Mobile Medical Applications: An Overview of FDA Regulation

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Mobile "Health Apps" – Many Are Medical Devices

- **FDA's Approach** – Sept. 2013 Final Guidance on Mobile Medical Applications
  - *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf*
- **Three "Categories" of Mobile Medical Applications (MMAs)**

  (1) those that FDA does not regard as medical devices at all and thus are outside its legal control;

  (2) those that are or may be medical devices, but that present a low risk to patients and will be the subject of "enforcement discretion;" and

  (3) those that are medical devices and present enough of a risk that FDA will exercise regulatory control over them. I will refer to these hereafter as ***Categories 1, 2 and 3,***

FDA Approach to MMAs

- **Platform is irrelevant** – iOS vs. Android vs. PC vs. Bluetooth, etc. – but limited to "handheld"
- **Focus on Risk –**
  - FDA will regulate those mobile medical apps that present a potential risk of safety to patients when the app functions incorrectly – **Cat. 3**
  - In contrast, FDA will exercise *enforcement discretion* on mobile apps that, despite being legally medical devices, have a lower risk profile in the event of a malfunction -- **Cat. 2**
    - However, where "lower risk" leaves off and a "risk of safety" begins is not clearly defined in the guidance.

Category 3 – Regulated Apps – *3 Types*

1. Apps that function as an extension of an existing medical device by connecting to it – either via wired or wireless links – to control the device, or display, store, analyze or transmit patient-specific data.
   - **Example**: App that can control a blood pressure cuff.
2. Apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to currently regulated medical devices.
   - **Example:** device attaching electrocardiograph to smartphone - AliveCor®

Category 3 – Regulated Apps – *3 Types …*

3. Apps that use patient-specific information for analysis to provide patient specific diagnosis, or treatment recommendations.

  – **Example:** apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy.

Category 2 – Enforcement Discretion – n=*6*

1. Apps that help patients self-manage diseases without providing specific treatment suggestions.

- **Example:** apps that coach patients with conditions such as diabetes with simple prompts to promote strategies for actions that will help their health situation such as maintaining healthy weight, getting optimal nutrition, etc.

2. Apps that help organize and track health info., but do not recommend any change in treatments.

- **Example:** apps the provide simple tools for patients with specific conditions or chronic disease to log, track, or trend their events or measurements (*e.g.*, blood pressure, drug intake, diet) and share this information with their healthcare provider (HCP) as part of a disease management plan.

Category 2 – Enforcement Discretion …

3. **Apps that provide easy access to information regarding the patient's health condition or treatment by matching patient-specific information (*e.g.*, diagnosis, treatments, allergies, signs or symptoms) to reference information normally used in clinical practice.**

- Example: apps that use a patient's diagnosis to provide an HCP with best practice treatment guidelines for common illnesses.

Category 2 – Enforcement Discretion …

4. Apps that help patients document and communicate potential medical conditions to providers that are not promoted for medical uses, but, due to other circumstances surrounding their distribution, may meet the medical device definition.

- **Example:** apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients and HCPs.

5. Apps that automate simple tasks for providers such as to perform basic calculations in clinical practice.

- **Example**: a medical calculator for body mass index (BMI).

Category 2 – Enforcement Discretion …

6. Apps that enable patients/providers to interact with personal health record (PHR) or electronic health records (EHR) and their systems.

- **Example**: an app that allows a patient a portal into their own health information.

Category 1 – Not Medical Devices

- **Many of today's popular apps -- and related devices** -- such as the FitBit® and Nike+®, if used for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions relating to developing or maintaining general fitness, health or wellness -- such as apps that log dietary intake, track normal sleep patterns, or calculate calories burned during exercise
  - ***Not medical devices*** unless they are marketed in a manner that meets the definition of a medical device.
    - *Source*: Footnote 32, in Appendix B, in 9/2013 Guidance

Recent Draft Guidance

- **FDA** -- June 2014 – Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf
  - MDDS – reclassified in Feb. 2011 from Class III to I
  - FDA – "does not intend to enforce compliance with the regulatory controls that apply to MDDS, MISDs, and MICDs due to the low risk they pose to patients and the importance they play in advancing digital health."

June 2014 Draft Guidance

- **Enforcement Discretion** – here it is explained (unlike in the 9/2013 MMA final guidance) as exempting marketers from:
  - Registration and listing
  - Premarket review
    - all 3 are already 510(k) exempt, but FDA said the E.D. would also extend to use deviations that ordinarily would require a 510(k)
  - Post-market reporting (but not clear as to whether that includes MDR or Section 522 requirements); and
  - Quality System Regulation

June 2014 – Proposed Edits to 9/2013 Final Guidance

- **Category 3, Type 1 MMA –**

> Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or ~~displaying, storing, analyzing, or transmitting patient specific medical device data~~ for use in active patient monitoring or analyzing medical device data.

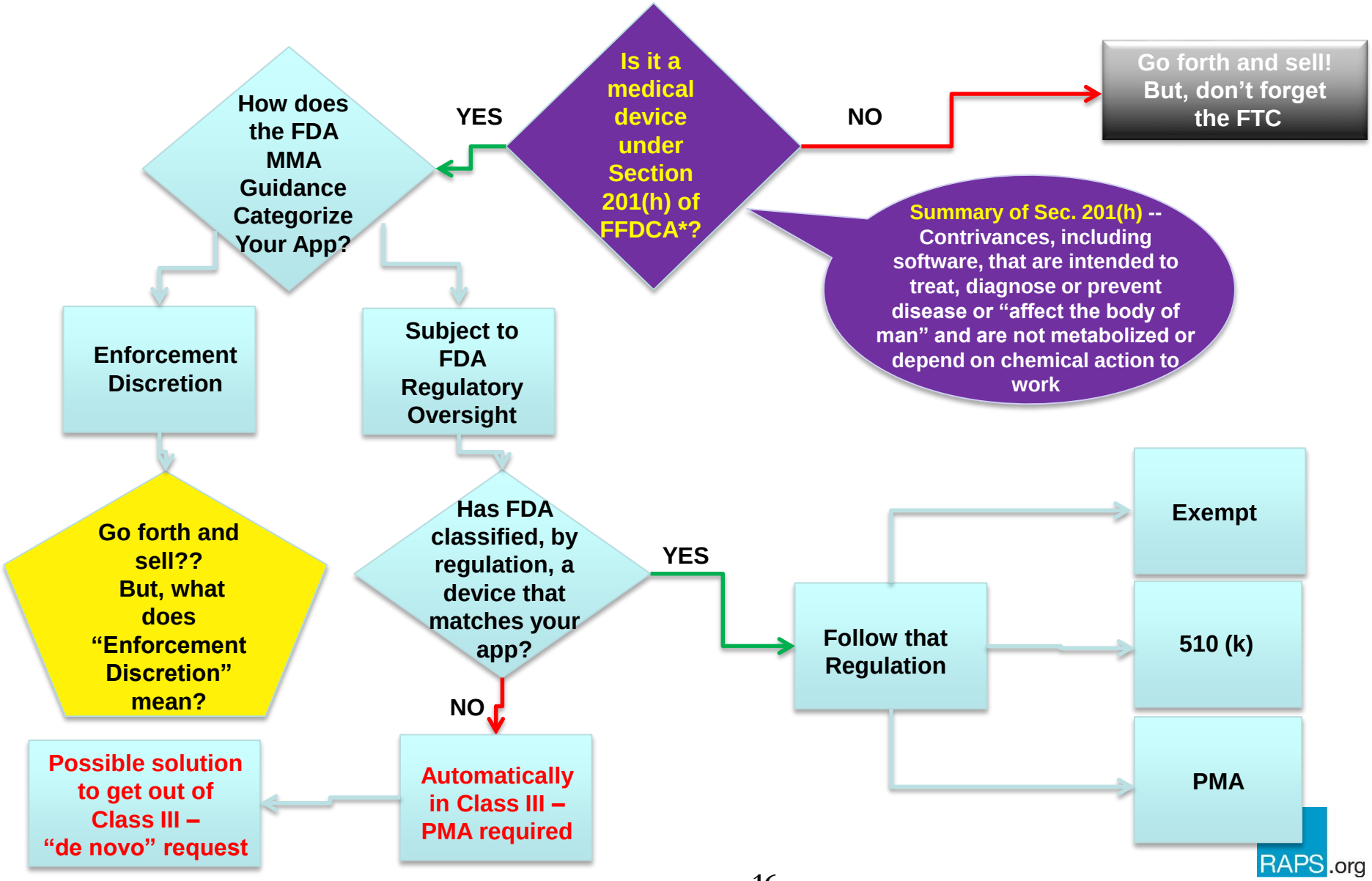
– "for use in active …" – not actually in 9/2013 Guidance

> *Examples of displays of patient-specific medical device data include:* remote display of data from bedside monitors, ~~display of previously stored EEG waveforms,~~ and display of medical images directly from a Picture Archiving and Communication System (PACS) server~~, or similar display functions that meet the definition of an MDDS~~. Mobile medical apps that display medical device data to perform active patient monitoring are subject to regulations associated with such devices.

June 2014 – Proposed Edits to 9/2013 Final Guidance …

- **New Category 2 -- Enforcement Discretion Device**
  - **7. Mobile apps that meet the definition of Medical Device Data Systems** – These are apps that are intended to transfer, store, convert format, and display medical device data, without controlling or altering the functions or parameters of any connected medical device, as defined in the MDDS classification regulation (21 CFR 880.6310). These mobile apps include those that are used as a secondary display to a regulated medical device and are not intended to provide primary diagnosis, treatment decisions, or to be used in connection with active patient monitoring (i.e., mobile apps that meet the MDDS definition).

Basics of Medical Device Regulation and Mobile Medical Apps



*FFDCA = Federal Food, Drug, and Cosmetic Act

MMA – For More Info

- **Duane Morris (DM)** – Basics of FDA Medical Device Regulation And How They Interface with FDA's Final Guidance on Mobile Medical Applications
  - http://www.fdacounsel.com/files/FDA_Basic_Device_Requirements_and_Mobile_Apps_with_3_appendices_20131116.pdf
    - **App. A** – DM – Oct. 2013 -- Summary of 9/2013 Guidance
    - **App. B** – DM -- Oct. 2013 -- Client Alert -- Key Unresolved Issues from 9/2013 Guidance
    - **App. C** – Flow Chart (*see* slide 16)

Questions?

- ***Call, e-mail or fax:***

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About Your Speaker

Michael A. Swit, Esq., is a Special Counsel in the San Diego office of the international law firm, Duane Morris, LLP, where he focuses his practice on solving FDA legal challenges faced by highly-regulated pharmaceutical and medical device companies.

Before joining Duane Morris in March 2012, Swit served for seven years as a vice president at The Weinberg Group Inc., a preeminent scientific and regulatory consulting firm in the Life Sciences. His expertise includes product development, compliance and enforcement, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for all types of life sciences companies, with a particular emphasis on drugs, biologics and therapeutic biotech products.

Mr. Swit has been addressing vital FDA legal and regulatory issues since 1984, both in private practice with McKenna & Cuneo and Heller Ehrman, and as vice president, general counsel and secretary of Par Pharmaceutical, a top public generic and specialty drug firm. He also was, from 1994 to 1998, CEO of *FDANews.com,* a premier publisher of regulatory newsletters and other specialty information products for FDA-regulated firms. He has taught and written on many topics relating to FDA regulation and associated commercial activities and is a past member of the *Food & Drug Law Journal* Editorial Board.

He earned his A.B., *magna cum laude*, with high honors in history, at Bowdoin College, and his law degree at Emory University, and is a member of the California Bar and previously was admitted in both Virginia and D.C., but is inactive in those jurisdictions.