

The Present FDA Regulation of HIT, including mHealth

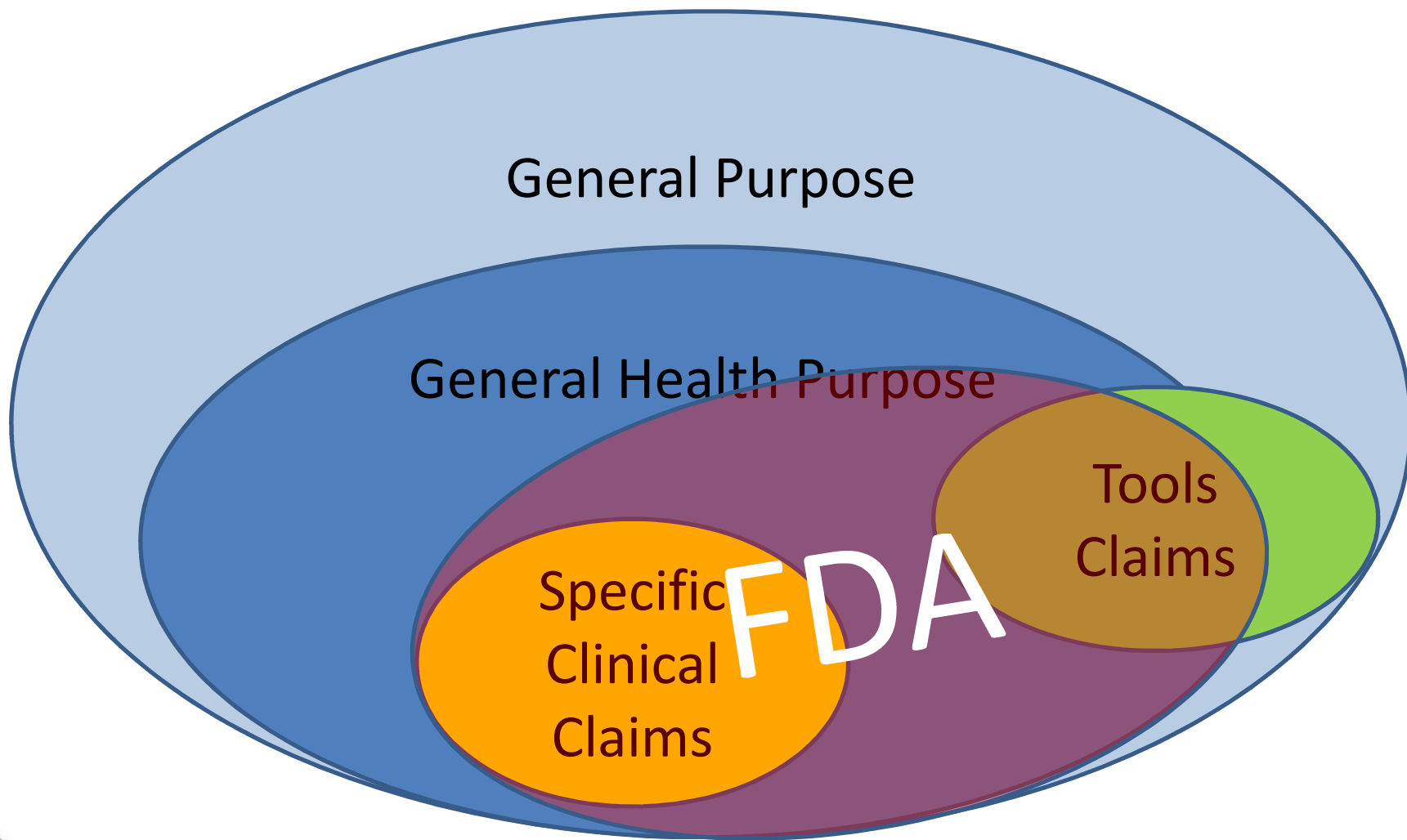
By Bradley Merrill Thompson

April 10, 2014

Where are we now?

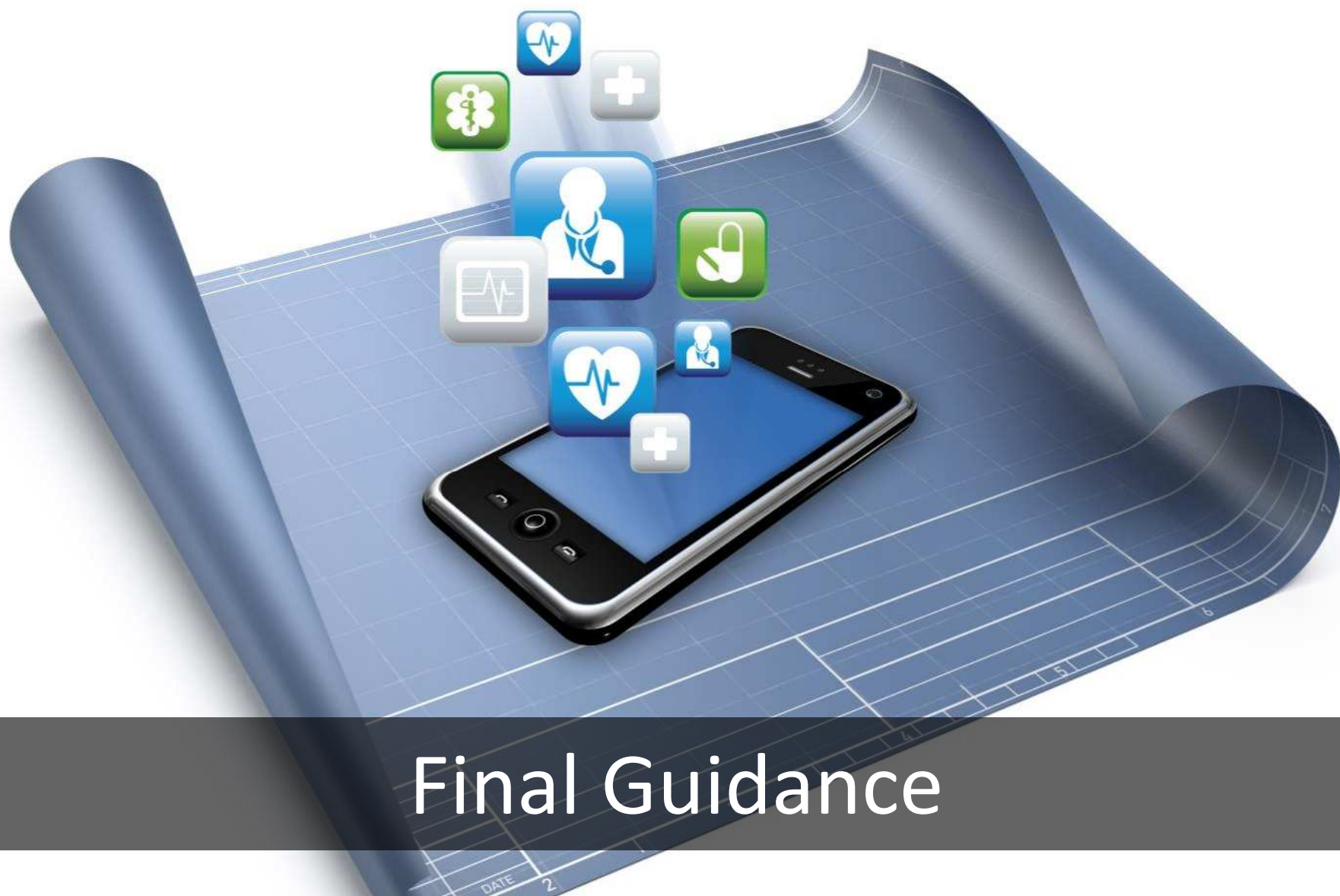
1. Understanding Intended Use
2. Which apps does FDA regulate?
3. What about hardware?
4. The CDS Conundrum
5. Who does FDA regulate?

Flavors of Intended Use



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Final Guidance

FDA draws the line between regulated/unregulated

What gets regulated?



**Regulated
Mobile
Medical Apps**

Mobile Apps subject to
Enforcement Discretion

Unregulated Mobile Apps

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



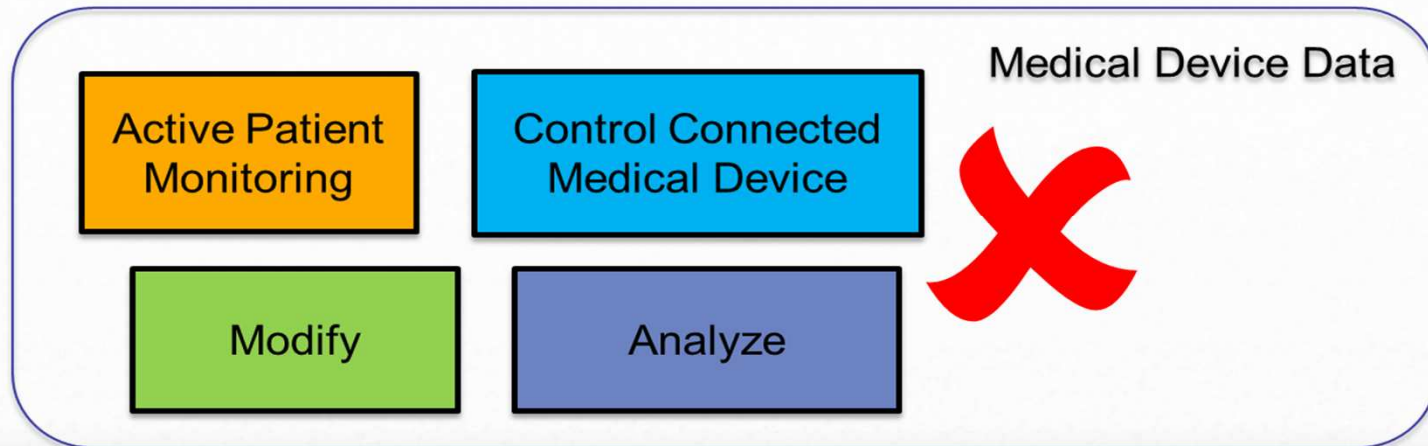
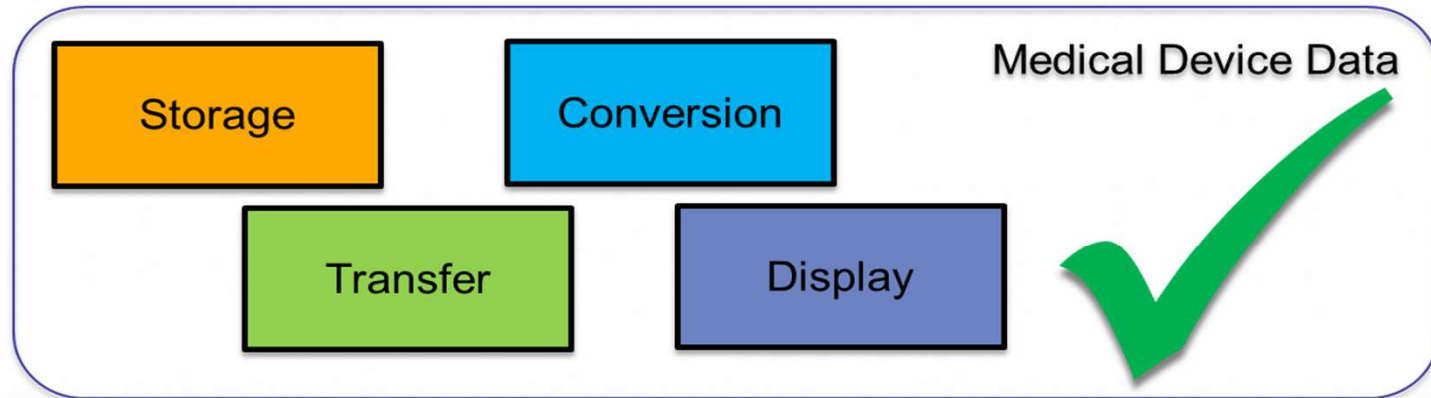
Success may depend on accessories

Example: control medical devices

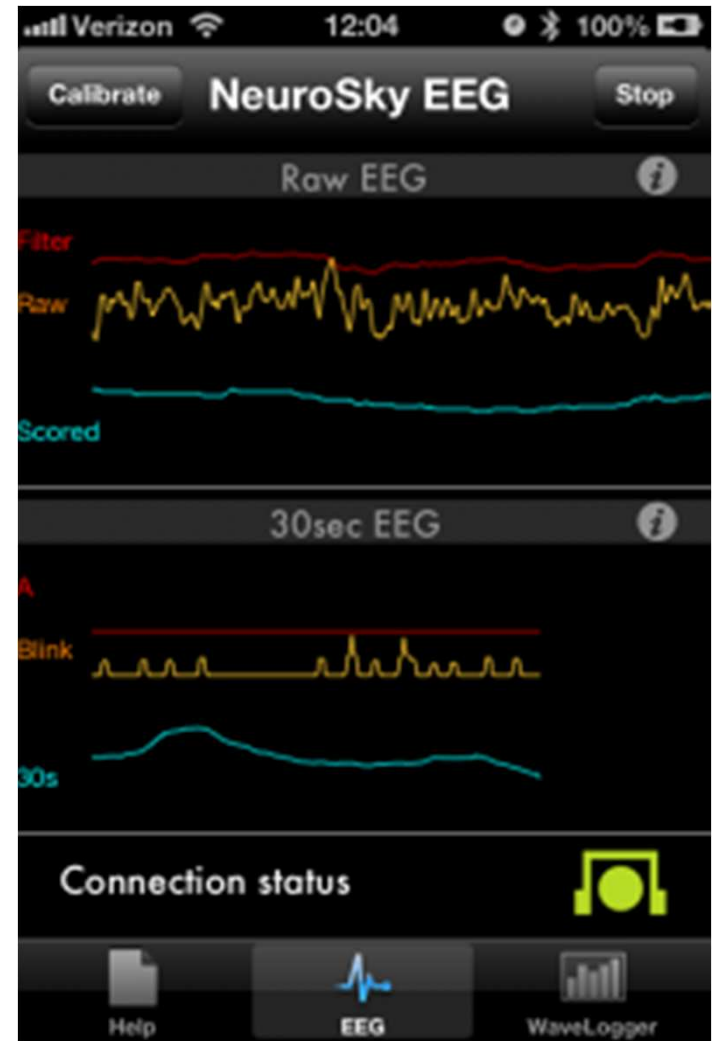


www.blessthisstuff.com

Example: MDDS



Example: display patient-specific medical device data



luciddreamingapp.com

Mobile Medical Apps

2. Functionalities similar currently regulated medical devices
 - a. Using special medical attachments
 - b. Using generic attachments
 - c. Using no attachments

Example

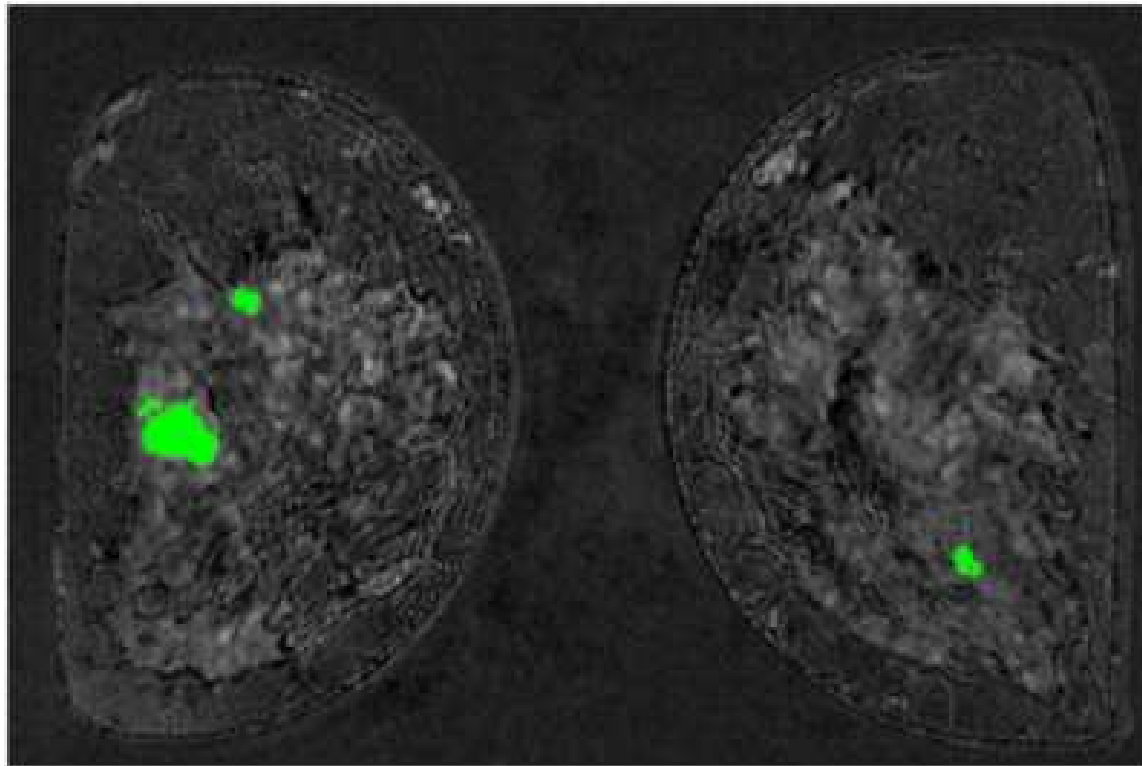


Mobile Medical Apps

3. [CDS]

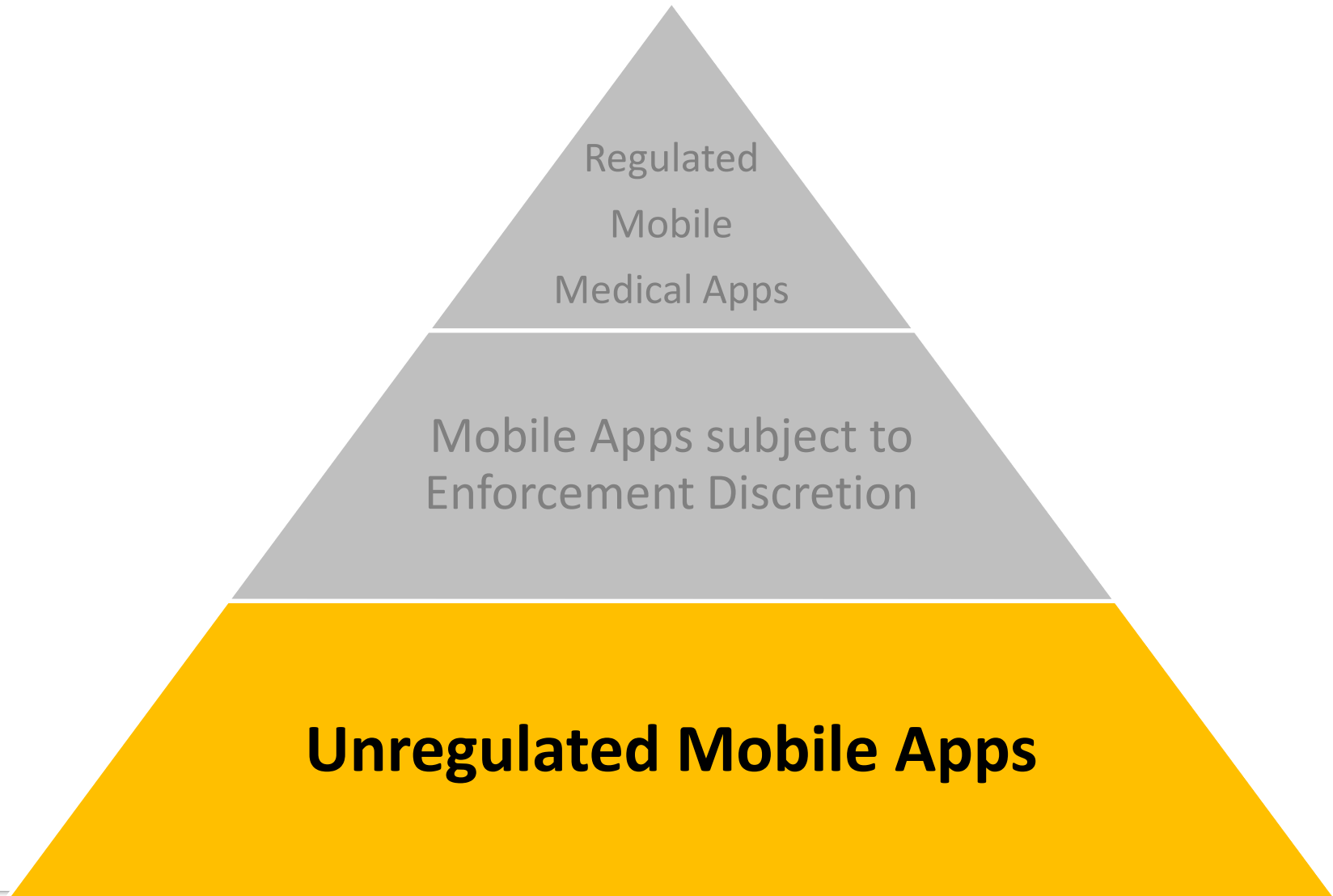
- a. performing patient-specific analysis and
- b. providing patient-specific diagnosis, or treatment recommendations.

Example



vomweg.net

Unregulated Mobile Apps

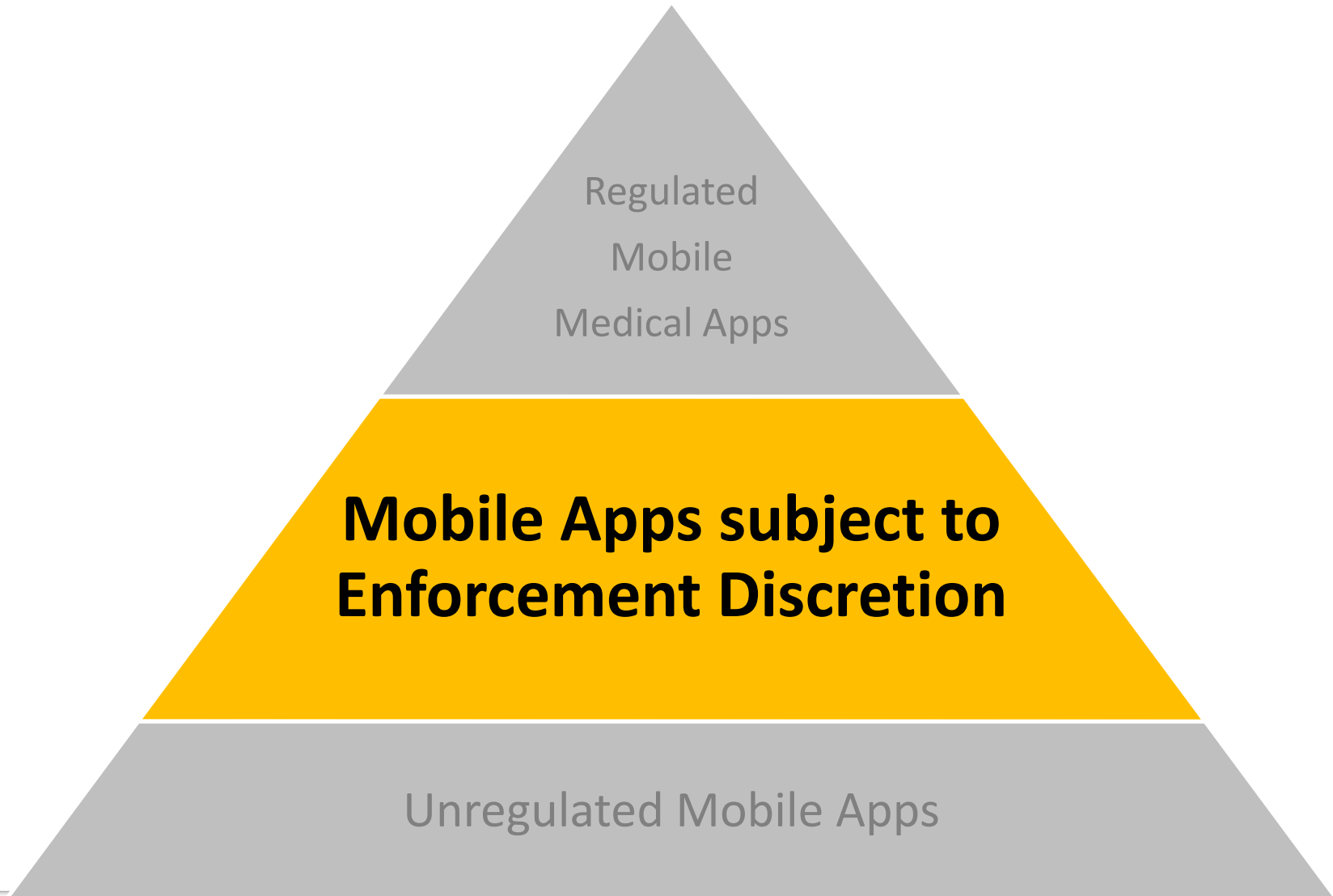


Unregulated Mobile Apps

5 categories

1. Electronic copies of medical textbooks
2. Educational tools
3. Facilitate patient access to information
4. Business operations in healthcare settings
(accounting, billing)
5. Generic aid (e.g. magnifying glass)

Mobile Apps subject to Enforcement Discretion



Mobile Apps subject to Enforcement Discretion

FDA decided to exempt low risk devices,
however

- May not meet definition of medical device
- May not be forever exempt
- Recommend quality system

Enforcement Discretion Categories

1. Patient motivators
2. Patient day-timers
3. Access to contextually relevant information
4. Certain telemedicine products
5. Simple professional calculators
6. Connections to EHR's

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Hardware

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

Other hardware

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



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Clinical Decision Support Software

- “This guidance does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making.”
- Will be addressed as part of FDASIA

But then final guidance includes CDS at every turn

What do we know today on CDS?

- September 2011 preliminary definition on CDS

Information

- Data from a medical device
- Environmental data (e.g., pollen count, temp.)
- Demographic data (e.g., age, sex, socio-economic status)

Conversion

- Algorithms (fixed or iterative)
- Formulae
- Database look-ups or comparisons
- Rules or associations

Clinical Decision



- Patient-specific
- Actionable result



Examples of CDS in FDA classification regulations

1 to 8 of 8 Results
for calculator

Results per page 10

New Search					 Export To Excel  Help	
Product Code	Device Name		Regulation Number	Device Class		
PDT	Burn Resuscitation Decision Support Software	Predictive Pulmonary-Function Value Calc...	868.1890	2		
NDC	Calculator, Drug Dose	Predictive Pulmonary-Function Value Calc...	868.1890	2		
BTY	Calculator, Predicted Values, Pulmonary Function	Predictive Pulmonary-Function Value Calc...	868.1890	2		
BZC	Calculator, Pulmonary Function Data	Pulmonary-Function Data Calculator	868.1880	2		
BZM	Calculator, Pulmonary Function Interpretator (Diag ...	Diagnostic Pulmonary-Function Interpreta...	868.1900	2		
JQP	Calculator/Data Processing Module, For Clinical Us ...	Calculator/Data Processing Module For Cl...	862.2100	1		
MPT	Contraception Calculator			Unclassified		
NVV	Digital Image, Storage And Communications, Non-Dia ...	Calculator/Data Processing Module For Cl...	862.2100	1		

Page Last Updated: 09/02/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Unregulated CDS Per MMA

- medical calculators for:
 - Body Mass Index (BMI)
 - Total Body Water / Urea Volume of Distribution
 - Mean arterial pressure
 - Glasgow Coma Scale score
 - APGAR score
 - NIH Stroke Scale
 - Delivery date estimator
- Use patient characteristics to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities
- Use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider

Unregulated CDS per FDASIA

- Evidence-based clinician order sets tailored for a particular condition, disease, or clinician preference;
- Drug-drug interaction and drug-allergy contraindication alerts to avert adverse drug events;
- Most drug dosing calculations;
- Drug formulary guidelines;
- Reminders for preventative care (e.g. mammography, colonoscopy, immunizations, etc.);
- Facilitation of access to treatment guidelines and other reference material that can provide information relevant to particular patients;
- Calculation of prediction rules and severity of illness assessments (e.g., APACHE score, AHRQ Pneumonia Severity Index, Charlson Index);
- Duplicate testing alerts;
- Suggestions for possible diagnoses based on patient-specific information retrieved from a patient's EHR.

Regulated CDS Per FDASIA

- Computer aided detection/diagnostic software;
- Remote display or notification of real-time alarms (physiological, technical, advisory) from bedside monitors;
- Radiation treatment planning;
- Robotic surgical planning and control;
- Electrocardiography analytical software.

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Who gets regulated?

- Definition of “manufacturer”
 - Need to understand “specification developer”
 - Who controls the specs?
 - Who controls the claims?
- Distributors are not manufacturers
 - But they are distributors
- Not regulated:
 - General IT
 - Communications firms

Apps Made by Doctors

- Doctor's apps for their own professional use are unregulated
 - May share with colleagues in their group practice
- Questions
 - What is a group practice?
 - Does the doctor need to code?

Summary: The Road Ahead

Living Document

- Final Guidance not static
 - Use of dynamic webpage
 - Public disclosure of questions?

Path Forward

- More guidance on scope of regulation
 - E.g. wellness, accessories, CDS
- How FDA will regulate?
 - Classifications (IMDRF)
- How will FDA enforce?
 - Preselling issue
 - Wanted: Evenhanded FDA Enforcement
 - MDDI, March 14, 2012
 - “Due to overwhelming success, pre-orders will no longer be available in the United States starting April 4th”

More Resources

- FDA Regulation of Mobile Health
 - Free eBook
 - 2nd edition, November, 2013, 80% new
 - www.MobiHealthNews.com download
- Roadshow on Managing App Dev. Under FDA
 - Major engineering schools
 - Speakers from companies with FDA cleared apps
 - FDA
 - www.mhealthregulatorycoalition.org

Questions?

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