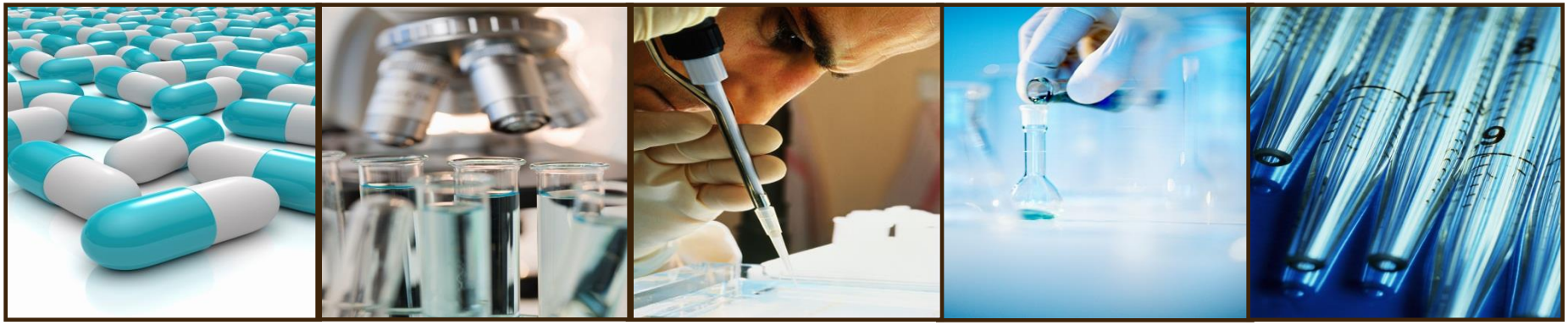

Healthcare on the Go:

Emerging Regulation of Mobile Health Technologies

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Agenda

- **FDASIA's Focus on Health IT**
- **FDA Draft Guidance on Mobile Medical Apps**
- **Recent Developments:**
  - **Congressional Hearing**
  - **FTC Guidance and Enforcement**
  - **Proposed Federal Legislation**
  - **State Guidance and Enforcement**

myVisionTrack

- Enables patients with retinal diseases to monitor their vision function between medical visits.
- Device stores test results, tracks disease progression, and automatically alerts a health care provider if it suspects significant deterioration of visual function.
- Product code:
  - HPT: Ophthalmic; perimeter, automatic, ac-powered
- Class II, prescription device.
- Cleared 2/22/2013.

Mobile MIM

- Used for the viewing, registration, fusion, and/or display for diagnosis of medical images (SPECT, PET, CT, MRI, X-ray, Ultrasound).
- Product codes:
  - LLZ: Picture archiving and communications system.
  - MUJ: Medical charged-particle radiation
  - therapy system.
- Class II, prescription device.
- Cleared 12/2/2011.

Airstrip Patient Monitoring

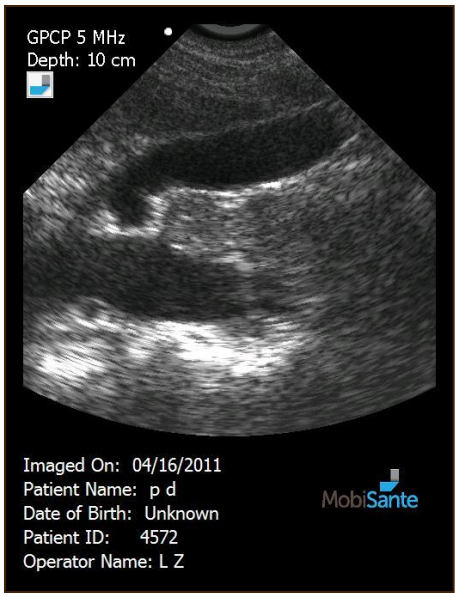
- Used for displaying physiologic and other patient information generated by other devices (*e.g.*, ECG waveform, heart rate monitor, intracranial pressure, urine output, blood pressure cuffs).
- Product code MWI: Cardiac monitor (including cardiotachometer and rate alarm).
- Class II, prescription device.
- Cleared 8/26/2011.

Withings Blood Pressure Monitor

- Used for blood pressure measurement.
- Contains a blood pressure cuff to be connected to an iPhone, iPad, or iPod Touch.
- Product codes:
  - DXN: Noninvasive blood pressure measurement system.
- Class II, OTC device.
- Cleared 5/20/2011.

MobiUS Ultrasound System

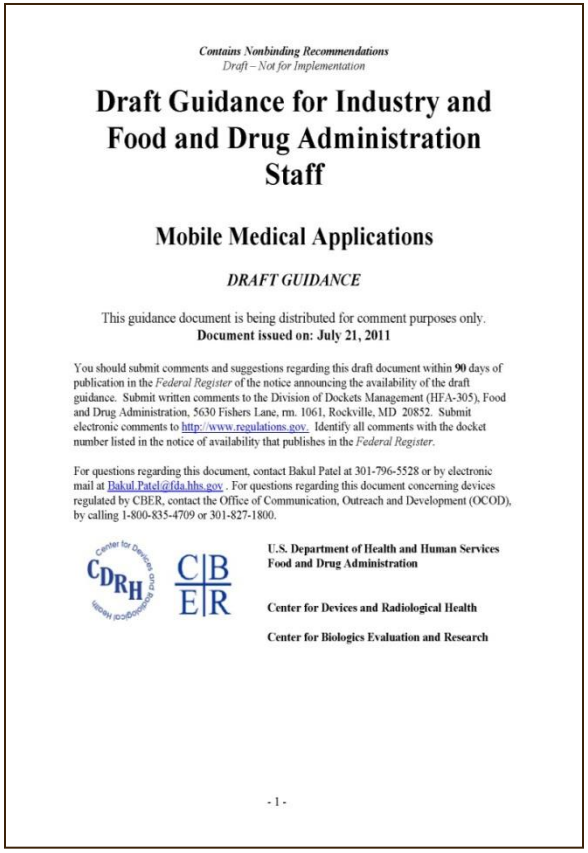
- Used for ultrasound imaging, measurement, and analysis.
- Contains a handheld ultrasound probe that connects to a smartphone.
- Product codes:
  - IYO: Ultrasonic pulsed echo imaging system.
  - ITX: Diagnostic ultrasonic transducer.
- Class II, prescription device.
- Cleared 1/20/2011.



Impact of Food and Drug Administration Safety and Innovation Act ("FDASIA")

- **FDASIA § 618 requires FDA to publish, by January 2014, a report on an "appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety and avoids regulatory duplication."**
  - With input from the National Coordinator for Health IT and FCC.
  - May convene a working group consisting of diverse stakeholders to assist in the development of the regulatory strategy.
- **During development of the report, FDA is permitted to move ahead with regulation of mobile medical apps.**
  - Earlier version of legislation would have stalled FDA's regulatory actions relating to mobile medical apps until release of the HHS report.

FDA Draft Guidance on Mobile Medical Apps



Contains Nonbinding Recommendations
Draft – Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Mobile Medical Applications

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: July 21, 2011

You should submit comments and suggestions regarding this draft document within **90** days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov . For questions regarding this document concerning devices regulated by CBER, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

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- On July 21, 2011, FDA issued a draft guidance document on mobile medical apps.
- FDA did not create a new category of devices.
- The existing device classifications and marketing pathways are to be applied to mobile medical apps.
- FDA plans to apply its regulatory oversight only to certain types of mobile apps:
  - "*This narrowly-tailored approach focuses on a subset of mobile apps that either have traditionally been considered medical devices or affect the performance or functionality of a currently regulated medical device.*"

FDA Draft Guidance: Definitions

- **Mobile Platform**
  - Commercial off-the-shelf computing platforms, with or without wireless connectivity, that are handheld in nature.
  - *E.g.*, smart phones, tablet computers, PDAs.

FDA Draft Guidance: Definitions

- **Mobile Application ("Mobile App")**
  - A software application that runs on a mobile platform, or
  - A web-based software application that is tailored to a mobile platform and is run on a server.

FDA Draft Guidance: Definitions

- **Mobile Medical App**
  - (1) A mobile app that
  - (2) Meets the definition of a "medical device," and
  - (3) Either:
    - Is used as an accessory to a regulated medical device, or
    - Transforms a mobile platform into a medical device.

FDA Draft Guidance: *Enforcement Discretion*

- FDA does not intend for the time being to regulate any mobile apps that meet the definition of a medical device, but that do not meet the definition of mobile medical app.
  - *i.e.*, apps that have medical device indications but that are not accessories to a medical device and do not transform a mobile platform into a medical device.

FDA Draft Guidance: Definitions

- **Mobile Medical App Manufacturer**
  - Any person or entity that manufactures mobile medical apps.
    - "Manufacture" may include initiation of specifications for, designing, labeling, or creating a mobile medical app, either from scratch or by using multiple software components, including commercial off-the-shelf software.

FDA Draft Guidance: Definitions

- **Mobile Medical App Manufacturer**
  - Does not include an entity that solely distributes mobile medical apps (*e.g.*, iTunes store, Android Market, BlackBerry App World).

  - Does not include manufacturer of a mobile platform if the platform is developed with no device intended use.

Mobile Medical Apps: Accessories to Medical Devices

- **Apps that connect to a medical device to either control the device or display, store, analyze, or transmit patient-specific data from the device:**
  - Apps that connect the mobile platform to vital signs monitors, bedside monitors, cardiac monitors, or other similar devices to provide remote access to visual or other information
  - Apps that process/analyze data from a blood glucose monitor
  - Apps that are used as patient screening tools for blood transfusion
  - Apps that connect to a home use diagnostic medical device such as a blood pressure meter, body composition analyzer, or blood glucose meter to collect historical data or to receive, transmit, store, analyze, and display measurements from connected devices
  - Apps that control a blood-pressure cuff connected to a mobile platform to inflate the cuff and measure a person's blood pressure
  - Apps that act as wireless remote controls or synchronization devices for MRI or X-Ray machines

Mobile Medical Apps: Accessories to Medical Devices

→These mobile medical apps are considered accessories to the parent medical devices with which they are used.

→In general, expected to comply with the same requirements and controls as the parent device.

Mobile Medical Apps: Transform Mobile Platforms into Devices

- **Apps that transform a mobile platform into a medical device through the use of display screens, sensors, or attachments:**
  - Apps that connect wirelessly to a blood glucose tester to display, calculate, trend, convert, or download results to a PDA
  - Apps that use a mobile platform to record response time and accuracy of patients completing a cognitive task and/or automatically score or interpret cognitive testing results
  - Apps that use a mobile platform's built-in features (e.g., light, vibrations, camera) to perform medical functions
  - Apps that use pictures or sound to diagnose conditions by comparing to previously determined diagnoses of images, symptoms, sounds, or other physiological measurements
  - Apps that generate signals to check the user's hearing
  - Apps that act as an electronic stethoscope
  - Apps that use a built-in sensor to detect falls

Mobile Medical Apps: Transform Mobile Platforms into Devices

→In general, these apps are expected to comply with the requirements and controls for the type of device into which the platform is transformed.

Mobile Medical Apps: Clinical Decision/Practice Software

- **Apps that allow the user to input patient-specific information and - *using formulae or a processing algorithm* - output a *patient-specific* result, diagnosis, or treatment recommendation that is used in clinical practice or to assist in making clinical decisions:**
  - Apps that act as calculators or utilize algorithms to produce an index, score, scale, or other similar calculations (e.g., pain index, NIH stroke scale)
  - Apps that calculate the amount of chemotherapy needed based on the patient's measurements
  - Apps that assist with patient-specific dosing (e.g., dosage calculators)
  - Apps that provide differential diagnosis tools for a clinician to systematically compare and contrast clinical findings (symptoms/ results, etc.) to arrive at possible diagnosis for a patient
  - Apps that collect blood glucose readings and caloric intake to help manage diabetes by calculating pre-meal insulin dose
  - Apps that define disease stage or progression, and provide a prognosis of a medical condition or predict a patient's response to treatment based on a analysis of physiological, laboratory, and other data

Mobile Apps that Are Not Mobile Medical Apps Under the Draft Guidance

- Electronic copies of textbooks, teaching aids, or reference materials
  - *E.g.*, electronic PDR, flash cards, lists of medical terminology.
  - Compare: App that allows user to input patient-specific information along with reference material to diagnose a disease or condition.

- Apps that log, record, track, evaluate, or help make decisions related to general health and wellness.
  - *E.g.*, diet logs, appointment reminders, exercise suggestions.
  - Not intended for curing, treating, seeking treatment for mitigating, or diagnosing a specific disease, disorder, patient state, or any specific, identifiable health condition.

Mobile Apps that Are Not Mobile Medical Apps Under the Draft Guidance

- Automation of general office operations, including billing, inventory, appointments, insurance transactions.
  - *E.g.*, apps that determine billing codes, apps to automate collection of patient history.
- Generic aids and that are not marketed for a medical function.
  - *E.g.*, general purpose magnifying glass.
- Electronic health record (EHR) systems or personal health record systems.

Congressional Hearing on Health IT

- March 2013: 3 days of hearings by the House Energy and Commerce Committee

- Hearings followed a letter to FDA Commissioner Hamburg that asked about:
  - Timing of Final Guidance on mobile apps
  - Impact of device excise tax on mobile apps
  - Whether FDA considered the "actual use" of an app, smartphone, or tablet to be a factor in whether to regulate the product as a medical device
  - Statistics around the number of mobile apps that have sought FDA approval, FDA review times for these products, and the number of apps that have been removed from the market by FDA

Key FDA Statements at House Hearing

- Christy Foreman, Director, CDRH Office of Device Evaluation:
  - FDA is adopting a "narrowly tailored" and "risk based" approach.
  - Final Guidance will be released by end of this fiscal year (October 1, 2013).
  - Final Guidance will address specific types of mobile apps that fall within FDA's enforcement discretion.
  - FDA plans to maintain a publicly available website that will list cleared/approved mobile medical apps and apps that fall within FDA's enforcement discretion.

Key FDA Statements at House Hearing

- "Strong safety signals" may cause FDA to regulate a medical app.
- FDA has reviewed ~100 mobile medical apps. FDA estimates that the review time for a mobile medical app 510(k) is 67 days.
- FDA does not expect mobile medical app developers "to seek Agency re-evaluation for minor, iterative product changes."
- Questions about the applicability of the medical device tax to mobile medical apps should be directed to the IRS.

FDA v. FTC Authority

- FDA and FTC share authority over the advertising and promotion of medical devices.
- FDA: FDA has authority over labeling for all devices and advertising for restricted devices.
  - Restricted devices are products that may be sold, distributed, or used only on a licensed practitioner's authorization or under conditions established by a PMA order or regulation.
- FTC: FTC has authority over advertising for non-restricted devices. FTC also regulates security and privacy associated with mobile app and software technologies.

FTC Enforcement Action Against Mobile Apps

- In September 2011, the FTC entered into a settlement with the manufacturers of two apps that claimed to treat acne: AcneApp & AcnePwner.
  - Both apps claimed to treat acne with colored lights emitted from smartphones.
  - FTC charged that both apps' promotional claims were unsubstantiated.
  - The two manufacturers paid a total $16,000 in fines.

FTC Guidance: *Marketing Your Mobile App* (August 2012)

- Tell the truth about what your app can do.
  - "*If you say your app provides benefits related to health, safety, or performance, you may need competent and reliable scientific evidence.*"
- Disclose key information clearly and conspicuously.
- Build in privacy considerations from the start.
- Be transparent about your data practices.
- Offer choices that are easy to find and easy to use.
- Honor your privacy promises.
- Protect kids' privacy.
- Collect sensitive information only with consent.
- Keep user data secure.

FTC Guidance: *Mobile Privacy Disclosures* (February 2013)

- Published on February 1, 2013.
- Provides specific recommendations for platforms, app developers, ad networks, and app trade associations.
- Recommendations for app developers:
  - Have a Privacy Policy and make sure it is easily accessible through the app store.
  - Provide just-in-time disclosures and obtain affirmative, express consent when collecting or sharing sensitive data, such as financial or health information.
  - Improve coordination and communication with ad networks and other third parties (*e.g.*, analytics companies), that provide services for apps so that accurate disclosures are provided to consumers (*e.g.*, about any analytics being performed).
  - Participate in self-regulatory programs, trade associations, and industry organizations to work on the development of uniform, concise privacy disclosures.
- Do-Not-Track mechanism

Proposed Federal Legislation

- In 2012, Rep. Mike Honda (D-CA) introduced the "Healthcare Innovation and Marketplace Technologies Act" ("HIMTA"), which would establish an FDA "Office of Mobile Health" to provide recommendations on mobile app issues and ensure compliance with privacy regulations and HHS requirements.
  - In response to concerns that "over-regulation" would stifle mHealth innovation and competition.
- In 2013, Rep. Hank Johnson released a discussion draft of the Application Privacy, Protection, and Security Act of 2013 ("APPS Act"), which would require that app developers provide transparency through consented terms and conditions, data security of collected data, and users with control to cease data collection.
  - In response to concerns about data collection and privacy on mobile devices.

Uptick in State Focus on Mobile Apps

- February 2012 -- CA Attorney General concluded that the state's Online Privacy Protection Act applies to mobile apps used by state residents.
  - The Act requires an operator of a website or online service that collects personal information from state residents to "conspicuously post its privacy policy."
  - The policy must explain what information the app collects and what entities are given the information → Can't just reuse website policy when website gathers less/different information.
  - CA and six leading mobile app platform developers released a "Joint Statement of Principles."

- October 2012 -- CA Attorney General sent hundreds of letters to mobile app developers about the applicability of the state law.
- December 2012 -- CA sued Delta Air Lines over its privacy practices for the Fly Delta mobile app.
- January 2013 -- CA Attorney General published "Privacy on the Go: Recommendations for the Mobile Ecosystem."

To Do's

- Know your device technology and product development partners.
- Establish internal oversight and controls to address aggressive FTC and state scrutiny of mobile technologies.
- Monitor developing law and regulation of mobile technologies -- both federal and state levels.
- Watch for Final FDA Guidance on Mobile Apps - October 1, 2013.

Questions?

Marian Lee is a partner in the FDA & Life Sciences Practice Group at King & Spalding. Ms. Lee advises medical device, pharmaceutical, and biotechnology companies on a wide range of FDA regulatory and compliance issues. She brings significant experience to matters involving promotion and product labeling, complaint handling and adverse event reporting, product recalls, clinical studies, product clearances and approvals, good manufacturing practice (GMP) and quality system (QS) requirements, regulatory risk audits, governmental investigations, and due diligence assessments of FDA-regulated entities. Ms. Lee also has particular expertise in the FDA and FTC regulation of advertising and social media, and the regulation of mobile health (mHealth) and health information technologies.

Law 360 recently selected Ms. Lee as a "Rising Star," one of four attorneys recognized in her field nationwide. She is a Fellow to the Leadership Council on Legal Diversity, and a member of the *Law 360* Life Sciences Editorial Advisory Board. At King & Spalding, Ms. Lee serves as the Deputy Hiring Partner of the Washington D.C. office.

Ms. Lee graduated from Harvard Law School and Harvard College, *magna cum laude* and Phi Beta Kappa.

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