



Device Regulation -- Past, Present, and Future

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Agenda

- A brief history of FDA regulation
- Theory of regulation
- Overview of FDA device regulation
- OUS device regulation
- Current FDA issues
- Future trends in device regulation

FDA is not the only regulatory agency impacting medical devices

- SEC
- OSHA
- FTC
- FCC
- OUS country regulations
- Etc.

A Brief FDA History

- 1906 Pure Food & Drug Act
 - Required food and drugs to not be adulterated or misbranded. Triggered by meat packing conditions documented in “The Jungle”
- 1938 Food, Drug, and Cosmetic Act
 - Required FDA approval for drug safety. Triggered by Elixir Sulfanilamide deaths due to diethylene glycol toxicity
- 1962 Drug Amendments
 - Increased Drug safety standard and required demonstration of effectiveness. Triggered by birth defects caused by Thalidomide.
- 1976 Device Amendments
 - Established premarket requirements for medical devices. Triggered by Dalkon Shield IUD injuries

A Brief FDA History (cont.)

- 1990 Safe Medical Devices Act (SMDA)
 - Established authority for Design Controls, Tracking, Postmarket Surveillance, Corrections and Removals reporting, and specific Penalties for non-compliance
- 1997 FDA Modernization Act (FDAMA)
 - Numerous changes intended to accelerate device approvals and reduce device approval “gap”
 - Established 30-day notice for certain manufacturing changes
- 2002 Medical Device User Fee and Modernization Act (MDUFMA)
 - Established Device User Fees
- 2007 MDUFMA II
 - Reauthorized Device User Fees.

Theory of regulation

- Society expects central government to help keep them safe (e.g., Steamboat Boiler Act of 1838)
- Safety is the second step (after physiological needs met) in Maslow's hierarchy
- Typically results in a generalized solution in reaction to a specific problem
- When in doubt, regulate. GAO never finds fault in overregulation!

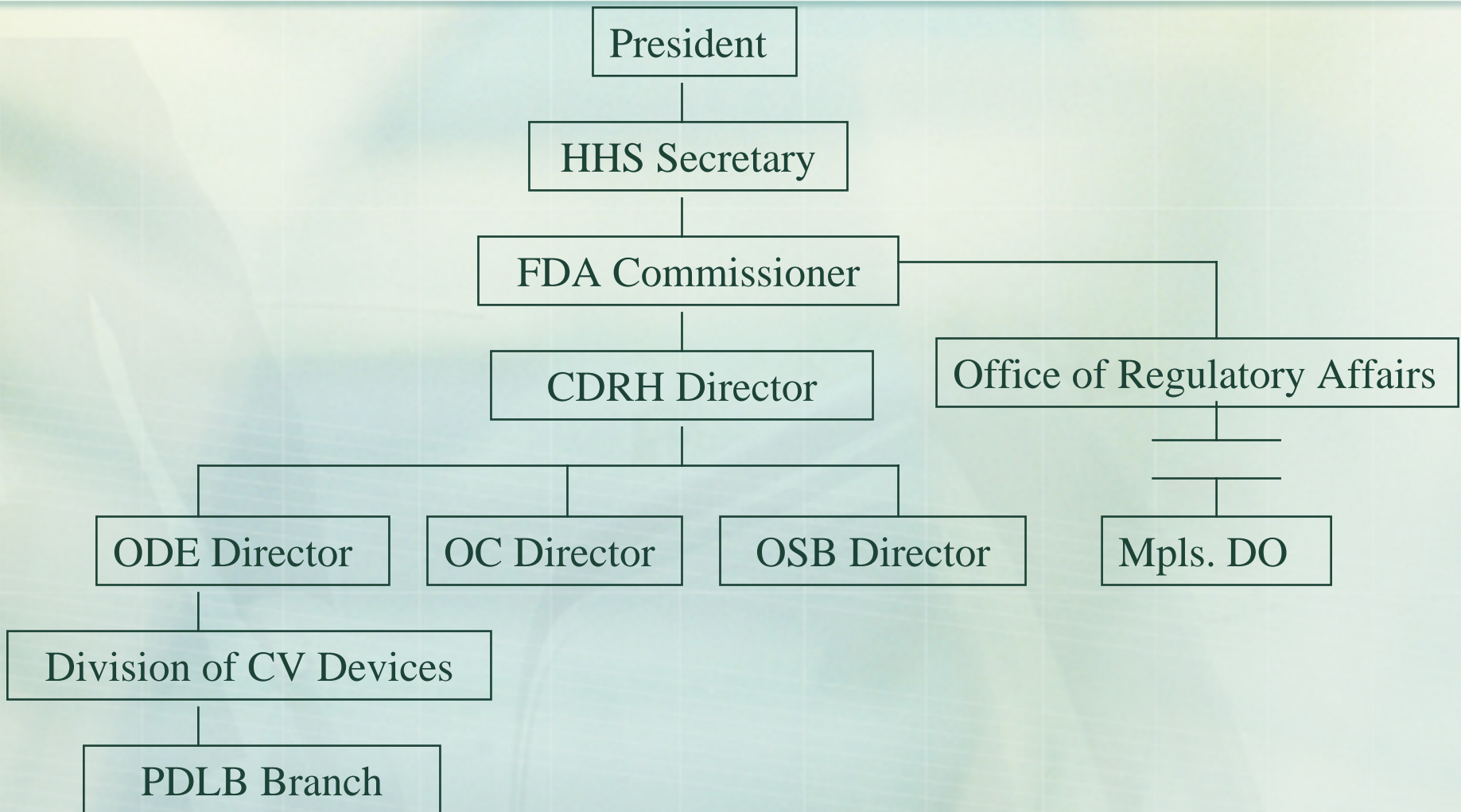
Regulation Begets Regulation

- Resources grow with time
- Activity finds other “problems”
- More regulation develops
- Opportunities for action abound!

FDA Is A Political Not A Scientific Agency

- Part of the executive branch
- Overseen by legislative and judicial branches
- Responds to public and political pressure (e.g., Plan B)
- Reactive to problems
- “A slow moving target that bleeds profusely when hit.”

FDA Organization Chart



Main FDA Device Regulations

- 21 CFR (Code of Federal Regulations)
 - Part 801 (Labeling)
 - Part 803 (Medical Device Reporting)
 - Part 806 (Corrections and Removals)
 - Part 807 (Registration, Listing, Premarket Notification (510k))
 - Part 812 (Investigational Device Exemption)
 - Part 814 (PreMarket Approval)
 - Part 820 (Quality Systems)
 - Part 821 (Device Tracking)
 - Part 822 (Postmarket Surveillance)
 - Part 860 (Device Classification)
- Parts 210/211 (Drug cGMP)

FDA Submission types

- PreMarket Approval (PMA)
- 180-day PMA-Supplement
- Real-Time Review PMA-Supplement
- 30/135-day Notice
- Investigational Device Exemption (IDE)
- IDE-S
- 510k
- PMA Annual Report

FDA PMA approval standard

- “... valid scientific evidence ... there is reasonable assurance that the device is safe and effective...”
- “Valid scientific evidence is evidence from well-controlled investigations ... that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use...”

User Fees

- User fees for medical devices updated in 2007 by MDUFMA II.
- Current fees (FDA FY08):
 - PMA ----- \$185,000
 - PMA-S ----- \$27,750
 - RTR PMA-S - \$12,950
 - 510K ----- \$3404
 - New fees for 30-day notice, reclassification petition, facility registration, PMA Annual report
- ~23% of CDRH budget in FY08
- Some improvement in performance goal incentives
- Overall approval times not improved
- FDA challenge to also find resources to support increased postmarket surveillance

OUS Device regulation examples

- European Community
 - Single Notified Body approval allows distribution throughout EC
 - Notified Bodies (e. g., TÜV) are private companies overseen by government Competent Authorities
 - Conformance to Directive (safety) presumed if compliant to harmonized standards
 - Lower standard of effectiveness than US
 - Requires license renewal every 3-5 years to continue distribution

OUS Device Regulation Examples

■ Japan

- Significant changes to Pharmaceutical Affairs Law (PAL) in 2005
- Reviews performed by PMDA, a quasi-governmental agency overseen by MHLW
- Very prescriptive submission requirements and very detail oriented review
- Very low tolerance for quality issues

How FDA ensures compliance

- Review of manufacturer S & E data prior to marketing (e.g., PMA)
- Review of manufacturer postmarket information
 - MDR
 - C&R reports
 - Postmarket studies
- Facility Inspections
- 483/Warning Letters
- Civil/Criminal penalties

Is FDA a burden on industry?

- Generally requirements reflect good business/science (there are exceptions!)
- FDA regulation provides barrier to entry for potential competitors
- Helps ensure market confidence and credibility with physicians, patients, and public (currently an issue!)
- The capability to comply with FDA regulations may be a competitive advantage

Recent FDA Postmarket Issues

■ Products

- ICDs
- DES
- Vioxx

■ Process

- MDR review/MAUDE database
- PMA Annual report content/review
- COA/522 postmarket studies
- Lack of FDA cross division communication
- Product change notification/approval

Future trends in device regulation

- Increased regulator to regulator communication
- Global Harmonization for device approvals?
- Focus on Supplier Controls part of QSR
- Increased focus on postmarket performance
- FDA user fees?
- More targeted approach to inspections
- Increased evidence required for device approval
- Increased device regulation in emerging markets (e.g., China, Korea, India)

Questions?

