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FDA's Mobile Medical App Guidance How Will It Impact You?

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- **Today's slides will be available for download on our homepage at www.ehidc.org**

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About eHealth Initiative

- Since 2001, eHealth Initiative is the only national, non-partisan group that represents all the stakeholders in healthcare.

- Mission to promote use of information and technology in healthcare to improve quality, safety and efficiency.

- eHealth Initiative focuses its research, education and advocacy efforts in four areas:
  - Using Data and Analytics to Understand and Improve Care
  - IT Infrastructure to Support Accountable Care
  - Technology for Patients with Chronic Disease
  - Connecting Communities through Data Exchange

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2013 **Health** Data Exchange & Interoperability Summit

October 30-31, Grand Hyatt, Washington, DC

Discussion Topics Include:

- Interoperability & Standards for Health Data Exchange
- Data Sharing in Accountable Care Organizations
- Breaking Down Silos: Exchanging Data Across the Continuum of Care
- Cybersecurity and Health Data
- Data Sharing to Improve Population and Public Health
- Sustaining the HIE Model: Defining the Value of Health Data Exchange
- Exchanging the Data with the Federal Government
- Protecting Patient Rights While Exchanging Data
- Connecting Health Data to Health Insurance Exchanges
- Data Sharing in Accountable Care Organizations
- Best Practices to Support a Trusted Environment for Exchange

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Thank You To Our Sponsors:

eHI Policy Workgroup webinar

- Insurance Exchanges
  - *Caitlin Sweany*, Senior Manager, PwC Health Research Institute
  - *Elizabeth Carpenter*, Avalere Health

- Thursday, October 17th, 4:00 – 5:00pm ET

- If you have questions, please contact Nadeen Siddiqui at Nadeen.siddiqui@ehealthinitiative.org

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Agenda

- Welcome and Introductions
  - **Rebecca Jones**, eHI (2:00-2:05)

- Presentations
  - **Bradley Thompson**, General Counsel, mHealth Regulatory Coalition (2:05-2:35)
  - **Gary Capistrant**, Senior Director of Public Policy, American Telemedicine Association (2:35 – 2:45)

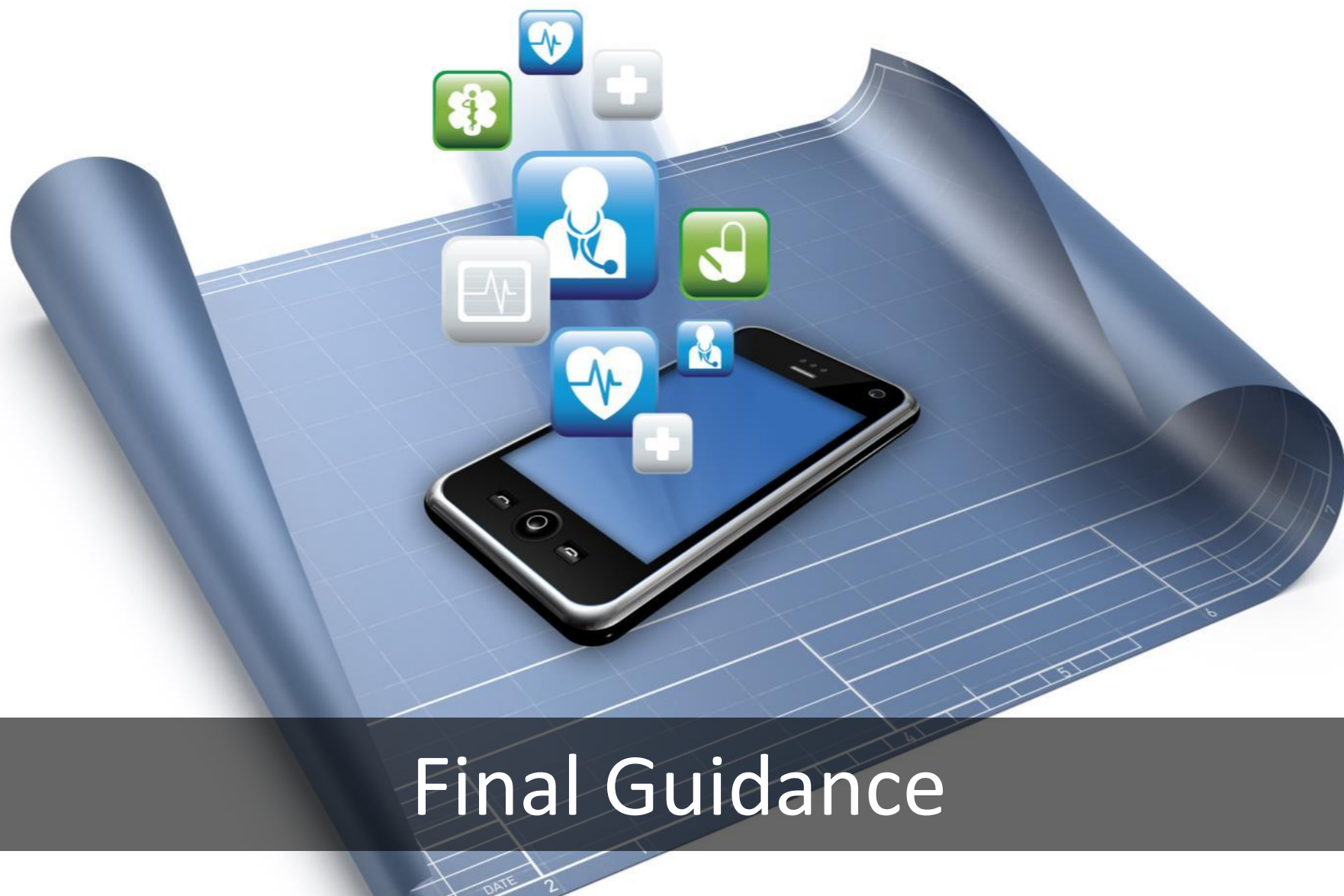- Questions from Audience (2:45– 3:00)

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What does FDA Consider a regulated App?

By Bradley Merrill Thompson

October, 2013

Topics

- **Which apps does FDA regulate?**

- What about hardware?

- Who does FDA regulate?

- Path forward

Final Guidance

FDA draws the line between regulated/unregulated

Unregulated Mobile Apps

Regulated

Mobile

Medical Apps

Mobile Apps subject to
Enforcement Discretion

Unregulated Mobile Apps

Unregulated Mobile Apps
5 categories

1. Electronic copies of medical textbooks

2. Educational tools

3. Facilitate patient access to information

4. General operations in healthcare settings (accounting, billing)

5. Generic aid

What gets regulated?

Regulated Mobile Medical Apps

Mobile Apps subject to Enforcement Discretion

Unregulated Mobile Apps

ebglaw.com

Mobile Medical Apps

- Focus on functionality and risk to patients regardless of platform
- Look at what FDA has regulated in the past.

Mobile Medical Apps

1. Accessories to a medical device
   - Mobile apps that are an "extension" to a medical device by connecting to the device to
     - Control the device or
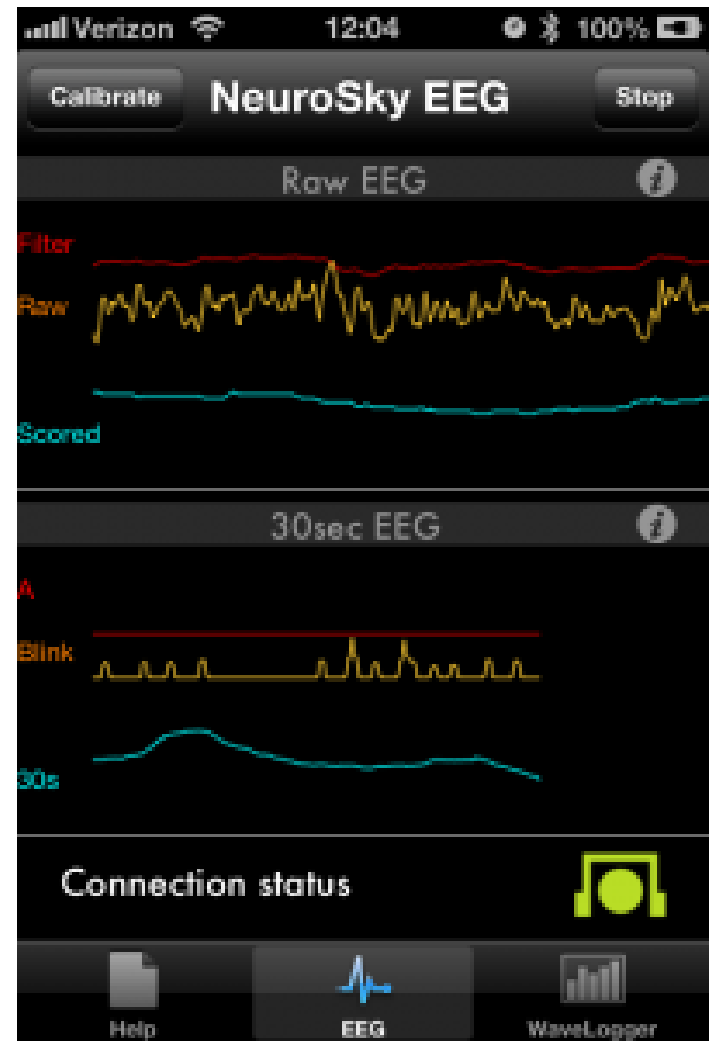   - Display, store, analyze, or transmit patient-specific medical device data

We all prize innovative accessories
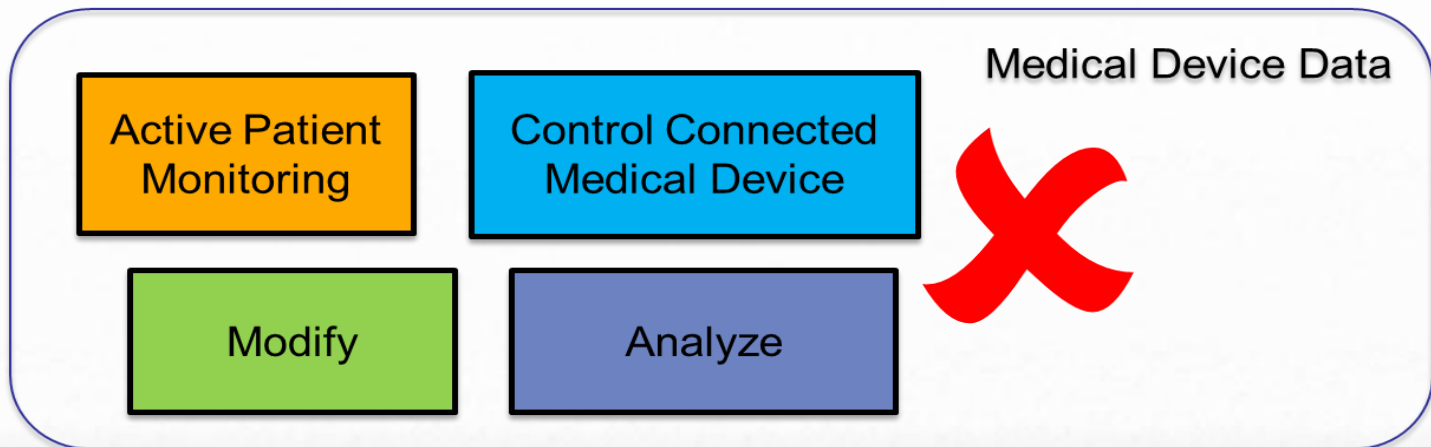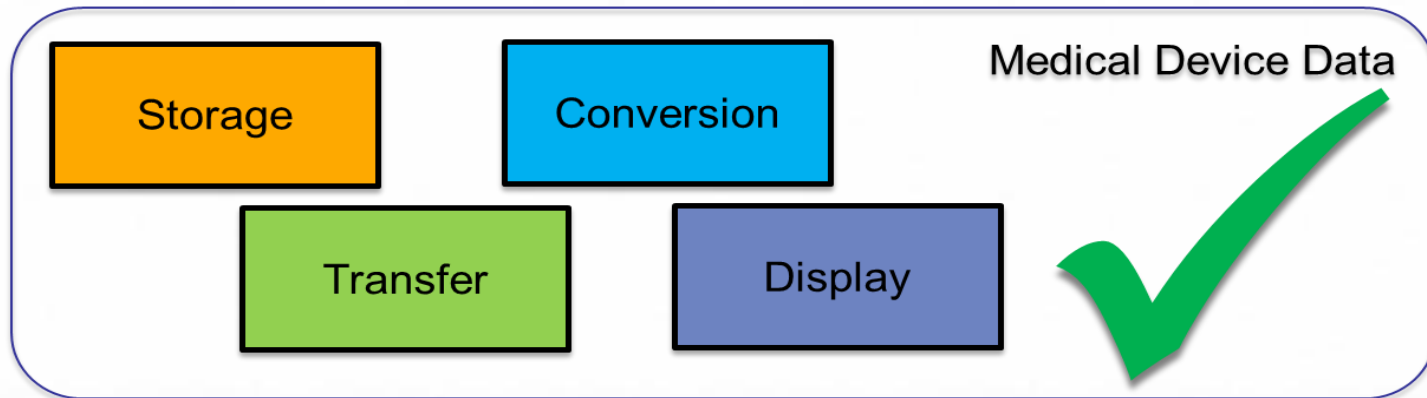
Example: control medical devices

www.blessthisstuff.com

Example: display patient-specific medical device data

luciddreamingapp.com

Mobile Medical Apps

2. Mobile apps that transform the mobile platform into a regulated medical device by

    a. using attachments, display screens, or sensors or

    b. including functionalities similar to those of currently regulated medical devices.

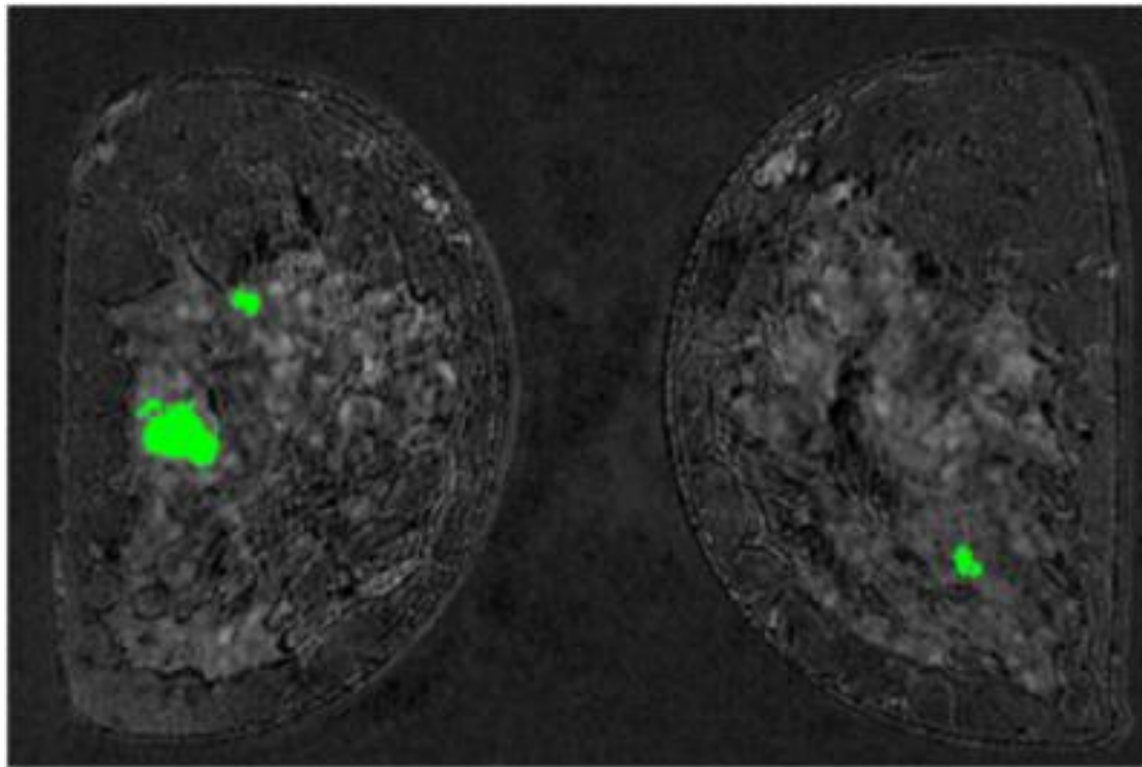# Example

Mobile Medical Apps

3. [CDS]
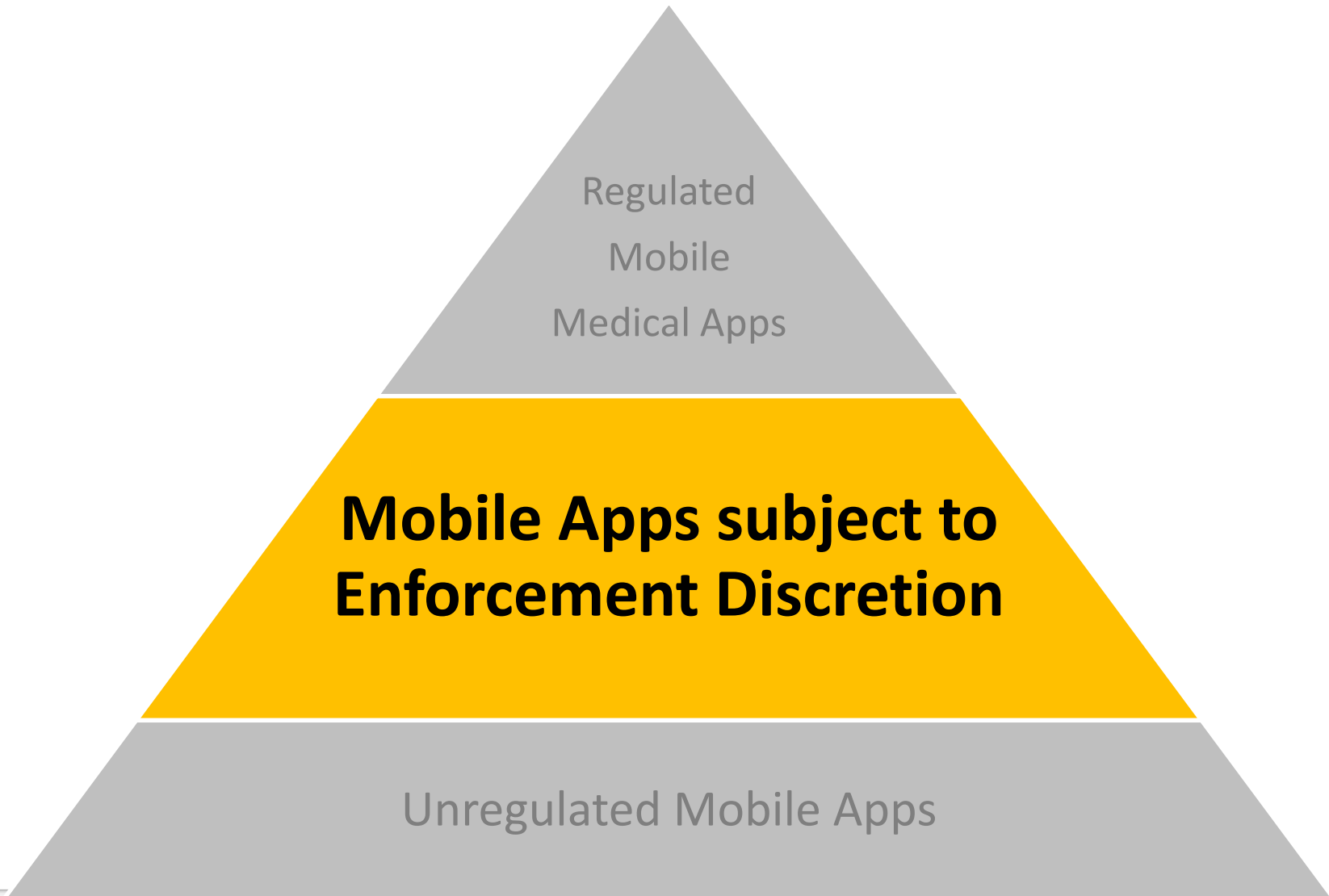
    a.   performing patient-specific analysis and

    b.   providing patient-specific diagnosis, or treatment recommendations.

Example

vomweg.net

Mobile Apps subject to Enforcement Discretion

Regulated Mobile Medical Apps

Mobile Apps subject to Enforcement Discretion

Unregulated Mobile Apps

The Law is Not Always Clear

Ihatepeas.com

Mobile Apps subject to Enforcement Discretion

- MAY or MAY NOT meet definition of medical device

- But they pose little risk

- What does it mean?

    - Quality system recommended

    - Premarket clearance not required

    - What else?

Enforcement Discretion Categories

1. Patient self-management
2. Patient daytimers
3. Patient access to contextually relevant information
4. Patient communication
5. Simple professional calculators
6. Connections to EHR's

Topics

- Which apps does FDA regulate?
- **What about hardware?**
- Who does FDA regulate?
- Path forward

Hardware

- FDA does not regulate:
  - ➤ Your smartphone
  - ➤ Your tablet
  - ➤ Usually

Other hardware

- If sold for a medical device intended use
  - Generic accessories
  - Wellness sensors

Topics

- Which apps does FDA regulate?

- What about hardware?

- **Who does FDA regulate?**

- Path forward

Who gets regulated?

- Definition of "manufacturer"
  - Need to understand "specification developer"
    - Who controls the specs?
    - Who controls the claims?

- Not regulated:
  - ➢ Distributors, by enforcement discretion
  - ➢ General purpose connection providers
  - ➢ Tool makers and providers

Unregulated Apps Made by Doctors

- Doctor's apps for their own professional use

- No commercial distribution
  - except other doctors in that practice

Topics

- Which apps does FDA regulate?
- What about hardware?
- Who does FDA regulate?
- **Path forward**

Path Forward

- The Final Guidance really only addresses the scope of FDA regulation

- Now questions of HOW FDA will regulate

- Transition from Guidance to enforcement
  - Enforcement against urinalysis app
  - Now crowd-funding issue

Living Document

- Final Guidance not static
  - ➢Public questions
  - ➢Use of dynamic webpage

January 2014 – Report from FDA, ONC and FCC on Health IT

Questions?

Bradley Merrill Thompson
bthompson@ebglaw.com

Industry Perspective:
What is the impact?

Gary Capistrant
Senior Director, Public Policy
American Telemedicine Association

Contact Gary:
Phone: 202.223.1294
Email: gcapistrant@americantelemed.org

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Questions?

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