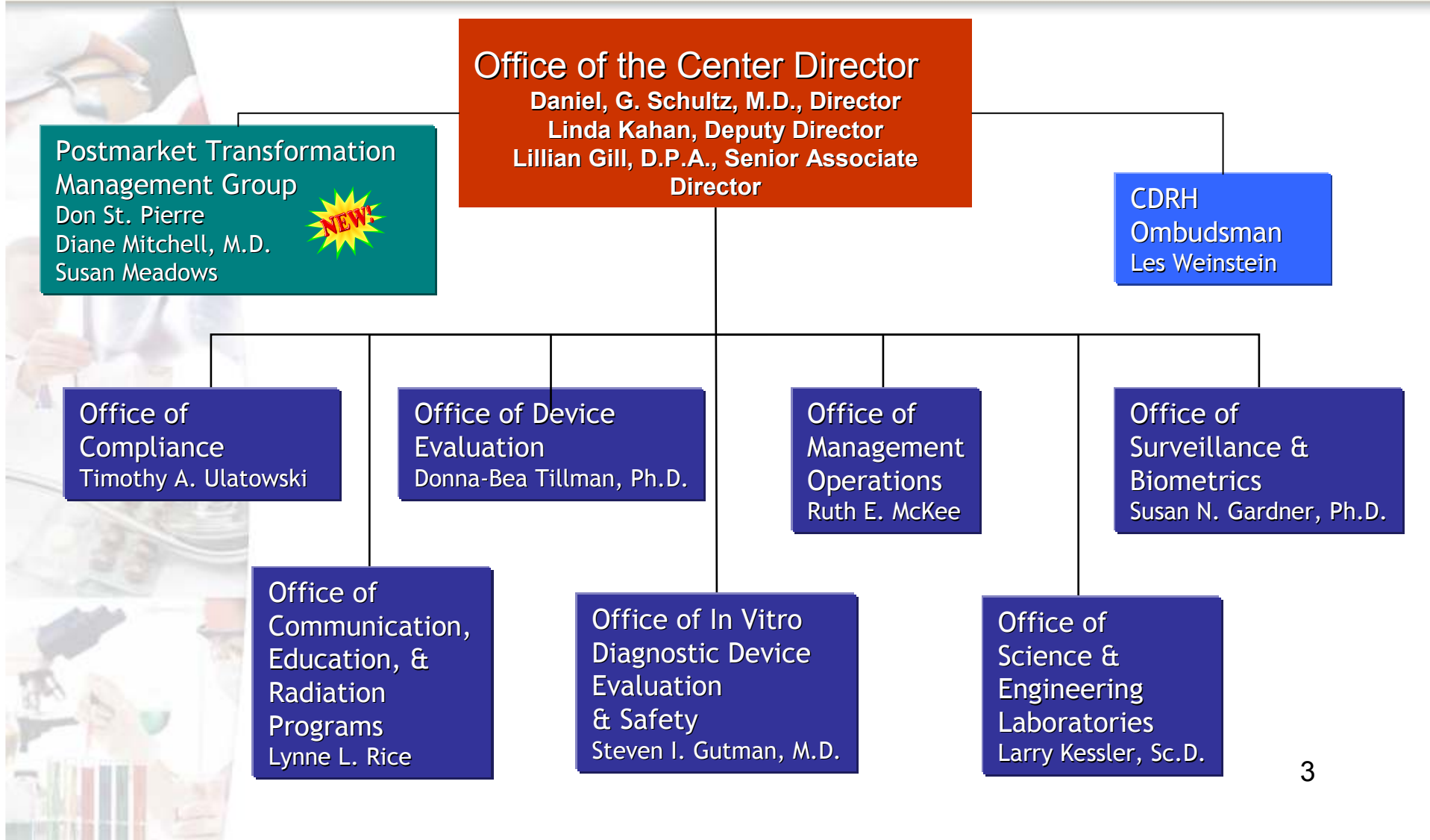
... while ensuring that devices currently on the market remain safe and effective.

Helping the public get science-based accurate information about medical devices and radiological products needed to improve health



CDRH's Organizational Chart

CDRH is a team of over 1,000 dedicated, highly skilled, and internationally respected public health employees





CDRH FY 2007 Priorities

1. Complete Postmarket Transformation assessment, create execution plan and begin phased implementation
2. Complete implementation of the program for Medical Device User Fees and finalize proposals for part II
3. Finalize CDRH Information Technology Strategic Plan and continue phased implementation
4. Complete comprehensive staff development plan to support workforce excellence
5. Develop a Critical Path plan for CDRH
6. Position CDRH for a successful transition to White Oak



Postmarket Transformation Priorities

1. Create a matrix organization to optimize medical device regulation across the Total Product Lifecycle
2. Develop metrics and methods for tracking postmarket issues
3. Pursue the development of unique identification (UDI)
4. Enhance utility of MedSun programs
5. Propose mandatory electronic MDR reporting



Postmarket Transformation Priorities

6. Revise and update the MAUDE system, and expand the premarket data-warehousing
7. Increase the quality and quantity of Center/ORA/OCC interactions
8. Develop and implement a risk-communication strategy
9. Design a pilot project to test the usefulness of quantitative decision-making methods



Communication & Outreach

Website Redesign Project

- To best meet the needs of consumers, healthcare professionals and industry

Industry Education Plan

- An effort across CDRH Offices to efficiently utilize all Agency resources to educate industry about pre- and postmarket activities



www.fda.gov/cdrh



Communication & Outreach

- **Collaborations** -- clinical community and professional groups
- **Meetings**
 - Postmarket Workshop (AdvaMed)
 - Risk Communication Workshop (AdvaMed)
 - Defibrillator Working Group – ICDs and AEDs (HRS, AdvaMed)



CDRH IT

- **CDRH Information Management Steering Committee (IMSC):**
 - Ensures IT projects are consistent with President's Management Agenda, HHS, FDA and Center strategic goals and priorities
 - Members are CDRH Senior Management
- **CDRH plans and monitors development of IT initiatives through CDRH IMSC. All major IT initiatives are required a project plan to Center Director. Progress is reviewed quarterly.**



Workforce Excellence

Workforce Development

- Deliver science and regulatory educational programs in support of training needs assessment
- Establish Competency Curricula
- Redesign Reviewer Training Program





Workforce Excellence

Workforce Readiness

- Create the framework to build a succession plan in support of CDRH mission, goals, and strategies
- Be prepared to successfully handle upcoming challenges and opportunities
 - Leadership continuity
 - Workforce readiness

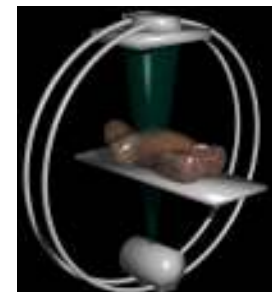


Research Prioritization

- Peer review type process to evaluate Office of Science and Engineering Laboratories activities
- Involves external scientific experts and internal regulatory experts from the premarket, postmarket, and compliance components of the Center



Cone-beam CT



Virtual Cath Lab





Research Prioritization

Have:

- Resulted in a more focused and productive research enterprise
- Forged collaborations across the Center and outside the Center
- Significantly strengthened the scientific quality of our regulatory actions



Cone-beam CT



Virtual Cath Lab



Preparing for the Future...

- **CDRH continues to face new challenges in regulating medical and radiological products and in ensuring their safe use**
- **Medical device regulation must be aligned with the future of medical device technology**



Preparing for the Future...

- **It is imperative that we have a regulatory process that is vigilant regarding the directions of those changes and capable of keeping pace with those changes**
- **Despite our best efforts to predict what our challenges and opportunities of the future will be, inevitably there will be surprises that will require an ability to adapt quickly to the unexpected**