Smartphone Applications as Adjuncts to Medical Devices: A Case Study in mHealth Regulation

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Outline

1) mHealth Overview
2) FDA Regulatory Framework for Devices
3) Regulatory Challenges
4) Case Study
5) Recommendations

mHealth: definition

"the use of portable devices such as smartphones and tablets for medical purposes, including diagnosis, treatment, or support of general health and well-being"

- Cortez *et al*.

mHealth: classifications

1) smartphone applications (“apps”)

2) smartphone-connected devices

3) wearable and wireless devices

4) handheld imaging platforms

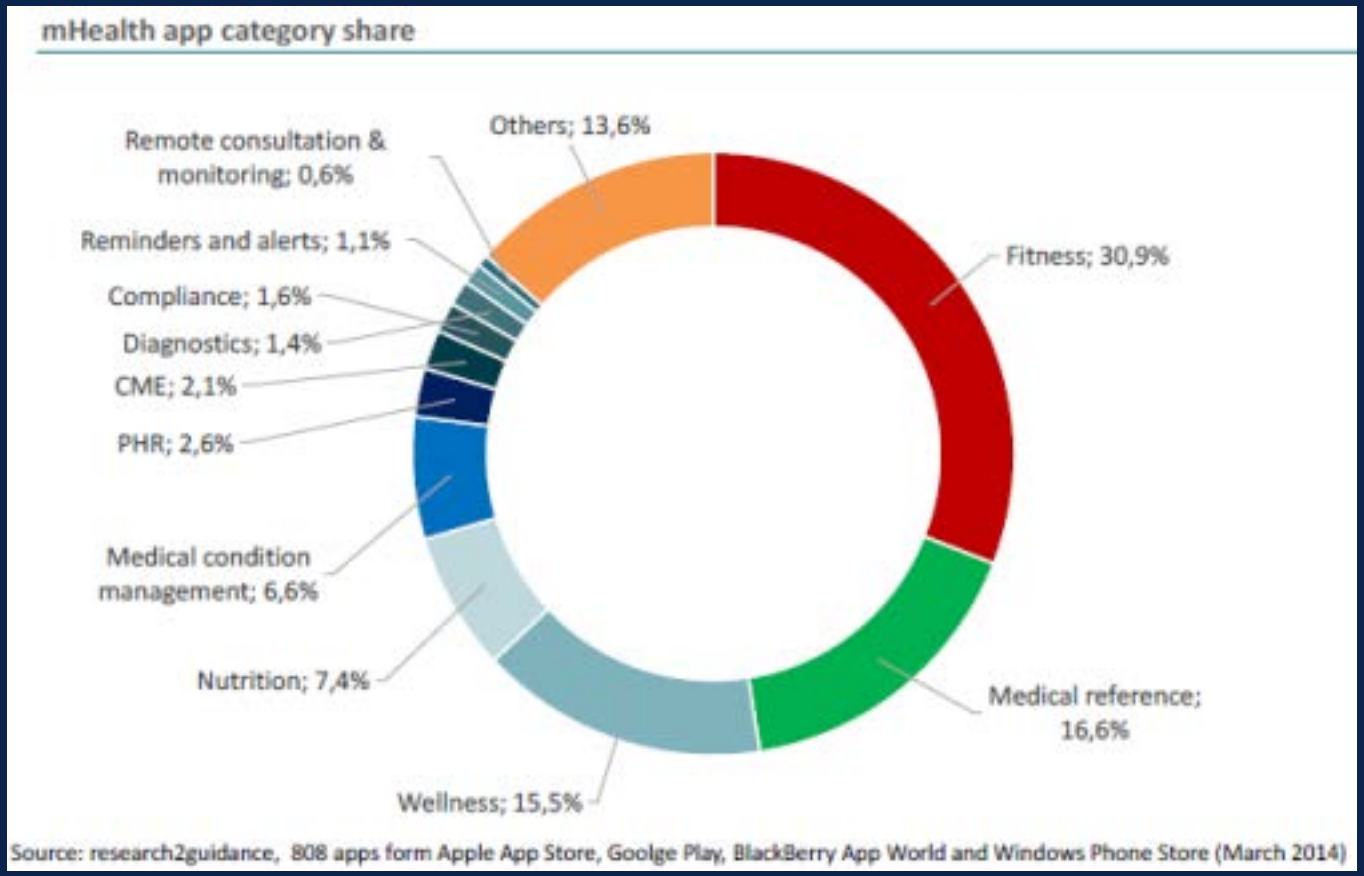
5) miniaturized sensor-based technologies*

- Bhavani *et al*.

mHealth: examples

Alamy Stock Photo; Wikispaces; Michigan Health Lab; UC San Diego; ClearPath Benefit Advisors

mHealth: uses



mHealth: landscape

1) Dramatic increases in use and variety*
   - 1 in 5 smartphone users downloaded/used health-related app
   - 165,000 health-related apps in major app stores (40,000 for medical uses)
   - 80% of US doctors incorporated smartphones into practice

2) Rapid change/innovation in technology

3) Short life-cycle/obsolescence driven by consumer demand/use

*2015-2016 data (Schoenfield; McInerny; Kilker)

mHealth: contributing factors

1) Rising burden of chronic disease

2) Moore's law (smaller, cheaper electronics due to exponential increase in computing power)

3) Patient-centric health care models

- Bhavani *et al.*

mHealth: challenges

1) Inadequate privacy protections

2) Inaccurate readings

3) User error by untrained consumers of apps designed for health professionals

4) Information overload for healthcare providers

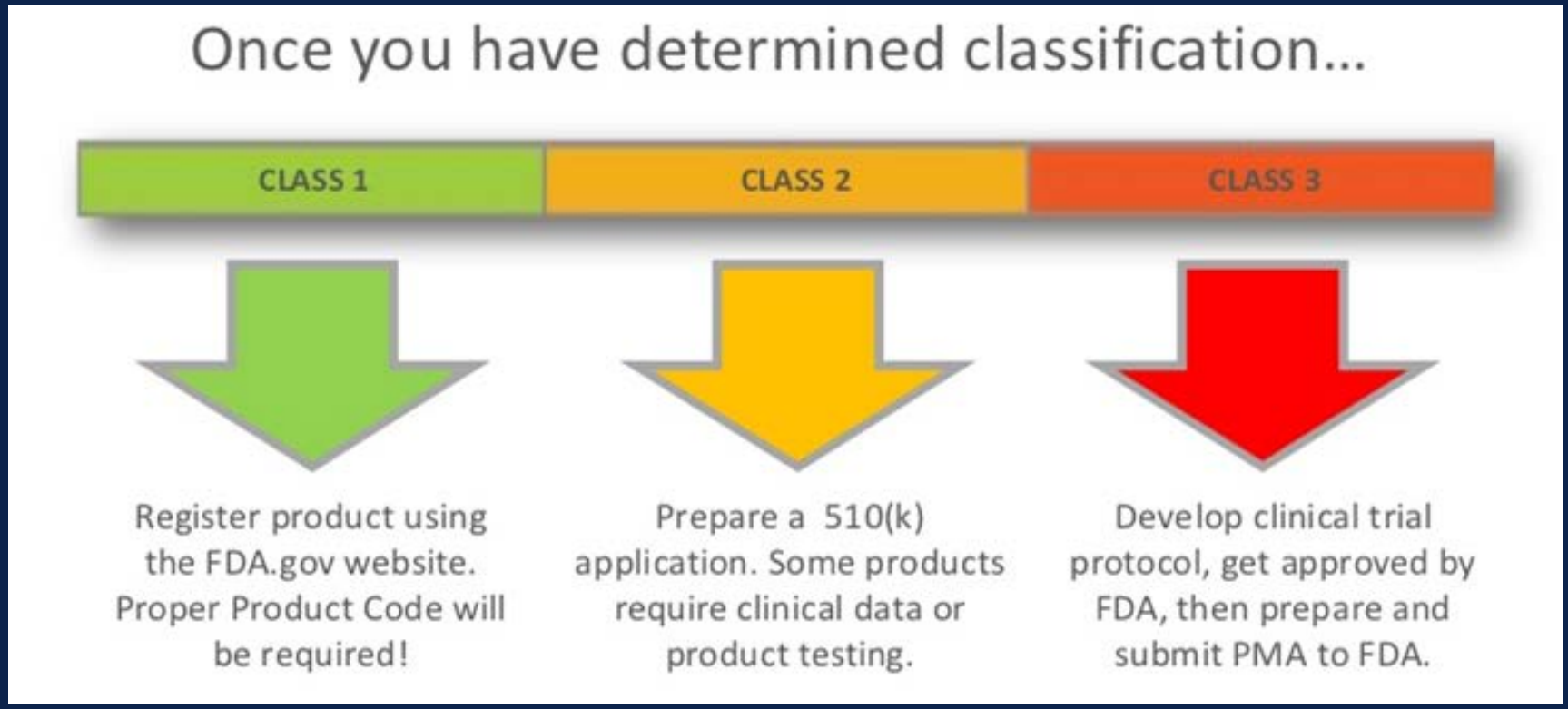
5) Minimal accountability from developers and healthcare providers for improper functioning of apps

FDA Regulation of Devices

Medical devices fall into three classes

CLASS 1	CLASS 2	CLASS 3
Examples: Elastic bandages Examination gloves Mechanical wheelchair	Examples: Infusion pumps Bone fixation screw Blood pressure kit	Examples: Pacemakers Dental lasers Heart valves
LOW RISK	MEDIUM RISK	HIGH RISK

FDA Regulation of Devices



post-market reporting

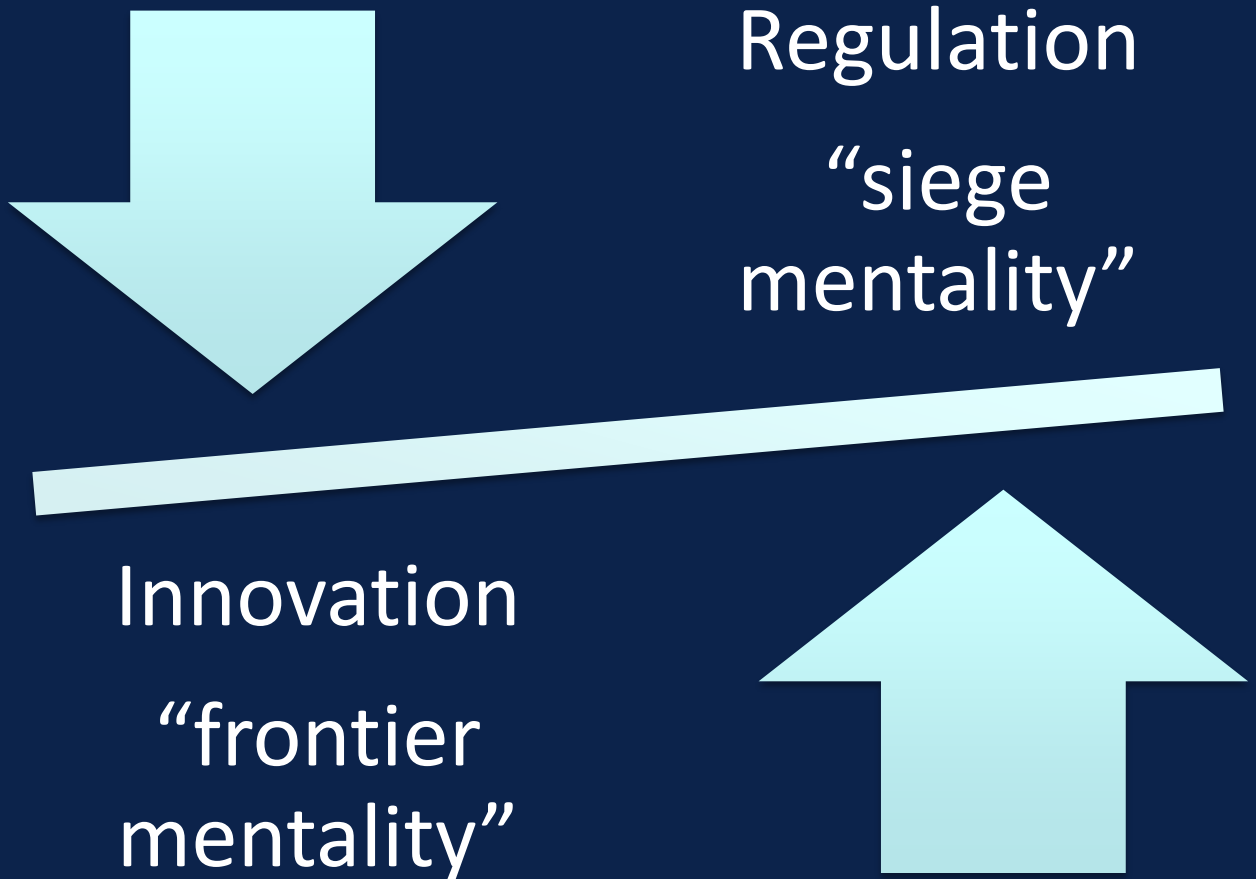
premarket notification

premarket approval

Competing considerations

- Information v. Intervention
- General Wellness v. Diagnosis
- Consumer v. Professional

Competing considerations

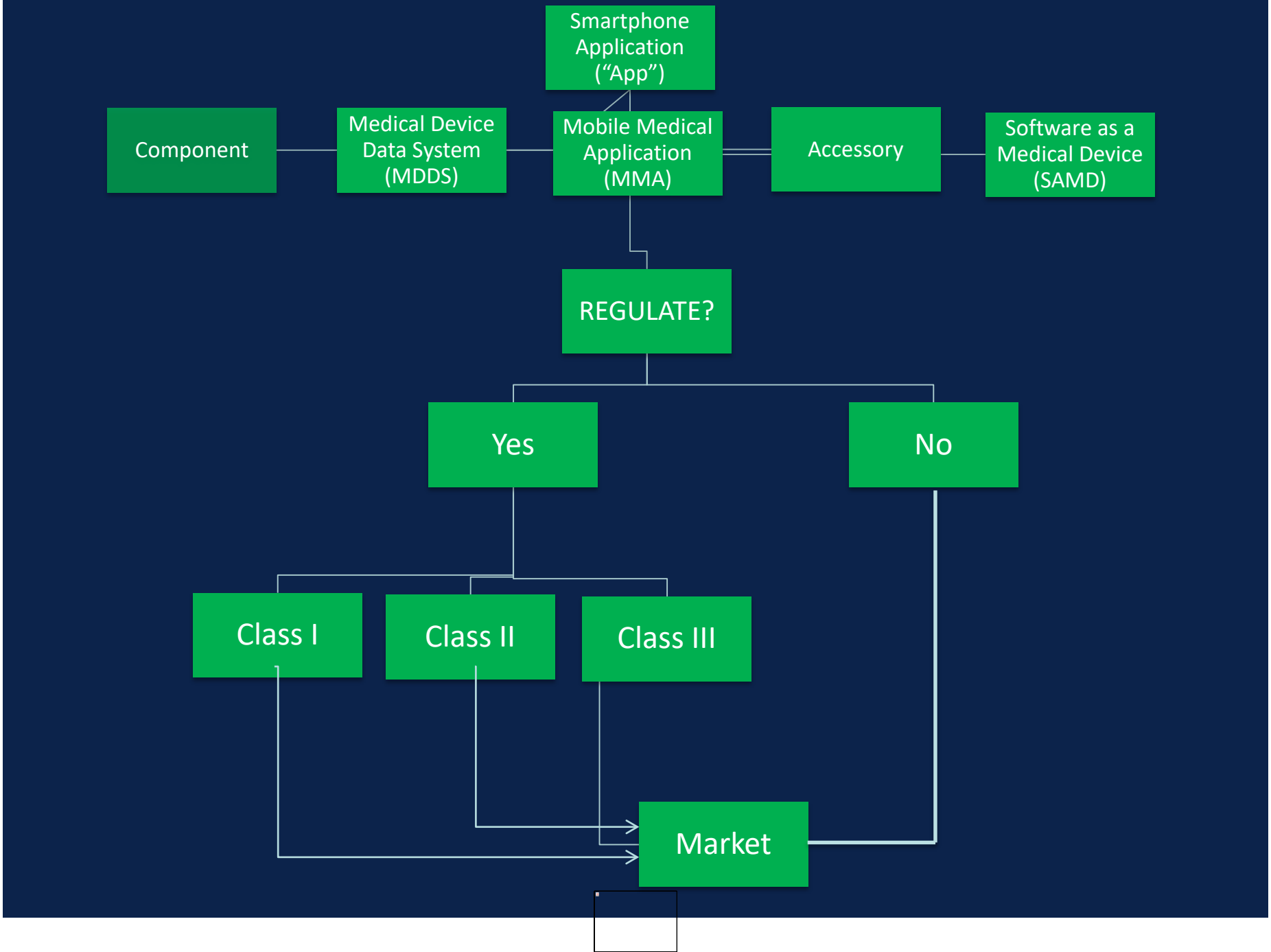


Current regulatory stance

FINDING: No additional regulation required for Health IT but clarity needed on certain aspects, including mobile medical apps

Case study

- Smartphone app connecting phone with computed tomography (CT) scanner (cleared as Class II medical device) to view images for use in orthopedic medicine


Smartphone Application ("App")
Component
Medical Device Data System (MDDS)
Mobile Medical Application (MMA)
Accessory
Software as a Medical Device (SAMD)
REGULATE?
Yes
No
Class I
Class II
Class III
Market

Recommendations

1) Distinguish between motivational/educational apps and apps that aid medical decision-making (regulate latter)

2) App certification for physician reference

3) App-specific approval pathway

4) In-house technical expertise

5) Dedicated FDA mHealth office

- Powell *et al*.; Cortez *et al*.

Thank you

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