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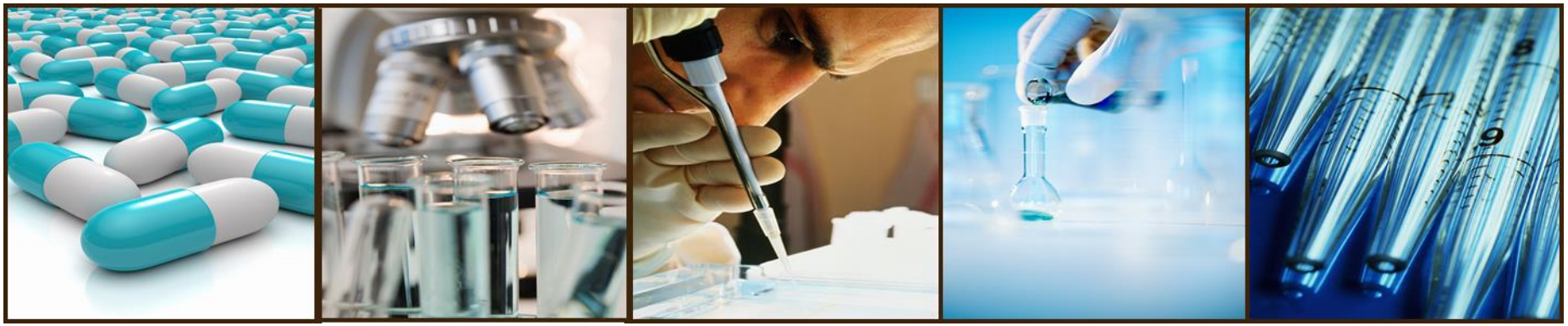
FDA Regulation of Health IT



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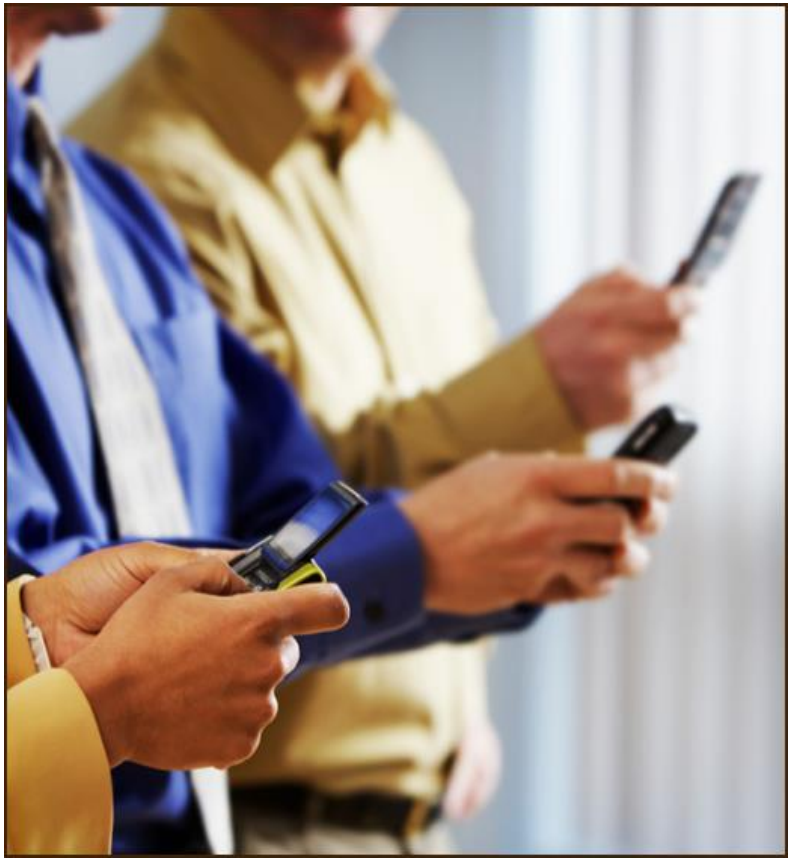
Agenda

- **FDA's Mobile Medical Applications Guidance**
- **FDASIA Health IT Report**



FDA's Mobile Medical Apps Guidance – September 2013

FDA's Regulatory Focus

- Issued by FDA on September 25, 2013
- FDA intends to apply its regulatory oversight to:
  - Mobile apps that are medical devices *and*
  - Whose functionality could pose a risk to patient's safety if the mobile app were to not function as intended.
- Focus on small subset of mobile apps that present a risk to patients.
- Focus on functionality, not the platform.
  - FDA does not regulate the sale or general/conventional consumer use of smartphones or tablets.

"Mobile Medical App"

- **Mobile Medical Application** – Mobile app that meets the definition of a device (FDCA § 201(h)) and either is intended to:
  - Be used as an accessory to a regulated medical device; or
  - Transform a mobile platform into a regulated medical device.

"Mobile Medical App Manufacturer"

- **Mobile medical app manufacturer** – any person or entity that manufactures mobile medical apps in accordance with 21 C.F.R. Parts 803, 806, 807, and 820.
  - Includes anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components.
  - Does not include persons who exclusively distribute mobile medical apps without engaging in manufacturing functions.
    - *Examples*: Google Play, iTunes store, and Blackberry App World.

FDA Regulatory Approach

- FDA "strongly recommends" that manufacturers of "all mobile apps that may meet the definition of a device":
  - Follow the Quality system regulations (21 C.F.R. Part 820) during design and development; and
  - Initiate prompt corrections.
- Regulated apps must meet requirements associated with applicable device classification.
  - Class I (general controls)
  - Class II (general controls and special controls)
  - Class III (premarket approval)
- Guidance identifies existing product codes for many regulated apps.

Regulated Mobile Apps

- Apps that are an extension of one or more medical devices by connecting to such devices for the purpose of controlling the device, or displaying, storing, analyzing, or transmitting patient-specific medical device data.
  - Apps that control the ability to inflate/deflate a blood pressure cuff through a mobile platform
  - Apps that control the delivery of insulin through an insulin pump by transmitting control signals to the pump from a mobile platform
  - Apps that calibrate or change settings in a cochlear implant
  - Apps that connect to a bedside or cardiac monitor and transfer the data to a central viewing station
  - Apps that display a previously stored EEG waveform or medical images
  - Apps that connect to a nursing station to display medical device data or connect to a physician's mobile platform for review, without controlling or altering the functions or parameters of any connected device (i.e., medical device data systems/MDDS)

Regulated Mobile Apps (cont'd)

- Apps that transform the mobile platform into a regulated medical device by using the platform's built-in features, attachments, display screens, or sensors, or by including functionalities similar to those of currently regulated medical devices.
  - Apps that use a sensor attached to a mobile platform to record, view, or analyze eye movements for use in the diagnosis of balance disorders
  - Apps that use an attachment to a mobile platform to measure blood oxygen levels for diagnosis of a disease
  - Apps that connect to a sensor or lead that is connected to a mobile platform to measure and display ECGs
  - Apps that use a sensor attached to a mobile platform or tools within the platform (e.g., accelerometer) to measure the degree of tremor caused by certain diseases
  - Apps that use an attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter

Regulated Mobile Apps (cont'd)

- Apps that become regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.
  - Apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy
  - Computer Aided Detection software (CAD)
  - Image processing software

Examples of Mobile Apps that Are Not Devices

- Apps intended to provide access to electronic "copies" of medical textbooks or other reference materials
- Apps intended for HCPs to use as educational tools for medical training or to reinforce previously received training
- Apps intended for general patient education and to facilitate patient access to commonly used reference information (can filter for patient-specific characteristics)
- Apps that automate general office operations in a health care setting and are not used for diagnosis, cure, mitigation, treatment, or prevention of disease
- Apps that are generic aids or general purpose products

Examples of Mobile Apps within FDA's Enforcement Discretion

- Apps that help patients self-manage their disease/condition without providing specific treatment or treatment suggestions
- Apps that help patients document, show, or communicate potential medical conditions to HCPs
- Apps that enable patients or providers to interact with PHR or EHR systems
- Apps that prompt a user to enter a drug they would like to take and provide information about drug-to-drug interactions reported in the literature

Examples of Mobile Apps Within FDA's Enforcement Discretion (cont'd)

- Apps that keep track of medications and provide user-configured reminders for improved medication adherence
- Apps that provide periodic educational information, reminders, or motivational guidance for smokers trying to quit, patients recovering from addiction, or pregnant women
- Apps that use GPS information to alert asthmatics of environmental conditions that may trigger symptoms
- Apps that use patient age, sex, and behavioral risk factors to provide patient-specific screening and preventive recommendations based on well-known and established sources

FDASIA Health IT Report – April 2014

FDASIA Section 618

- Section 618 of FDASIA required FDA, in consultation with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC), to develop a report that –
  - "contains a proposed strategy and recommendations 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."
- FDASIA Health IT Report published in early April 2014.
- Public comments due by July 7, 2014.

Key Takeaways

- "limited, narrowly-tailored approach"
- "primarily relies on ONC-coordinated activities and private sector capabilities"
- No new or expanded regulations for health IT are recommended.
- Focus on health IT "functionalities", not the specific platforms.
  - Administrative health IT functionality
  - Health management health IT functionality
  - Medical device health IT functionality

Key Takeaways (cont'd)

- Proposes new Health IT Safety Center – develop best practices, technology standards, and validation and assessment tools
- "Priority Areas":
  - Promote the use of quality management principles
  - Identify, develop, and adopt standards and best practices
  - Leverage conformity assessment tools
  - Create an environment of learning and continual improvement

Administrative Health IT Functionality

- Admissions, billing and claims processing, practice and inventory management, scheduling, general purpose communications
- Analysis of historical claims data to predict future utilization or cost-effectiveness
- Determination of health benefit eligibility
- Population health management
- Reporting on quality measures.

→**Poses limited or no risk to patient safety.**

→**No additional oversight required.**

Health Management Health IT Functionality

- "Most" clinical decision support (CDS)
- Health information and data exchange
- Data capture and encounter documentation
- E-access to clinical results
- Medication management
- Knowledge management

→**Poses <u>low risk</u> compared to potential benefits.**

→**<u>ONC</u> to have primary responsibility.**

Medical Device Health IT Functionality

- "Small subset" of "higher risk" CDS
- Computer-aided detection software
- Remote display or notification of real-time alarms from bedside monitors
- Radiation treatment planning

→**FDA to maintain primary responsibility.**

→**ONC and FCC may have complementary activities (e.g., interoperability between medical device and EHR, use of wireless spectrum for medical devices)**

Clinical Decision Support (CDS)

Examples of CDS categorized under Health Management IT Functionality (ONC oversight):

- Evidence-based clinician order sets tailored to a particular condition
- Drug-drug interaction alerts
- Most drug dosing calculations
- Suggestions for diagnoses based on patient-specific information from an EHR
- Reminders for preventive care (e.g., immunizations)
- Drug formulary guidelines
- Calculation of prediction rules and severity of illness assessments (e.g., APACHE score)

Priority Area: *Promote Use of Quality Management Principles*

- "Judicious application" of quality management principles and processes to health IT
- Joint effort between government and health IT stakeholders, rather than formal regulatory approach
- Improve transparency around quality management principles

Priority Area: *Identify, Develop, and Adopt Standards and Best Practices*

- Allow flexibility in design and development to meet needs while setting acceptable levels of performance
- Some existing consensus standards may be applicable to health IT, e.g., quality management systems
- ONC has responsibility for advancing development of health IT standards and best practices
- Focus on health IT design and development; local implementation, customization and maintenance of health IT; interoperability; quality management; and risk management

Priority Area: *Leverage Conformity Assessment Tools*

- Application of conformity assessment tools in a risk-based, flexible manner "to distinguish high quality products, developers, vendors, and organizations from those that fail to meet a specified level of quality, safety, or performance"
- Certification, testing, inspection, and/or declaration of conformity
- Self-assessment vs. accreditation by a third party
- Could apply to an entire product, developer, or organization, or only to a specific performance characteristic, process, or system
- Role of private sector vs. government

Priority Area: *Create an Environment of Learning and Continual Improvement*

- Challenges: contractual limitations, fear of liability, and practices that discourage free flow of information
- Identifying and reporting "serious health IT-related safety events to a trusted source that can aggregate and analyze information and disseminate findings"
- Promoting transparency and information sharing, education and learning, and adoption of interventions and mitigations
- New Health IT Safety Center


Thank
You!

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Marian J. Lee is a partner in the FDA & Life Sciences Practice Group at King & Spalding. Marian advises pharmaceutical, medical device, and biotechnology companies on a wide range of FDA regulatory and compliance issues. She brings significant experience to matters involving promotion and advertising, complaint handling and adverse event reporting, product recalls, clinical studies, product clearances and approvals, good manufacturing practices (cGMP) and Quality System (QS) analyses, compliance risk audits, government investigations, and due diligence assessments of FDA-regulated entities. Marian has particular expertise in the federal and state regulation of social media and mobile health (mHealth) technologies.

Law 360 selected Marian as a "Rising Star," one of four attorneys recognized in her field nationwide. She is a member of the Food and Drug Law Institute (FDLI) Policy Forum Editorial Board and the *Law 360* Life Sciences Editorial Advisory Board. She also was a Fellow to the Leadership Council on Legal Diversity (LCLD).

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