Who We Are

HEADQUARTERS
Boston, MA

FOUNDED
1998

TEAM
75-100 personnel
(~60 FTEs and ICs)

Laurie Halloran
President and CEO

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Chief Operating Officer

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Managing Director

Paola Murphy
Managing Director

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Managing Director & Chief Medical Officer
Today’s Presenters

Peter Ohanian
Principal Consultant

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Topic Introduction

- mHealth Scope
- Current Regulations and Guidance
- Current real-world scenarios
What is Mobile Technology?

• NOT wired, traditional devices
• NOT closed system technology
• NOT proprietary devices
Mobile Technology & mHealth

• Mobile device
• Phone/cellular communications
• Many available to consumers
• Increasingly used in patient care
What is a Medical Device?

“...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

**recognized in the official National Formulary**, or the United States Pharmacopoeia, or any supplement to them,

**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

**intended to affect the structure or any function of the body** of man or other animals, and which does not achieve its primary 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 primary intended purposes."

Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act
Most products in the mHealth space will need to consider:

“...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...”

Does your solution meet this part of the definition?

To help, FDA has provided additional guidance on three categories of products:

- General Wellness Product
- Medical Device Data System
- Mobile Medical Application
Regulatory Landscape

- **No FDA regulatory enforcement**
  - General Wellness Product
  - Medical Device Data System
  - Mobile App

- **FDA regulatory enforcement**
  - Mobile Medical App
  
  **Includes:**
  - Premarket Review
  - Registration and Listing
  - Labeling
  - QSR
  - MDR
Regulatory Landscape
General Wellness Products

A General Wellness Product is **low risk** and is intended to **maintain a healthy lifestyle**.

A product is **NOT** low risk if it:

- Is invasive
- Is implanted
- May pose a risk to the safety of users and other persons if controls are not applied (e.g. lasers or radiation exposure)
Regulatory Landscape
General Wellness Products

A General Wellness Product.....:

**Is**
- Plays music to “soothe and relax” and to manage stress
- Monitors/records energy expenditure and cardiovascular workout activities
- Monitors/records food consumption to “manage dietary activity for weight management...”
- Reminder to keep exposed skin out of direct sunlight when the UV index is high
- Monitor pulse rate during exercise

**Is Not**
- Sunlamp tanning products
- Implants
- Laser skin rejuvenation product
- Neurostimulation product
Regulatory Landscape
Medical Device Data Systems

• Medical Device Data Systems can be deployed on mobile platforms

• Medical Device Data Systems (MDDS) can transfer, store, convert and display medical device data. It does not modify the data or control another medical device. It is not used for active patient monitoring.

• A Medical Device Data System (MDDS) is “officially” a Class I exempt device (880.6310)

• FDA will not enforce compliance
Regulatory Landscape
Medical Device Data Systems

A Medical Device Data System.....

Is
• Stores patient data such as blood pressure readings for review at a later time
• Converts digital data generated by a pulse oximeter into a format that can be printed
• Displays previously stored electrocardiogram for a particular patient
• Transmits a child’s temperature from school to parent
• Remote display of information from blood glucose meter

Is Not
• In hospital patient monitoring
• Used for active patient monitoring such as a telemetry station
• Receives or displays information, alarms or alerts from a home monitoring device that is intended to alert caregiver to take immediate action
Regulatory Landscape
Mobile Medical Applications

Mobile App
Software that runs on a mobile platform

Mobile App that MAY meet the definition of a device BUT is low risk

Mobile Medical App
A Mobile App that meets definition of a device

No FDA regulatory enforcement

FDA regulatory enforcement
Regulatory Landscape
Mobile Medical Applications

- Medical Textbooks
  - PDR
- Anatomy diagrams
- Educational tools
- Determine billing codes
- Magnifying glass app
  - Amplify audio

- MDDS
  - Body Mass Index calc
  - Transmit photos
  - Log/track health info
  - Send alert to first responders

- Electronic stethoscope
  - CPR assist
  - Change setting on infusion pump
  - Controls inflation of BP cuff
  - Transfer data from bedside to central
  - Display medical images for diagnosis

No FDA regulatory enforcement
FDA regulatory enforcement
Regulatory Landscape
Other Considerations

• **Health Insurance Portability and Accountability Act (HIPAA)**
  If the device is creating, receiving, maintaining or transmitting identifiable health information, HIPAA may apply.

• **Cybersecurity**
  If the device connects to another device, the internet or other network, or to portable media, appropriate cybersecurity safeguards need to be considered.

• **Federal Trade Commission Act**
  Prohibits deceptive or unfair acts or practices, including those related to privacy and data security, and those involving false or misleading claims about safety or performance.
Regulatory Strategy
Do I Need One?

- Classifying your product as a General Wellness Product, MDDS, or Mobile App effectively removes the product from FDA regulatory requirements. Be sure to get it right!
- If in doubt, partner with an organization that will guide you through the process
- FDA is available to help. Consider utilizing the Q-Sub pre-submission process or submitting a 513(g) request for classification information
Regulatory Strategy
Do I Need One?

Is it a Medical Device?
What is the intended use?
How will it be marketed?
Competitive products?

Determine Device Class and Classification

Identify Regulatory Requirements
Premarket review
Registration and Listing
QSR
Labeling
MDR

Document!!!
Regulatory Strategy
Decision Tree

Mobile Health Apps Interactive Tool


- Helps in understanding the regulations that apply when developing a health related app for mobile devices
5. Is your app intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease?

**YES**

Your app is a medical device subject to the FD&C Act.

**GO TO QUESTION 6** to see if the FDA intends to apply its regulatory oversight for your type of app.

**NO**

The FD&C Act does not apply. Your app is not considered a medical device and is outside of FDA purview. For examples of mobile apps that are not medical devices, see Appendix A of the FDA’s Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff [PDF].

**GO TO QUESTION 8** to see if the FTC Act applies.

6. Does your app pose “minimal risk” to a user?

According to the FDA, “minimal risk” apps are those that are only intended for one or more of the following:

- Help users self-manage their disease or condition without providing specific treatment suggestions;
- Providing users with simple tools to organize and track their health information;
- Providing easy access to information related to health conditions or treatments;
- Helping users document, store, or communicate potential medical conditions to health care providers;
- Automating simple tasks for health care providers;
- Enabling users or providers to interact with Personal Health Records (PHR) or Electronic Health Record (EHR) systems; and
- Transmitting, storing, converting format or displaying medical device data, as defined by the FDA’s Medical Device Data Systems regulations.

**YES**

**NO**
Real-world Case Discussion
Alivecor iPhone ECG

- iPhone and Android compatible
- “Medical Grade” ECG
- $99 direct
Fitbit (and other fitness bands)

Children's Hospitals and Clinics of Minnesota is using the popular fitness wearable to measure activity and sleep in its young diabetic patients.

Carolinas HealthCare launches app platform that allows consumers to download data from more than 70 mobile devices – including Fitbits – to a patient portal that they can then share with their doctors.

Fitbit helps man get vital heart treatment in Camden hospital
First recorded case of doctors using device to make medical decision (phillyvoice.com)
Powerdot Muscle Stimulation

• Smartphone-controlled
• Electrical muscle stimulation (EMS)
• “Boost muscle strength, power and endurance.”
• Speed muscle recovery
MyDario – Smartphone-based glucometer

- Smartphone-based
- Device available commercially
American Well

Telemed Sidekick App

- supplements a live video consultation with images taken on the iPhone.
- Doctors can now easily snap and send pictures of EKGs, Xrays, patient history, and more to a specialist consulting through our Telemed Tablet.
- Images are not saved or stored after the visit, protecting patient privacy and ensuring compliance

Support ER doctors at critical moments

Emergency physicians can reach out to specialists for on-demand guidance through the Telemed Tablet, using the Sidekick app to put still images like Xrays and CT scans in front of them. Specialist expertise helps ER doctors deliver the right care, right in the moment.
References

- FDA Guidance – “Medical Device Data Systems, Medical Image Storage Devices and Medical Image Communications Devices, February 9, 2015
- FDA Guidance – “Mobile Medical Applications”, February 9, 2015
- FDA Guidance – “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, October 2, 2014
- FDA Guidance – “Postmarket Management of Cybersecurity in Medical Devices”, January 22, 2016 DRAFT
- FDA Guidance – “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”, February 18, 2014
Thank You!

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