Regulating the Initial Wave of Mobile Medical Apps

AACC Emerging Technologies Conference

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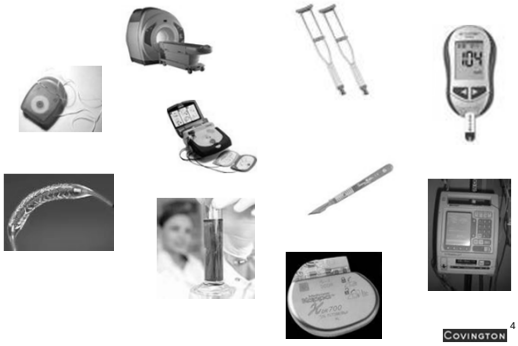
Agenda

- Basics of FDA Device Regulation
- Mobile Medical Apps

Basics of FDA Medical Device Regulation

What are medical devices?



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What Are Medical Devices?

- Type of Product:
  - an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory
- Intended Use:
  - diagnose disease or other conditions,
  - cure, mitigate, treat, or prevent disease in man or other animals, or
  - affect the structure or any function of the body of man or other animals
- Mechanism of Action:
  - does not achieve its primary intended purposes through chemical action within or on the body, and
  - which is not dependent upon being metabolized for the achievement of its primary intended purposes

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Classification of Devices

- Class I – Least Risk
  - Most are exempt from premarket review
  - Subject to "general controls"
  - Examples: dental floss, hospital beds
- Class II – Intermediate Risk
  - Most require clearance of a premarket notification (510(k))
  - General + "Special" controls" (e.g., standards, guidances)
  - Example: glucose test system
- Class III – Highest Risk
  - Require premarket approval application (PMA)
  - Can be "restricted" devices
  - Example: coronary stents

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Pathways to Market

1. Exempt Devices
   - No FDA premarket review
   - Still subject to "general controls"
2. 510(k) Notification
   - Must show "substantial equivalence" to a "predicate device"
   - 90 day review period
   - "Clearance" not "approval"

Pathways to Market (Cont.)

3. Premarket Approval Applications ("PMAs")
   - Applications for FDA approval to market
   - Prove device is safe/effective for intended uses
   - Must include data from "well-controlled investigations"
   - PMA Contents:
     - Marketing history
     - Summary of studies
     - Results of nonclinical laboratory studies
     - Results of clinical investigations involving human subjects
     - Other information

"Least Burdensome"

- FDA must require "the least burdensome means" of demonstrating:
  - Substantial equivalence for 510(k) device
  - Effectiveness for PMA device
- Where clinical data are needed, FDA should consider alternatives to randomized controlled trials
- Concept is to be applied throughout device development process

Mobile Medical Applications (MMAs)

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Software and Mobile Medical Apps

- Rapid innovation in medical software space:
  - Software integrated into traditional devices
  - Stand alone software: electronic health records, mobile medical apps, clinical decision support tools, etc.
- FDA has long taken the position that freestanding software can be a "device" subject to FDA clearance/approval.

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Final Guidance on Mobile Medical Apps

- Described certain mobile applications that FDA will regulate as "mobile medical apps" (MMAs) under its device authorities
- To qualify as an MMA, an app must:
  - Meet the definition of "device" in the FDCA, and
  - Either (1) be an accessory to a regulated device, or (2) "transform the mobile platform into a regulated device"
- If an MMA, traditional device requirements apply, including general controls and possibly clearance/approval requirements

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Final Guidance: Three Categories of Mobile Apps

1. Mobile apps that are not medical devices
   - Don't meet the definition of "device"
   - Intended use is key
2. Mobile apps that
   - Are medical devices, but pose a lower risk
   - FDA will not enforce medical device requirements
3. Mobile Medical Apps
   - Medical devices whose "functionality could pose a risk to a patient's safety if [it] were not to function as intended"

So What If It's an MMA?

- MMA will be regulated as a medical device
- Device must meet requirements associated with applicable device classification
- "Manufacturer" subject to civil and criminal penalties for compliance failures

MAs That Are Not Devices (e.g.)

- Apps that provide electronic copies of medical textbooks, teaching aids, or reference materials
  - E.g., medical dictionaries, first-aid reference manuals
- Apps that serve as medical training tools
  - E.g., surgical training videos/simulators, interactive anatomy diagrams, Board certification prep apps
- Apps for patient education of facilitate access
  - E.g., clinical trial finders, portals for HCP communication
- General aids for "generic" purposes
  - E.g., magnifying glass not specifically intended for medical purposes

Enforcement Discretion MAs (e.g.)

- Apps that supplement clinical care, by coaching or prompting, to help patients manage their health
- Apps that provide health information tracking tools
- Apps that serve as “smart” med. reference tools
- Apps specifically marketed for doctor/patient communication of potential medical conditions
- Apps that perform simple calculations routinely used in clinical practice (e.g., Apgar score)
- Electronic health records

What are MMAs?

- Apps that are an extension of one or more medical devices for purposes of controlling the device or displaying, storing, analyzing patient-specific medical device data



What are MMAs?

- Apps that transform the mobile device into a medical device similar to traditional devices


What are MMAs?

- Apps that allow that perform patient-specific analysis and provide patient-specific diagnoses and/or treatment recommendations

QUESTIONS?

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