



Mobile Medical Apps – Draft Guidance

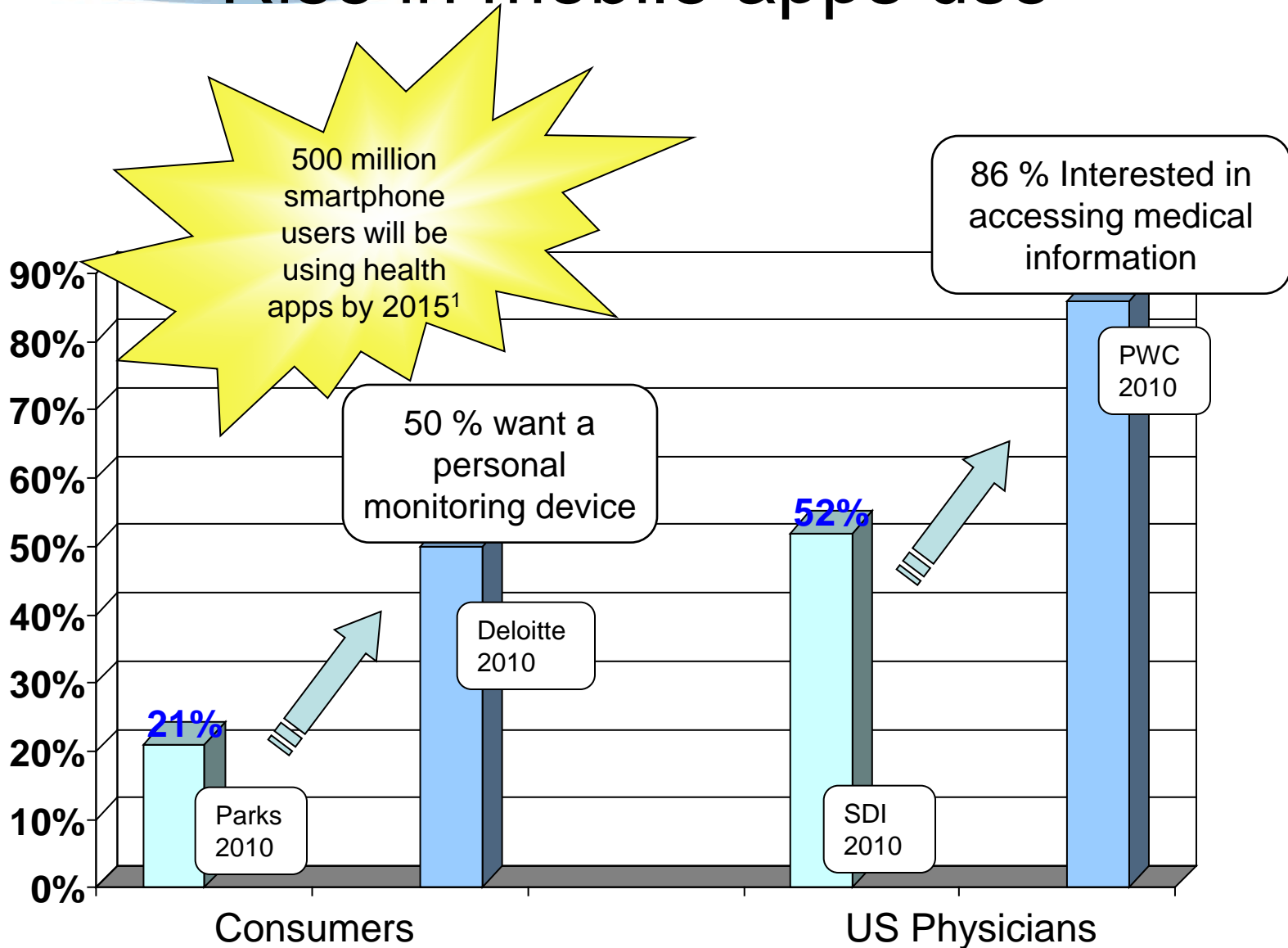
July 27, 2011

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Center for Devices and Radiological Health

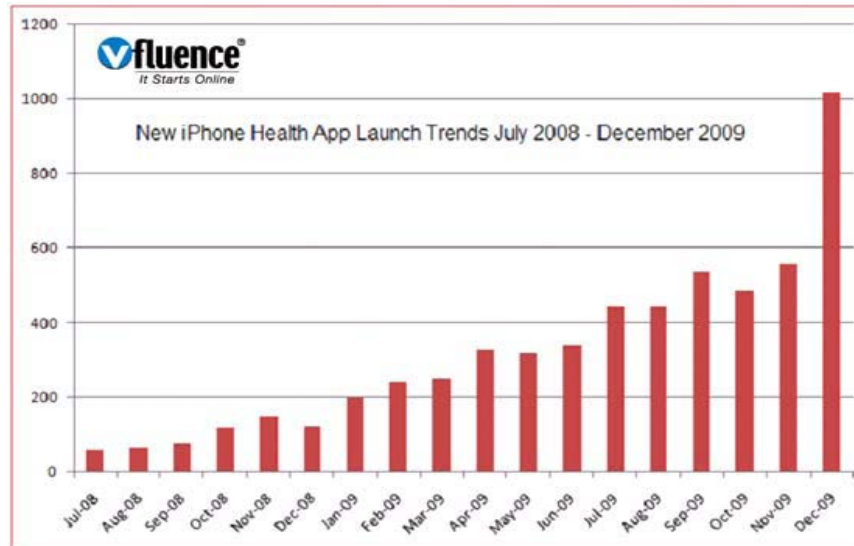
Rise in mobile apps use



¹ Research2Guidance 2010

Sample app store metrics

- May 23, 2011 (400,000 active apps according to <http://148apps.biz/>)
 - Healthcare & Fitness -- 9,428
 - Medical -- 6,848
- Trends captured by v-fluence.com



Uncertainty for mobile medical apps

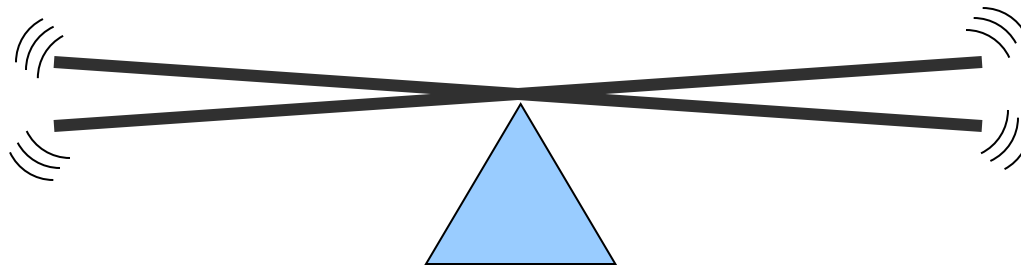
- Request for clarity on...
 - FDA's Role, and
 - Expectations

- From various sources...
 - App developers
 - Healthcare market entrants (carriers, entrepreneurs, etc)
 - Traditional medical device manufacturers
 - Investors

Striking the right balance



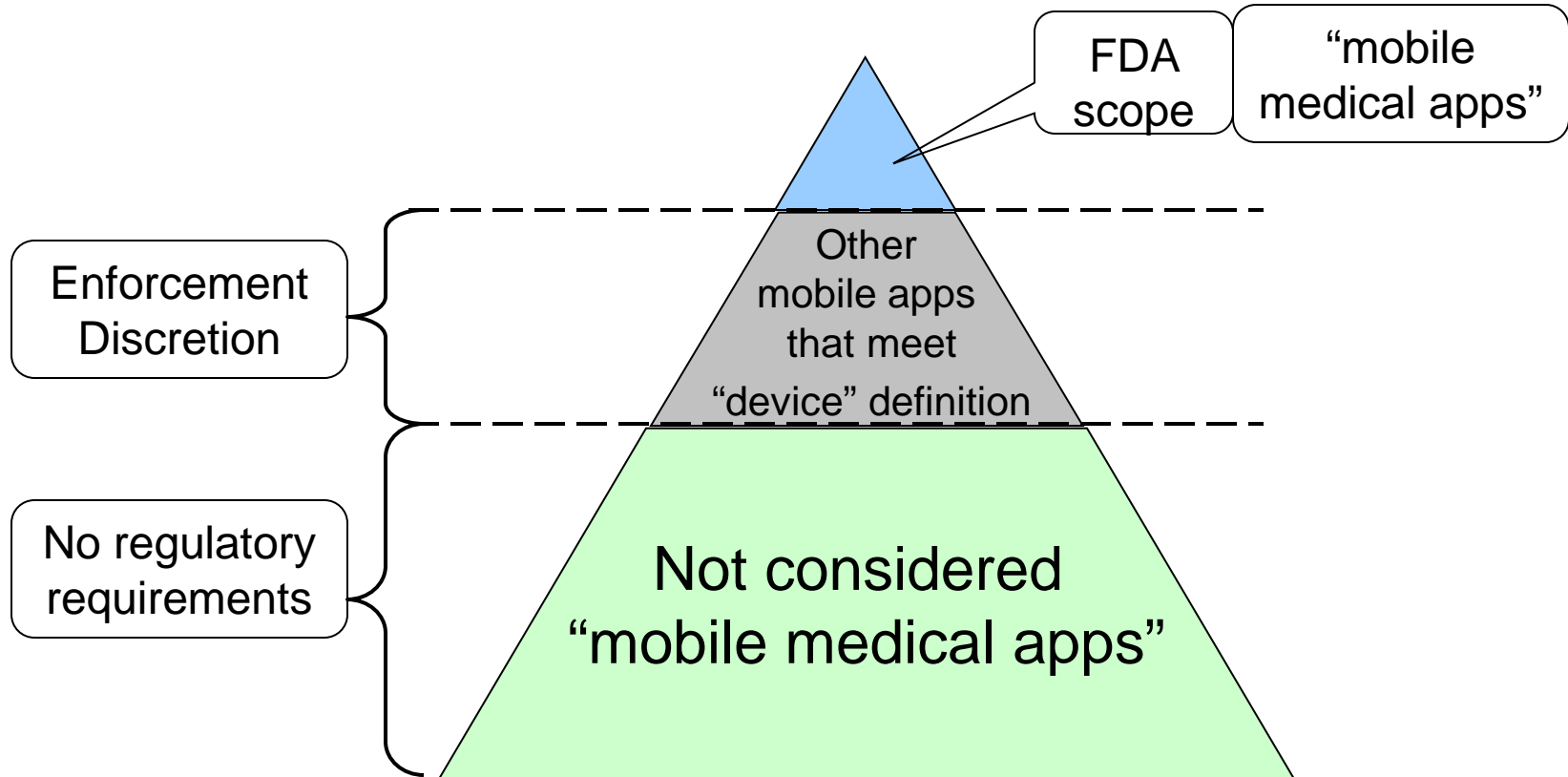
**FDA/Center's
strategic Goals**



**Protect
Public
Health**

**Promote
Public
Health**

Proposed scope for oversight



Mobile Medical Apps

- Intended for use that meets the definition of medical device under section 201(h) and either,
 - are used as an accessory to already regulated medical deviceor
 - transforms a mobile communication device into a regulated medical device

Currently regulated apps

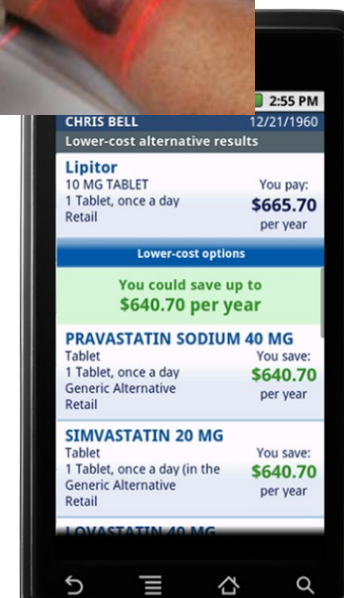
Wound measurement and documentation system



Mobisante:
smartphone-based
ultrasound

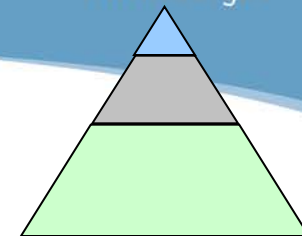


Mobile MIM for
the iPhone &
iPad

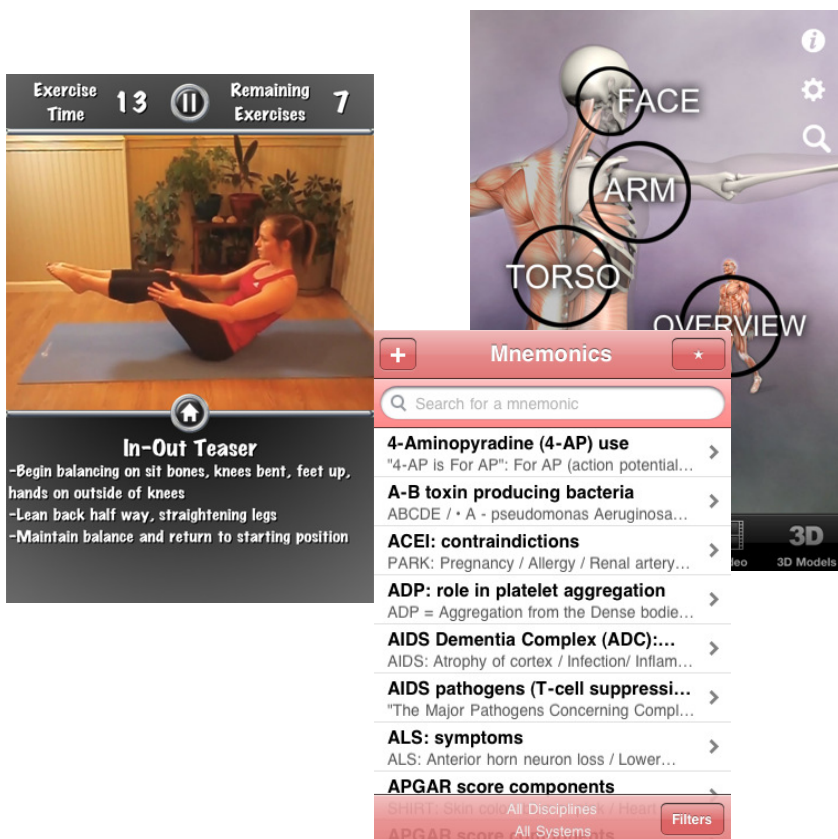


Medco Pharmacy
mobile app

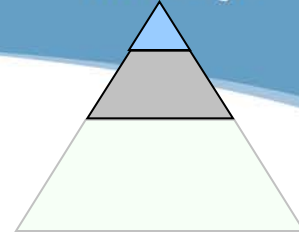
Providing clarity



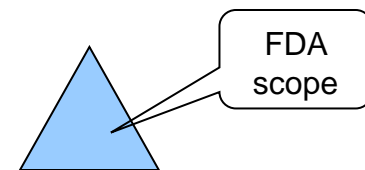
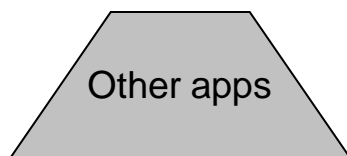
- NOT mobile medical apps
- Mobile medical apps



Mobile medical apps - approach



- Enforcement Discretion for all other apps that are
 - Patient self- management apps
 - Simple tracking or trending apps (not intended for treating/adjusting medication)
- FDA Scope – Mobile medical apps that
 - Is a traditional medical device
 - Is a part of or extension of a traditional medical device



Examples

- **Enforcement Discretion**
 - Vital sign tracking and trending
 - Weight management for specific disorder
 - General symptom checker
 - Tracking exercise/physical activity
 - Tracking acid reflux patterns
 - Obesity behavioral modification apps
- **Oversight**
 - 3-lead ECG
 - Phone based stethoscope
 - Radiology image viewer for diagnosis
 - Blood pressure cuff controller
 - Insulin pump remote controller
 - Smart phone attachments for In-Vitro Diagnostics (IVD)

FDA seeking feedback on

- Scope of Mobile medical apps and other aspects of the guidance
- Proposed approach for accessories to medical devices
- Framework for stand-alone software that provides support in making clinical decisions

Submit comments @

<http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0530-0001>