Purpose

- Purpose of today’s presentation
  - Identify the newly-regulated industry
  - Identify the newly regulated products and the basis for that regulation
  - Overview the regulations directed at MMAs and the risks of non-compliance
    - Regulation is complicated. It involves:
      - Classifying devices, premarket and postmarket reporting, ongoing duties and responsibilities, testing and documentation responsibilities and more.
      - Significant risks involved for failures to comply
        ✓ (seek advice of counsel!)

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The Rise of Smartphones

- The Smartphone is a staple of business and personal computing around the world.
- Smartphone adoption has outpaced the PC globally.

Smartphone/Tablet Adoption and Use

- By the end of 2013, of the *global* population:
  - 22% will own a smartphone
  - 20% will own a PC
  - 6% will own a tablet
- Smartphone users are increasingly using their phones for Apps as opposed to the web or other functionality.
- Users are willing to pay for that functionality:
  - Smartphone Apps were an $8 Billion industry in 2012
  - Growing at ~25%/yr
New Devices as Well!

- Wearables
  - Google Glass
  - Smart Watches
  - Increasingly capable SmartBands
    - 17 million projected to be sold in 2014
    - 45 million shipments by 2017
  - Phones with integrated health sensors
    - Samsung Galaxy S5
    - Apple iPhone 6 (rumored)

The Mobile Medical App (MMA)

- There is a large range of Mobile Medical Apps available on the market, involving a host of regulatory issues and significant risks.
  - FDA Regulation
  - HIPAA
- Also represent a huge opportunity
  - Cost savings for Healthcare Providers
  - Patient control over their condition
  - Business opportunity for developers
Federal Gov’t Has Taken Notice

- 2011: FTC orders the removal of 2 smartphone apps from their app stores designed to cure acne using red and blue light.
  - AcneApp- Fined $14,294
  - Acne Pwndr- Fined $1,700
- Removal based in part on FDA documents and recommendations

The FDA Acts

- September 25, 2013
  - FDA Releases “Guidance for Industry” entitled “Mobile Medical Apps”
  - Creates a set of rules and procedures for App makers, designers and sellers for:
    • What is regulated
    • Who is regulated
    • How it is regulated
What is Regulated?

- Medical Devices
  - 21 U.S.C. § 201(h)
    - A device of any kind that is
      ✓ Recognized as a Medical device in the National Formulary, U.S. Pharmacopoeia, or any supplement to them;
      ✓ Intended for use in the diagnosis, treatment, cure, mitigation or prevention of a disease or condition in man or other animals; or
      ✓ Intended to affect the structure of the body, and does not do so via chemical action within the body, and is not dependent upon being metabolized for its affect.
  - Thus, tools used in the diagnosis, treating, monitoring of conditions are Medical Devices. Cures are not.
- Types of Device Approvals to Market
  - PMA
  - 510(k)

Mobile Medical Apps

- Three kinds of MMAs under 201(h)
  - Non “Medical Device” apps
    - Not regulated
  - Apps that interact with a recognized “Medical Device”
    - Regulated
      - The phone/tablet plus some other piece of hardware or software.
  - A piece of software that is designed to convert the phone/tablet into a Medical Device
    - Regulated
    - Software only
Platform Agnostic

- Determining whether something is a “Medical Device” is not based on
  - Software type
  - Platform type
    - Local, cloud/SAAS, web-app etc
- FDA focus is on functionality
  - What it does
  - What the provider claims it does
  - Risk functionality poses to users
    - Example: LED vs LED marketed as ophthalmoscope replacement

1- Non “Medical Device” Apps

- These apps are not Medical Devices under 201(h) and are not regulated by the FDA
  - Reference guides
    - E-books, text books etc, including digital versions of physician reference manuals (DSM, etc), medical dictionaries
  - Educational tools, videos, diagrams, images, test-prep apps
  - Coaching, informational apps for general patient education or reference
  - Apps for healthcare practice administration
  - **Apps not used in the diagnosis and/or treatment of diseases or other conditions**
2- Apps that Interface with a Medical Device

- Blood chemistry monitors

- Fitness Trackers
“Epic ECG”

AliveCor/AliveECG
3- Apps that Convert Hardware

- Mobile MIM (February 2011)
  - X-ray reading app for iPhone and iPad
- Becomes a Medical Device
  - Used in the diagnosis of diseases or conditions
- May use built-in sensors of phone
  - Accelerometer, gyroscope, mic, light sensors
- Dosage Calculators
- Note: Resolution MAY be an issue!
  - If Resolution is important to the correct diagnosis or treatment (reading X-rays, CT-scans etc)

The Exceptions to the Rule

- FDA has indicated there is a group of Mobile Medical Apps that it will, for now, choose to exercise “enforcement discretion”
  - i.e., NOT regulate
  - These apps are considered “low risk” and are not going to be the subject of FDA regulation.
The Exceptions to the Rule

- Officially, these apps are those that:
  - Help Patients self-manage their disease, but don’t provide treatment options
  - Provide patients with simple tools to track health
  - Provide access to information related to their health issues
  - Help patients communicate health issues to providers
  - Automate simple tasks for providers
  - Electronic medical records access apps

Exceptions Continued…

- Examples include:
  - Coaching apps for patient-specific illnesses
  - Internal-use-only apps for doctors within a practice
  - Tracking apps that also send data to the physician
  - Automated advice-providing apps that source recommendations from well-known/established authorities, based on user-provided data.
  - Lists of drug interactions
  - Location-aware apps that alert allergy/asthma sufferers to hazardous conditions
  - Motivational apps
  - Games based on physical therapy regimens
  - WebMD-style apps that ask for symptoms and return possible causes
  - Patient-info access apps
  - Health/Exercise Trackers (FitBit, Nike FuelBand etc)
The Regulated Entity Spectrum

- Hosting Services
- App Stores
- Cloud Services
- Regulated Mobile Medical App Manufacturers
- SAAS, PAAS and other infrastructure providers
- Not Regulated
- Contract Developers
- Software Development Companies
- Phone/Tablet hardware manufacturers
- Not Regulated

Who is Regulated?

- “Mobile Medical App Manufacturers”
  - A new group of companies
  - Likely never before regulated by the FDA
  - Unfamiliar with FDA regulatory schemes, including:
    - Reporting requirements
    - Entity, facility and device registration requirements
    - Risks and consequences of failures to comply
- The definition is flexible and may change in the future
  - Released Guidance documents are “nonbinding” on the FDA, but absolutely binding on regulated individuals and devices/apps!
Who are Mobile Medical App Manufacturers?

- Focus by the FDA is on parties responsible for the App in question.
  - Regulated:
    - The entity that produces the App, or is responsible for its production
    - Any entity who manufactures and sells any hardware accessory for use with an App
    - Any entity that rebrands, repackages or bundles a Mobile Medical App

Who is NOT regulated?

- NOT Regulated:
  - Cell phone/tablet manufacturers (Samsung, HTC, Nokia, LG)
  - Phone OS manufacturers (Apple, Google, Microsoft)
  - Contract software developers
  - Distributors of pre-written code to be included in App
  - Service providers for cloud infrastructure, SAAS, servers, hosting etc.
  - App Stores (iTunes Appstore, Google PlayStore etc)
  - All this, despite that, without these components, the App cannot function.
  - If one of these companies does make a MMA later, it will become a regulated entity. i.e., if Apple makes an iPhone app (Healthbook) that qualifies as an MMA, Apple will become a regulated company.
How Are Apps Regulated?

- FDA applies a risk-based classification system
  - **Class I**
    - Lowest risk
    - General Controls Applied
  - **Class II**
    - Moderate risk
    - General and Special Controls Applied
    - Premarket Notification required
  - **Class III**
    - High risk
    - General Controls and Premarket Notification
  - App must be classified early in order to be aware of the responsibilities the creator has to the FDA and public.

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Regulatory Requirements - General Controls

- Establishment Registration (21 C.F.R. § 807)
  - Annual requirement
  - Register the company and the App(s) it makes
- Quality System Registration (21 C.F.R. § 820)
  - Create standards for the App that ensure safety and efficacy in design, production and distribution of the App.
  - INCLUDES apps FDA is "exercising enforcement discretion"!
- Labeling Requirements (21 C.F.R. § 801)
- Premarket Notification (21 C.F.R. § 807)
- Ongoing Duty to Report Corrections, Removals and Additions (21 C.F.R. § 806)
  - Voluntary or involuntary (may involve removal from the market and fines)
General Controls

Continued

- Medical Device Reporting (21 C.F.R. § 803)
  - In the event of reports that the App may have reasonably led to death or serious bodily injury
  - AKA “Medical Device Reporting”
  - There are significant initial and ongoing requirements in such an event:
    - Initial reporting
    - 5-day reports
    - Create process for identifying and evaluating the App at fault
    - Conduct an investigation and evaluate any App-related causes
    - Record Keeping requirements

General Controls

Continued

- Premarket Notification (21 C.F.R. § 807)
- At least 90 days before distribution of the App IF:
  - It is the first time it has been distributed;
  - If it is a device already in distribution, but is making significant changes to design, components, method of manufacture or use.
    - Emphasis on safety and use
    - Updates and new software versions might apply to this requirement!
    - This includes updates that result from OS upgrades.
Classifying Your App

- The FDA maintains a Database of Medical Device classifications and numbers
- Two ways to Classify:
  - Search by Specialty (area of medicine) and Keyword
  - Search in the Regulations by Specialty
    - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm
  - Will provide a “Panel” number and a Classification (I, II or III)
- Classification is important and complex. Get help!

Exemptions

- Some Class I devices are exempt from some of the General Control requirements
  - Ex: Premarket Notification
  - Based on the low-risk nature of the device type
- Some Class II devices are subject to “Special Control” requirements that add or exempt General Control requirements
  - Add additional reporting requirements or ongoing reporting responsibilities, or even remove premarket notification.
The Bottom Line

- The FDA has defined a new class of entities it will be regulating:
  - Mobile Medical App Manufacturers
- The FDA has defined a new class of Medical Devices it will be regulating:
  - Mobile Medical Apps
  - With exceptions (for now!)
- The regulatory requirements for each are a risk-based system that creates significant responsibilities for those affected.
- These entities are likely unaware of such regulation, and inexperienced with compliance with FDA Medical Device requirements.

One More Thing…

- There are many other regulatory issues at issue with Mobile Medical Apps and Devices.
- These can carry just as many risks and responsibilities as the FDA regulations
- Example: HIPAA, which deals with the privacy of patient health information is particularly implicated with devices and apps whose sole function is the collection of patient health data.
- Seek advice of counsel when entering this market! Tread carefully!
Questions

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