The Office of the National Coordinator for Health Information Technology

HIT Policy Committee

FDASIA Workgroup Kickoff Meeting

April 29, 2013
10:00 – 12:00 PM Eastern

HealthIT.gov

Agenda

- Opening Remarks
- Welcome
- Introductions
- Process and Procedures for Federal Advisory Committee Workgroups
- Workgroup Scope
- Tri Agency Overviews
- Next Steps
- Public Comment

FDASIA Workgroup Members Introductions

- **David Bates, Chair**, Brigham and Women's Hospital
- **Patricia Brennan**, University of Wisconsin-Madison
- **Geoff Clapp**, Better
- **Todd Cooper**, Breakthrough Solutions Foundry, Inc.
- **Meghan Dierks**, Harvard Medical Faculty, Division of Clinical Informatics
- **Esther Dyson**, EDventure Holdings
- **Richard Eaton**, Medical Imaging & Technology Alliance
- **Anura Fernando**, Underwriters Laboratories
- **Lauren Fifield**, Practice Fusion, Inc.
- **Michael Flis**, Roche Diagnostics
- **Elisabeth George**, Philips Healthcare
- **Julian Goldman**, Massachusetts General Hospital/ Partners Healthcare
- **T. Drew Hickerson**, Happtique, Inc.
- **Jeffrey Jacques**, Aetna
- **Robert Jarrin**, Qualcomm Incorporated
- **Mo Kaushal**, Aberdare Ventures/National Venture Capital Association
- **Keith Larsen**, Intermountain Health
- **Mary Anne Leach**, Children's Hospital Colorado
- **Meg Marshall**, Cerner Corporation
- **Mary Mastenbrook**, Consumer
- **Jackie McCarthy**, CTIA - The Wireless Association
- **Anna McCollister-Slipp**, Galileo Analytics
- **Jonathan Potter**, Application Developers Alliance
- **Jared Quoyeser**, Intel Corporation
- **Martin Sepulveda**, IBM
- **Joseph Smith**, West Health
- **Paul Tang**, Palo Alto Medical Foundation
- **Bradley Thompson**, Epstein Becker Green, P.C
- **Michael Swiernik**, MobileHealthRx, Inc.

Federal Ex Officios

- **Jodi Daniel**, ONC
- **Bakul Patel**, FDA
- **Matthew Quinn**, FCC

Process & Procedures for Federal Advisory Committee Workgroups

- HIT Policy Committee (HITPC) is a Federal advisory Committee subject to the Federal Advisory Committee Act (FACA).
- Role of the HITPC is to advise the National Coordinator for Health Information Technology on a policy framework for the development and adoption of a nationwide health information infrastructure .
- FDASIA Workgroup is a subcommittee to the HITPC and cannot provide advice or recommendations directly to ONC, the Workgroup only reports to the HITPC
- All Workgroup meetings are open to the public, and ONC values and encourages public input
  - Additional avenues for public input are virtual listening sessions, blog postings, hearings
- Majority of the Workgroup meetings are held virtually with possible in person meetings
- Audio recordings for each Workgroup meeting are posted on the ONC website along with all the meeting materials
- All official calendar appointments and meeting materials are distributed from the ONC FACA Meetings email account

- Agency 101's
  - –Authority
  - –Current Activities

Office of the National Coordinator for Health IT (ONC)

- Authority (2-fold):

1. Administer voluntary certification program for health IT

   Title XXX of Public Health Service Act (PHSA), section 3001(c)(5):

   The National Coordinator…shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle.

2. Adopt standards, implementation specifications, and certification criteria for health IT (PHSA section 3004)

Health IT defined (section 3000(5)) to mean:

hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information

Office of the National Coordinator for Health IT (ONC)

- Current activities:
  - Administer ONC HIT Certification Program
    - Current focus is on electronic health record (EHR) technology
  - Issued draft Health IT Patient Safety Action and Surveillance Plan (Dec 2012)
  - Coordinate with FDA, AHRQ, CMS, and many other federal agencies on the intersection of health IT and patient safety

Federal Communications Commission

FCC Activities in Healthcare and Health IT

FDASIA Workgroup
April 29, 2013

Matt Quinn
Director of Healthcare Initiatives

Federal Communications Commission

Mission

The FCC was established by the Communications Act of 1934 and is charged with regulating interstate and international communications by radio, television, wire, satellite and cable. The FCC's jurisdiction covers the 50 states, the District of Columbia, and U.S. possessions.

Staff & Offices

- Approx. 1700 Attorneys, Engineers, Economists, et al
- HQ at 445 12th St, SW, Wash., DC
- Lab in Columbia, MD
- Field Offices: 3 Regional, 16 District, 8 Resident Agent

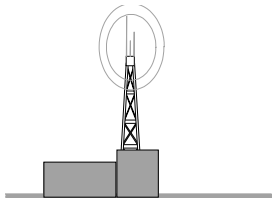
*Commissioners Group Photo, May 2012*L to R: Commissioner Jessica Rosenworcel, Commissioner Robert M. McDowell, Chairman Julius Genachowski, Commissioner Mignon Clyburn and Commissioner Ajit Pai.

www.fcc.gov

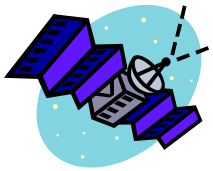
FCC Areas of Responsibility

- **Spectrum**
  - FCC manages non-federal spectrum
  - Promote access to airwaves for wireless medical devices, radio services that support Health IT applications
- **Rural Health Care Program**
  - Support broadband for health care providers
  - Promote telemedicine adoption
- **Broadband**
  - Advance wireline and wireless communications services and technologies
- **National Broadband Plan**

Licensed Radio Services



- Broadcasting

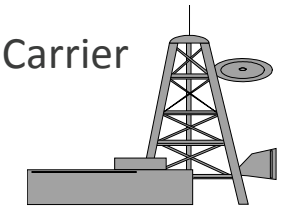


- Satellite

- Private Wireless
  - Public Safety
  - Industrial
  - Aviation
  - Marine
  - Amateur

- Commercial Mobile
  - Cellular
  - Personal Communicatio
  - Advanced Wireless
  - 700 MHz
  - Broadband Radio Service

- Fixed Wireless
  - Private
  - Common Carrier



Standards For Licensed Radio Services

- Primarily focus on interference control
  - Frequency
  - Power Output
  - Bandwidth/Channels
  - Spurious Emissions
- Other:
  - RF Exposure
  - Hearing aid compatibility
  - E-911

- Rules strive to be technology neutral
- FCC *generally* has not regulated:
  - Protocols (i.e. LTE, WiMAX)
  - Performance
  - Reliability
  - Compatibility

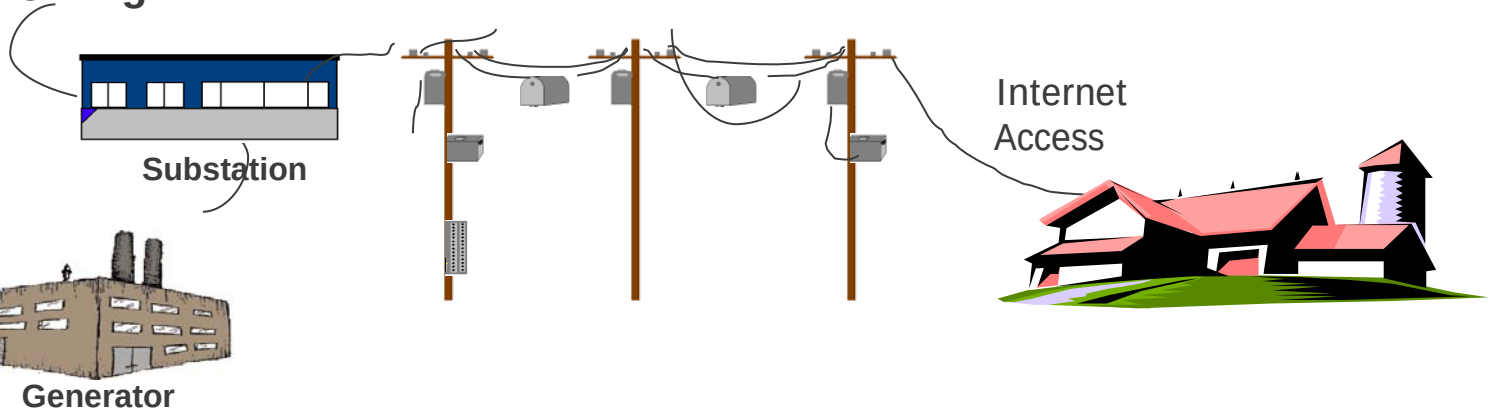
Unlicensed Devices (Short Range Devices)

Part 15 provides for unlicensed devices: May not cause harmful interference and must accept any interference that may be received.

Business & home networking

Metropolitan & Community Networks – WISPs

Devices for Consumer And Business Applications



Technical Standards for Unlicensed Devices

- Primarily focus is on interference control
- Operating frequencies/restricted bands
- Power/signal strength
- Out-of-band and spurious emissions
- Industry has developed protocol standards within the framework of the rules: Wi-Fi, Bluetooth; Zigbee; Homeplug, etc.

Equipment Authorization Required

- Multi-tiered equipment authorization program - - many devices self-declared
- Most transmitters must be certificated by FCC or telecommunications certification body
- Equipment may not be imported or marketed until certificated
- Check label for FCC ID
- Grants of certification available on FCC web site

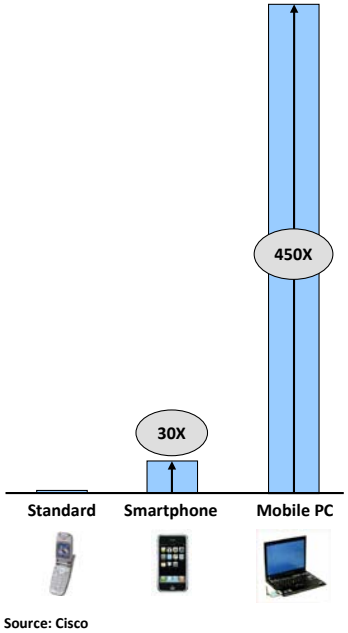
Equipment Authorization (EA)

Office of Engineering and Technology (OET)

See http://www.fcc.gov/oet/ea/

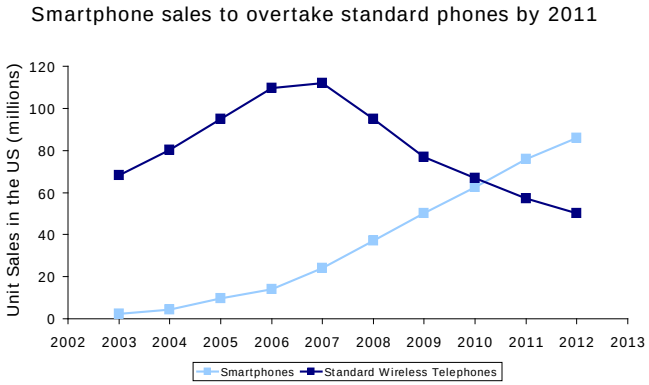
FCC Id: XXXYYYY

Why it matters for health care: Spectrum is the "oxygen" that wireless broadband needs to thrive



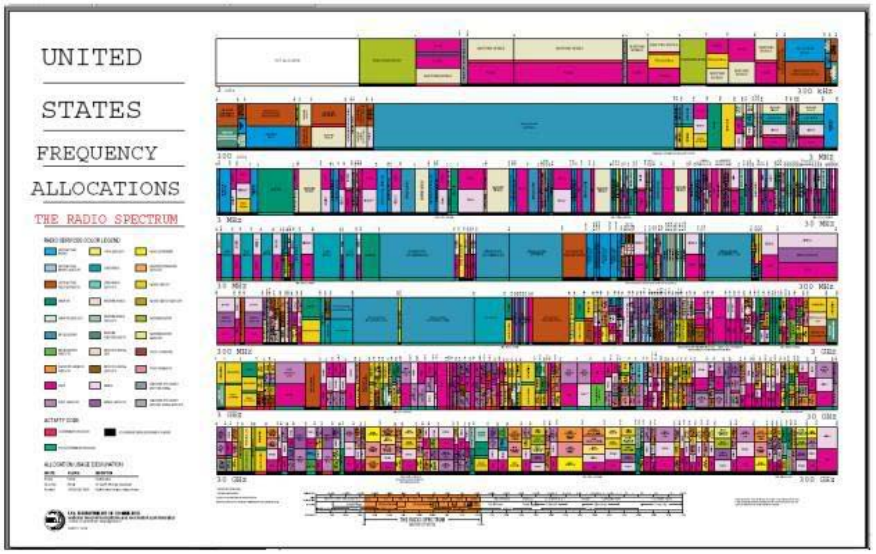
Source: Cisco

Hungry Devices



Source: TIA, Wilkofsky Gruen Associates from "TIA's 2009 ICT Market Review and Forecast".

Consumer Apps



National Purposes

Civic Engagement

Telemedicine

Public Safety

Smart Grid

FCC – FDA Cooperation

- FCC and FDA have worked together for many years:
  - FCC: Office of Engineering and Technology and Wireless Telecommunications Bureau
  - FDA: Center for Devices and Radiological Health
  - Meet regularly to discuss topics of mutual interest
- Past and ongoing topics:
  - Managing interference to telemetry systems from DTV
  - Managing transition of telemetry in 450 MHz band
  - Identifying new spectrum for telemetry systems
  - Electromagnetic Compatibility (EMC)
  - Hearing aid compatibility of wireless phones
  - Radio frequency Exposure
- Ongoing consultation among FCC and FDA staff:
  - Guidance for wireless medical apps
  - Guidance for EMC
  - Guidance for RF safety

Joint Statement on Wireless Medical Devices
U.S. Food and Drug Administration Federal Communications Commission

July 26, 2010

- Innovation in broadband and wireless-enabled medical devices holds significant promise for enhancing health and reducing the costs of health care for all Americans. Examples include wireless sensors that remotely monitor heart rhythm and portable glucose monitoring systems. All Americans should be afforded the opportunity to benefit from medical technology advances with improved broadband and wireless technology.

- Developing and integrating wireless and broadband communications technology with medical devices and applications requires agencies to assure that such devices operate in a safe, reliable and secure manner.

- It is important for the federal government to provide leadership and encourage innovation and investment in new health care technologies that enable patients, doctors, and other health professionals to access the highest quality care.

- The American public -- including industry, providers, patients, and other interested stakeholders -- should have clear regulatory pathways, processes, and standards to bring broadband and wireless-enabled medical devices to market. This includes clarity regarding each agency's scope of authority with respect to these devices, predictability regarding regulatory pathways, and streamlining the application process, as appropriate, to facilitate innovation while protecting patients.

- The FDA and the FCC agree to build upon this initiative launched today to proactively serve the national interest in finding innovative solutions to America's health care challenges.

Food and Drug Administration (FDA)	Federal Communications Commission (FCC)
Commissioner Dr. Margaret Hamburg	Chairman Julius Genachowski

mHealth Task Force

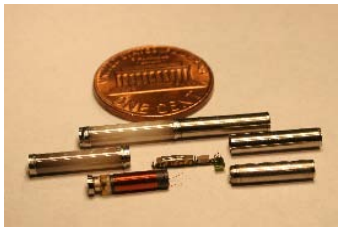
- FCC held mHealth Summit to bring together academia, industry and gov't to accelerate adoption of wireless health technologies.
- mHealth Task Force released its report and recommendations to the public (Sept 2012)
  - Goal: **For mHealth technology to become a routine medical best practice within five years.**
- FCC has acted on key recommendations:
  - Enable wireless test beds
  - Create the Health Care Connect Fund
  - Promote international spectrum usage for MBANs
  - Enhance FCC coordination with CMS
  - Hired a permanent Director of Health Care Initiatives
  - Improve interagency alignment, data sharing, and cooperation
  - Launch FCC.gov/health

FCC Actions

- Granted waivers for various medical devices
  - Boston Scientific
  - Dexcom
  - Enteromedics
  - Pending: Second Sight

- Adopted rules to expand spectrum for medical implant communications service
  & created medical device service

- Proposed rules to provide spectrum for:
  - medical body area networks (MBANs)
  - nerve stimulators to restore motion



Thank You!

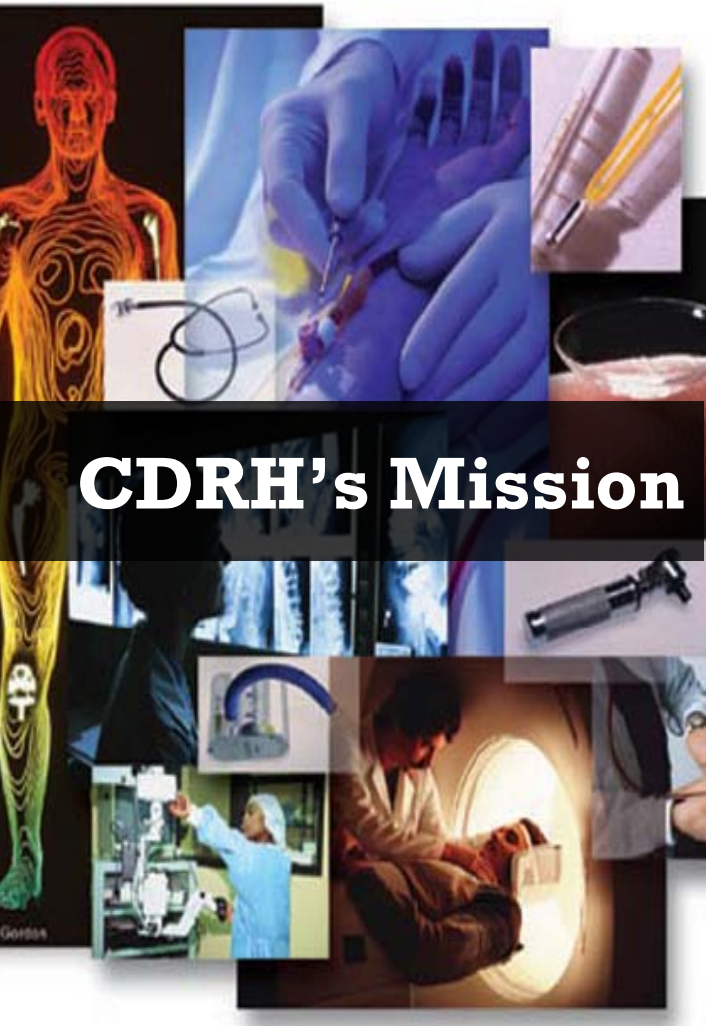
Matt Quinn
Director of Healthcare Initiatives
Federal Communications Commission (FCC)
Email: matthew.quinn@fcc.gov

Overview of Medical device Regulations

Center for Devices and Radiological Health

Overview

- CDRH mission
- Types of medical devices
- Medical device software
- Risk based approach
- Smart oversight



CDRH's Mission

- We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
- We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee.
- We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Vision

- **Patients** in the U.S. have **access** to high-quality, safe, and effective medical devices of public health importance first in the world.
- The U.S. is the world's leader in regulatory science, medical device **innovation** and manufacturing, and radiation-emitting product safety.
- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and **facilitates** device approval or clearance.
- Devices are legally marketed in the U.S. and remain **safe, effective, and of high-quality.**
- Consumers, patients, their caregivers, and providers have **access to understandable science-based information** about medical devices and use this information to make health care decisions.

Definition of Device

SEC. 201. [321] For the purposes of this Act –

(h) The term "device" … means an instrument, apparatus, implement, **machine, contrivance, implant, in vitro reagent, or other similar or related article**, including any component, part, or accessory, which is--

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals**, or

(3) **intended to affect the structure or any function of the body of man or other animals**, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Medical Device

The Section 201(h) of the Food, Drugs and Cosmetics Act defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.

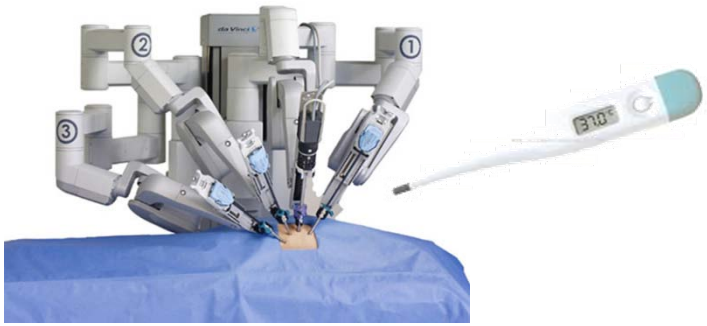
- As simple as a tongue depressor or a thermometer

- As complex robotic surgery devices

The products we regulate…

..include medical device software…

Software in a device

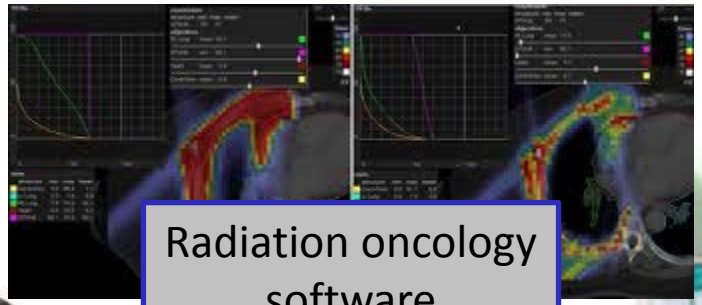


Software as a device

Software that is used in the manufacturing process of a device

Examples of software as devices

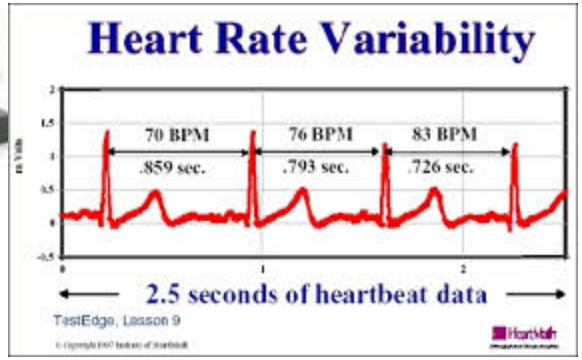
EEG analysis software

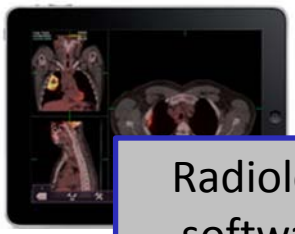


Radiation oncology software

Lab information systems

Diabetes management





Radiology software

Clinical lab software

…using a risk based approach since 1976

Increasing Risk

Classification determines extent of regulatory control (Risk Based)

Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

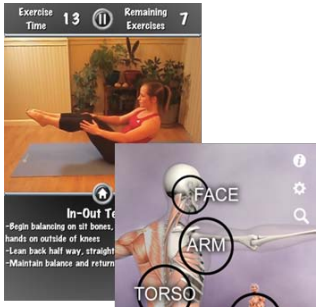
Special Controls (addressing Risk)
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)

Mobile medical apps draft guidance

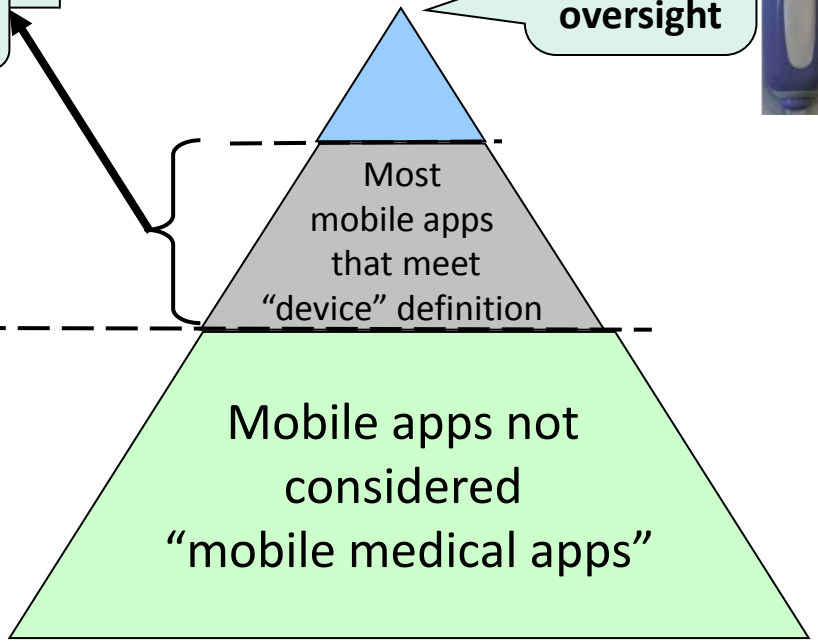
- Patient self- management apps
- Simple tracking or trending apps (not intended for treating/adjusting medication)

Enforcement Discretion

Proposed focus of oversight



No regulatory requirements



Proposed mobile medical apps policy

Active oversight – if mobile app meets the definition of medical device under section 201(h) and either,

- are used as an accessory to already regulated medical device,
  or
- transforms a mobile communication device into a regulated medical device.

FDA's approach

- **Smart regulation**
  - Focus oversight on higher patient risk technology /software
  - Selective use of regulatory tools appropriate for technology
  - Scaling back from traditional approach (class 1, Class II Class III)
  - Relying on a quality systems approach

- **Examples of recent actions**
  - MDDS down classification – no premarket submission
  - Mobile medical apps – focused on small subset – encouraging innovation in mHealth

Conclusion

- FDA recognizes the importance of balancing patient safety while facilitating innovation

- FDA has a menu of tools that we plan to apply judiciously