FDA U.S. FOOD & DRUG ADMINISTRATION

Fostering Digital Health Innovation: FDA's Approach to Mobile Apps

FDA Small Business
Regulatory Education for Industry (REdI)
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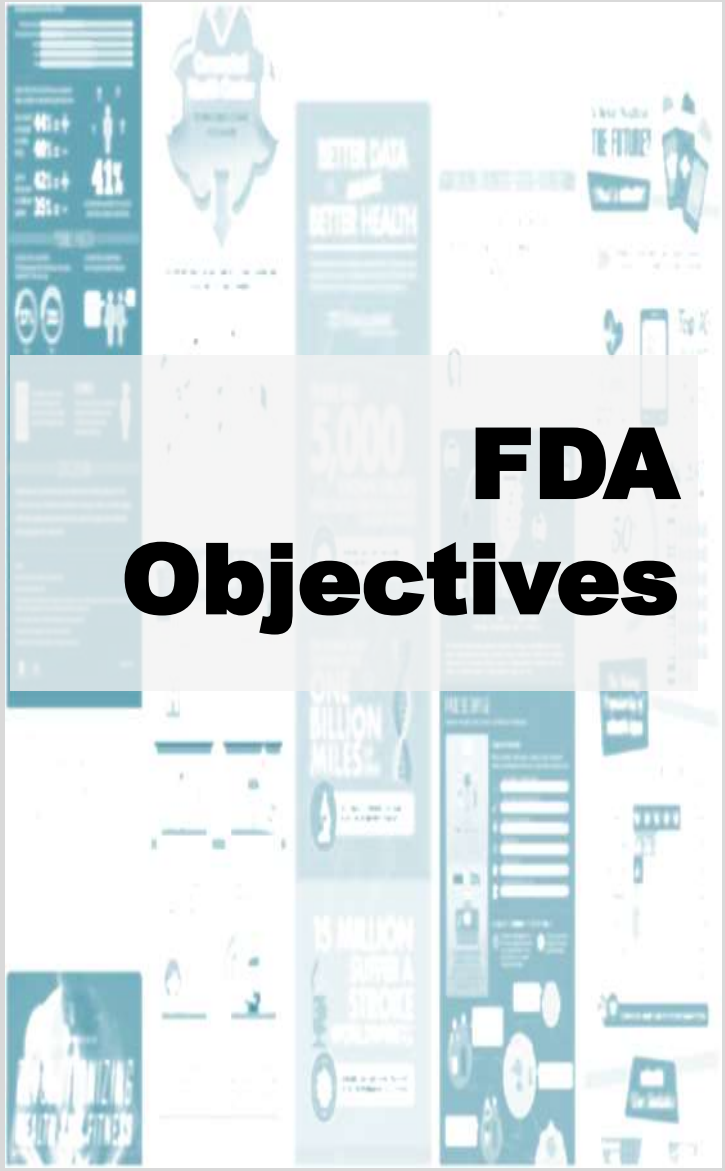
Imagine Digital Health Innovation

https://www.youtube.com/watch?v=rj_FGR8qwnE&feature=youtu.be

Learning Objectives

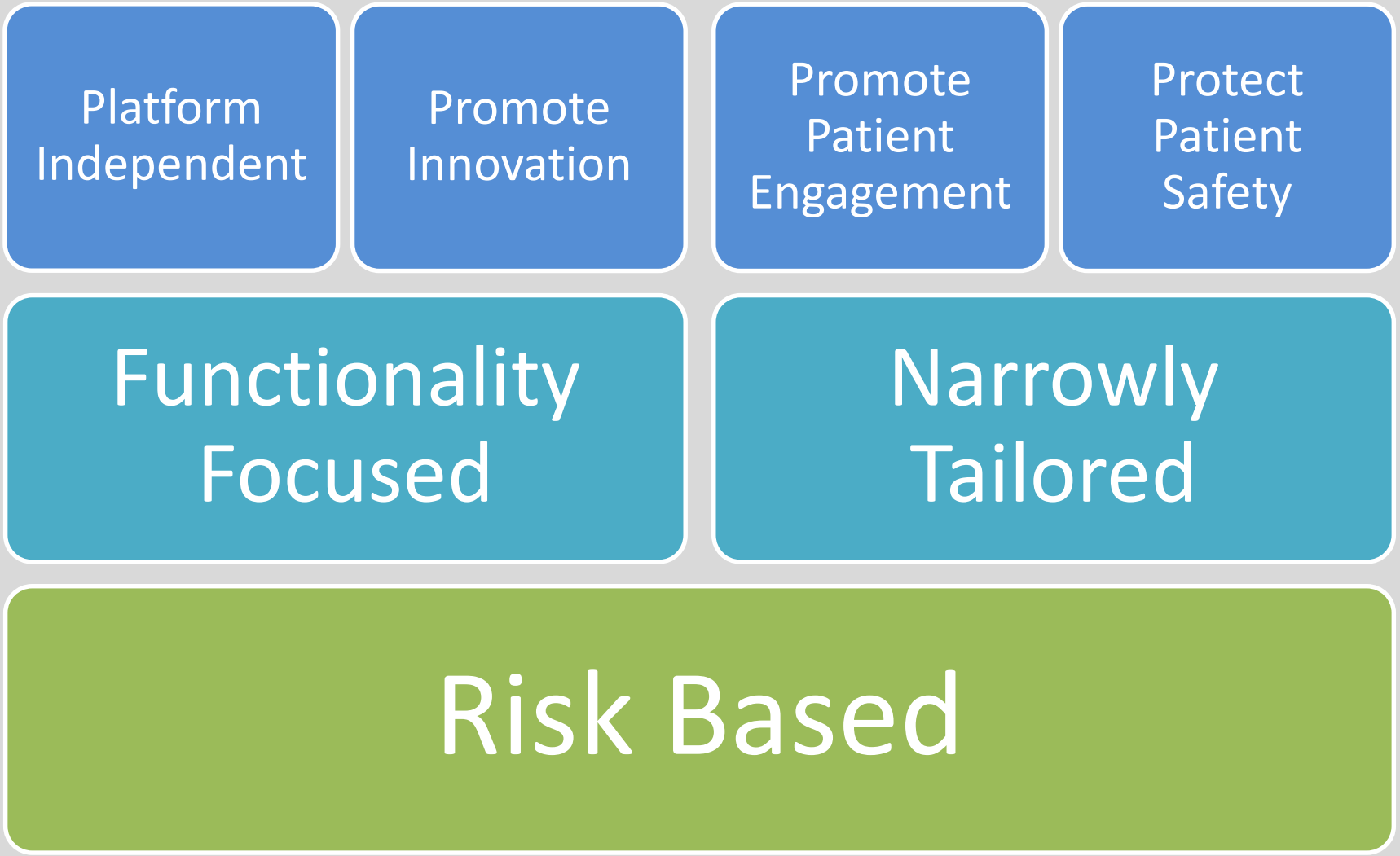
- Learn basis terminology involved with mobile apps
- Understand FDA's risk-based approach to regulating mobile medical apps
- Use examples to illustrate how FDA distinguishes apps from mobile medical apps



FDA Objectives

- **Enable patient-centered public health**
  - Digitization touches every aspect of healthcare
- **Foster trust in innovative technologies**
  - To enable new health care paradigm
- **Partner with customers**
  - To be digital-future ready

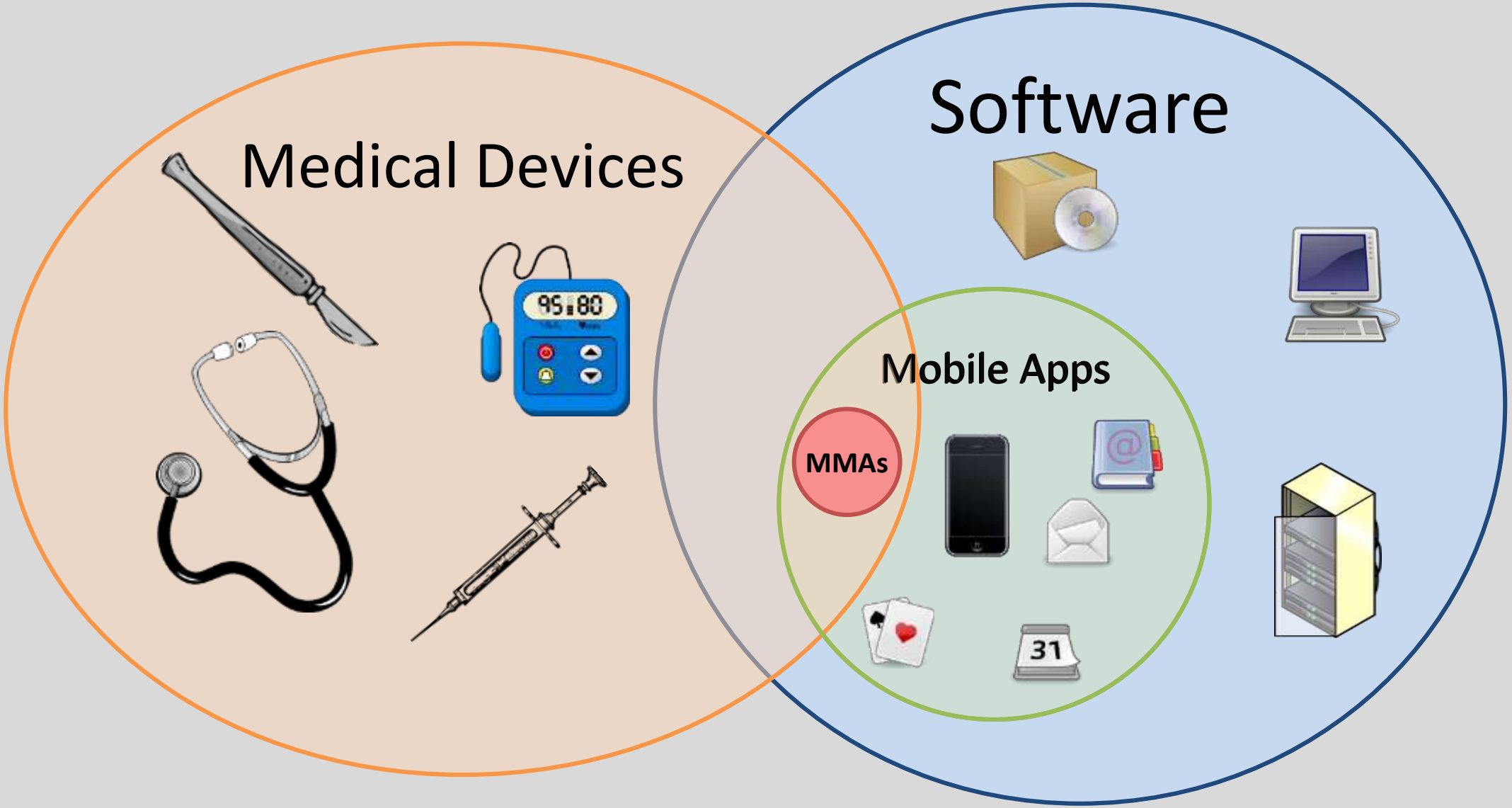
Smart Regulation Principles



Mobile Platform

- Commercial off-the-shelf (COTS) computing platforms
  - with or without wireless connectivity
  - handheld in nature
- Examples:
  - smart phones, tablets and other portable platforms
- FDA **does not** regulate mobile phones or other general purpose computers

Mobile Apps Landscape



Mobile Medical App

- Software application
- Executed on a mobile platform that meets the definition of device

AND

- is used as an accessory to a regulated medical device; or
- transforms a mobile platform into a regulated medical device.

Mobile Medical Apps Guidance

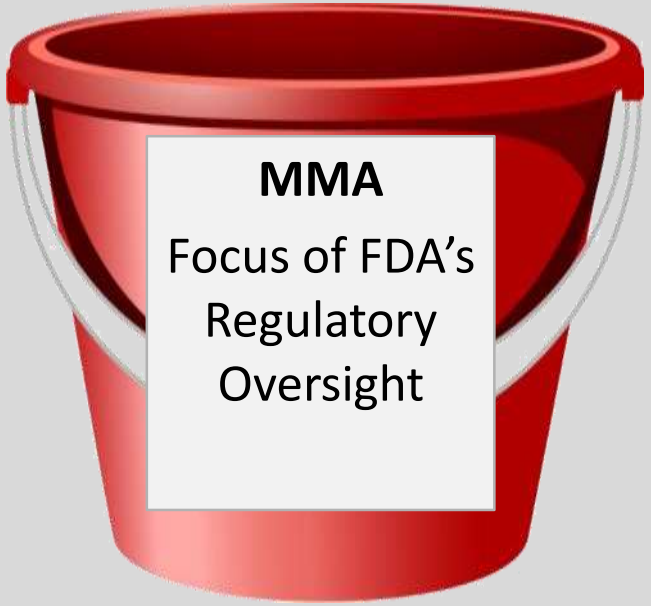
- Focuses only on functionality and not platform
- Identifies types of apps to which FDA doesn't intend to enforce regulatory controls
- Clarifies what is not a device

Intended Use

- The intended use of a mobile app determines whether it meets the definition of a device.

- May be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives.

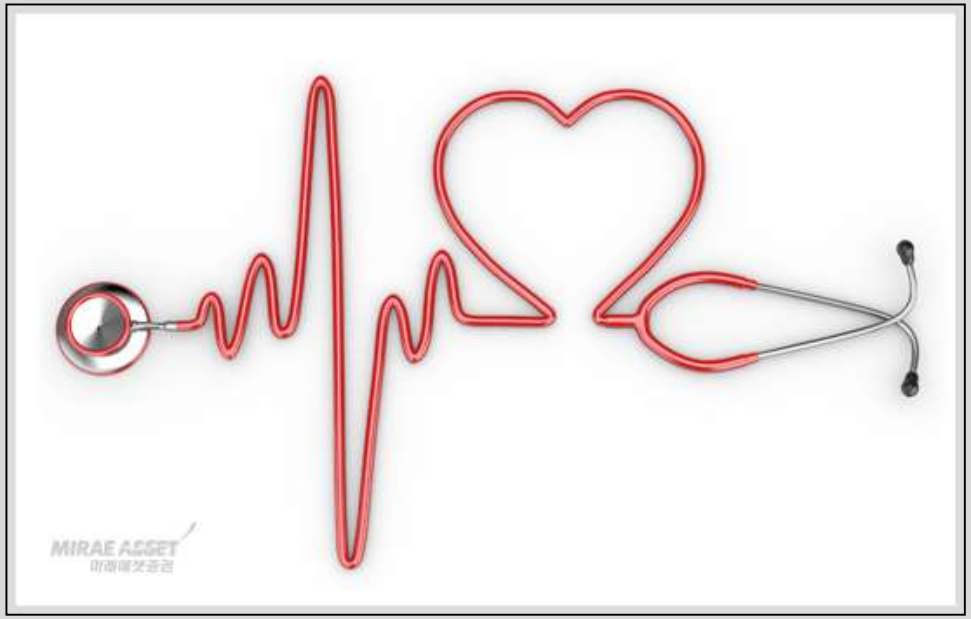
FDA's Risk-Based Approach



Not a device | Lower Risk | Higher Risk

Transforms the Mobile Platform into a Medical Device

By using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.



Examples

- ECG electrodes that connect to a mobile platform to measure, store, and display ECG signals
- Mobile app uses sensors on a mobile platform for creating electronic stethoscope function

Apps that are Extensions of a Medical Device

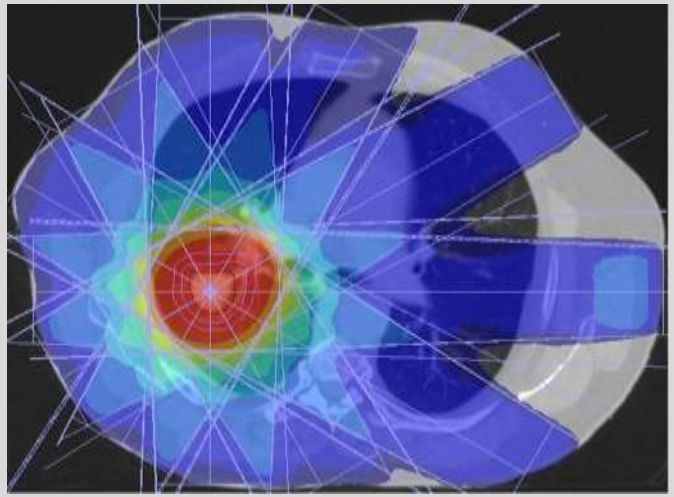
By connecting to such device(s) for purposes of controlling the device(s) or analyzing medical device data.

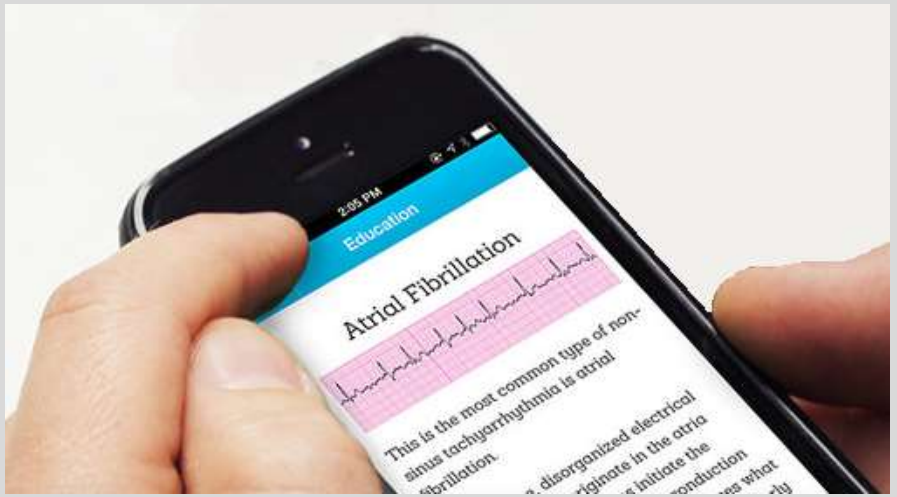
- App that provides the ability to control inflation and deflation of a blood pressure cuff through a mobile platform.

Provide Analysis, Diagnosis or Treatment

Performs patient-specific analysis and provides patient-specific diagnosis, or treatment recommendations.

- Apps that use patient-specific parameters and calculate dosage for radiation therapy
- App that detects Atrial Fibrillation





Tools for Tracking and Trending

Provide patients with simple tools to organize and track their health information.

- Log, track, or trend health events or measurements (e.g., blood pressure measurements, drug intake times)

Perform Simple Calculations

Perform simple calculations routinely used in clinical practice.

- Examples include:
  - Body Mass Index (BMI)
  - Total Body Water / Urea Volume of Distribution
  - Glasgow Coma Scale score
  - APGAR score
  - NIH Stroke Scale

Poll - How does FDA regulate this app?

A startup designs a mobile app that tracks and trends glucose levels by the user on a smartphone. The glucose values are transmitted from a glucometer that is cleared by FDA to transmit glucose values via Bluetooth.

A. **Mobile medical app**

B. **FDA does not intend to enforce compliance with regulatory controls**

C. **Not a medical device**

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Poll - How does FDA regulate this app?

A startup designs a mobile app that performs patient-specific analysis and calculates insulin dosage.

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How does FDA regulate this app?

A startup designs a mobile app that stores and transmits blood pressure data to the cloud for later viewing by the patient's healthcare provider.

1. **Mobile medical app**
2. **FDA does not intend to enforce compliance with regulatory controls**
3. **Not a medical device**

21st Century Cures Act

Amended definition of "device" in the Food, Drug and Cosmetic Act to **exclude** certain software functions intended...

(A) for **administrative support**;

(B) for maintaining or encouraging a **healthy lifestyle**;

(C) to serve as a **electronic patient records**;

(D) for **transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information**; *and*

(E) to **provide recommendations to health care professionals for clinical decisions**, where the user can independently review the basis of the recommendation.

General patient education

An app is used to provide daily allergy forecast information to asthma patients.

The app is considered:

A. Mobile medical app
B. FDA does not intend to enforce compliance with regulatory controls
C. Not a device

Differential Diagnosis

A patient inputs symptoms via text or voice. The app shows a list of diseases and conditions that may be associated with the symptoms. The app doesn't provide treatment recommendations and doesn't interact with any medical device or sensor.

The app is considered:

A. Mobile medical app
B. FDA does not intend to enforce compliance with regulatory controls
C. Not a device

Sleep Apnea

A mobile app uses sensors attached to a tablet to measure physiological parameters during sleep and is intended for use in diagnosis of sleep apnea.

The app is considered:

A. **Mobile medical app**
B. **FDA does not intend to enforce compliance with regulatory controls**
C. **Not a device**

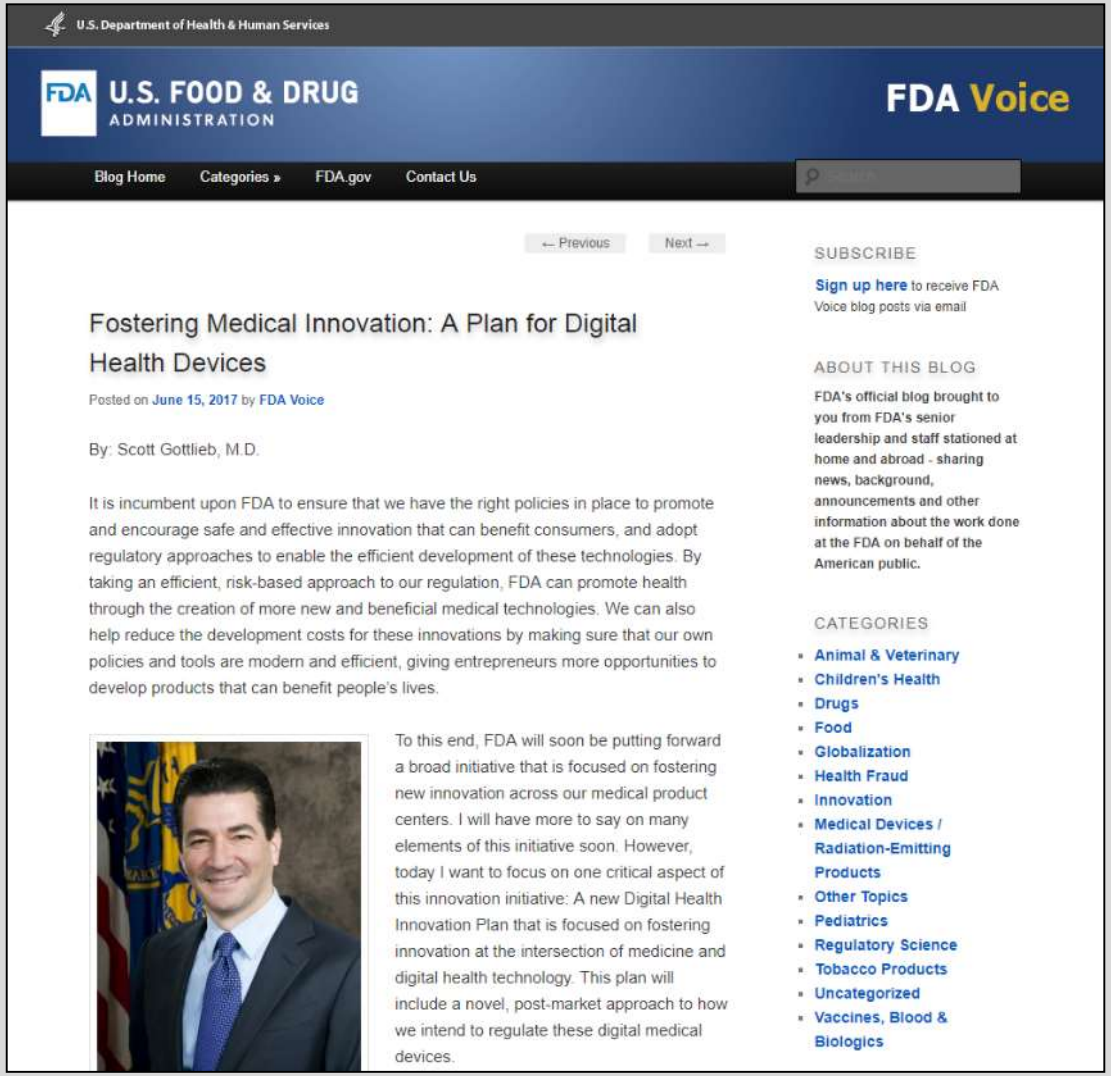
Wearable Technology

A device uses wearable technology and phone app to monitor for minor and major stroke symptoms and provides alerts for patients and healthcare professionals.

The app is considered:

A. Mobile medical app
B. FDA does not intend to enforce compliance with regulatory controls
C. Not a device

New Technology Paradigm
Advancing Digital Health Innovation



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Fostering Medical Innovation: A Plan for Digital Health Devices

Posted on June 15, 2017 by FDA Voice

By: Scott Gottlieb, M.D.

It is incumbent upon FDA to ensure that we have the right policies in place to promote and encourage safe and effective innovation that can benefit consumers, and adopt regulatory approaches to enable the efficient development of these technologies. By taking an efficient, risk-based approach to our regulation, FDA can promote health through the creation of more new and beneficial medical technologies. We can also help reduce the development costs for these innovations by making sure that our own policies and tools are modern and efficient, giving entrepreneurs more opportunities to develop products that can benefit people's lives.

To this end, FDA will soon be putting forward a broad initiative that is focused on fostering new innovation across our medical product centers. I will have more to say on many elements of this initiative soon. However, today I want to focus on one critical aspect of this innovation initiative: A new Digital Health Innovation Plan that is focused on fostering innovation at the intersection of medicine and digital health technology. This plan will include a novel, post-market approach to how we intend to regulate these digital medical devices.

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Launch of FDA/CDRH Pre-Cert for Software Pilot Program

Publication of FDA/CDRH Digital Health Innovation Action Plan

Digital Health Innovation Action Plan

Explore new streamlined pathway for software

Launch an innovative pilot precertification (Pre-Cert) program to build a new approach to digital health technology, working with our customers and leveraging internationally harmonized principles for software regulation

- ❑ Tailored to this category of products with continual updates and upgrades
- ❑ Accommodates distinctive nature of digital health technology
- ❑ Fosters, not impedes, innovation

Summary

- Landscape of Mobile apps
- FDA's tailored approach to mobile apps
- Examples of mobile medical apps

Questions

Please evaluate this session:

surveymonkey.com/r/DEV-D1S06

Call to Action

1. **Become familiar with CDRH's Mobile Medical App Guidance:**

   www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

1. **Contact Us with your Questions:**

   Digitalhealth@fda.hhs.gov


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