5th Annual Florida Telehealth Summit

Telemedicine and Medical Devices

FDA Regulation of Medical Devices: What You Need To Know

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- We declare that we have no proprietary, financial or other personal interest of any nature or kind in any product, service and/or company that will be discussed or considered during the proposed program.

Agenda

- Why does this matter?
- Definition
- Regulatory Framework and Perspective for Mobile Apps and Telehealth Products
- FDA Enforcement

FDA Regulation

- Multiple stakeholder involvement in telemedicine/digital health activities
  - Patients
  - Practitioners
  - Researchers
  - Traditional device developers/ etc.....
- Many stakeholders are new to understanding/considering FDA regulatory requirements - such as mobile app developers (consider providers are frequently becoming developers)

FDA Regulation

- FDA has been working to provide clarity on the following topics in the digital health
  - Wireless medical devices
  - Mobile Medical Apps
  - Health IT
  - Telemedicine
  - Software as a Medical Device (SaaS)
  - General Wellness
  - Medical Device Data Systems
  - Medical Device Intraoperability

FDA Regulation

- FDA regulation has broad impact
  - Modalities (synchronous vs. asynchronous)
  - State regulation
  - Reimbursement/Coverage
  - Off label uses of new or modified devices

One of the newest modalities is mHealth: includes on-line services and mobile apps marketed to consumers – frequent use in telemedicine

FDA Regulation:
Device
Software
Apps.....

What is a "Device"?

The term **"device"** . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for **use in the diagnosis of disease** or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) **intended to affect the structure or any function of the body of man** or other animals, and

which **does not achieve its primary intended purposes through chemical action within or on the body** of man or other animals and which is **not dependent upon being metabolized for the achievement of its primary intended purposes . . . .**

FDCA § 201(h), 21 USC 321(h)

Discussion Questions

- Questions for each:
  - ✓ Is it a device, drug, non-device, other?
  - ✓ What's the basis for this categorization?
- Example 1: Plastic earpiece promoted as a appetite suppressant diet aid
- Example 2: A hand-held portable oxygen delivery system promoted as performance-enhancing by enabling athletes to have the "winning edge"
- Example 3: Software solely used to log, record, track, evaluate, or make decisions or suggestions related to developing or maintaining general health and wellness
- Example 4: Software that controls a laser light on a mobile medical platform labeled for use to help illuminate printed reading materials
- Example 5: Software that controls a laser light on a mobile medical platform promoted for use in examining and documenting patient movements
- Example 6: Software allowing the user to input patient-specific information along with reference material to automatically diagnose a disease or condition

Overview: FDA's Three Medical Device Classes

- Class I
- Examination gloves, hand-held surgical instruments
- General Controls
- Most exempt from premarket submission

- Class II
- Diagnostic ultrasound, eye contacts
- Special Controls
- Premarket Notification (510k clearance)

- Class III
- Joint replacements, heart valves
- Premarket Approval (PMA)

See: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Device Classifications

Class I

- General controls are sufficient to provide reasonable assurance of safety and effectiveness.
- General Controls
  - Adulteration and misbranding provisions
  - Establishment registration and device listing
  - Premarket notification - 510(k) when required (most are exempt)
  - Recall notification and repairs
  - Replacement or refund
  - Records and Medical Device Reports (MDR)
  - Banned devices
  - Good Manufacturing Practices (unless exempt)
- Examples: scalpels; tongue depressors.
- *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Device Classifications (cont.)

Class II

- General controls alone are *insufficient* to provide reasonable assurance of safety and effectiveness.
- Generally must meet general controls - most Class II devices require 510(k) clearance and applicable special controls.

  Special Controls
  - Performance Standards
  - Post-market surveillance
  - Patient registries, guidelines, recommendations and
  - "Other Appropriate Actions" as identified by CDRH
- Examples: lasers for general surgery, diagnostic ultrasound.

Device Classifications (cont.)

Class III

General controls and special controls alone are *insufficient* to provide reasonable assurance of safety and effectiveness

Applicable to devices that

- support or sustain human life; or
- are of substantial importance in preventing impairment of human health; or
- present an unreasonable risk of illness or injury; or
- are not substantially equivalent to a legally marketed Class I, Class II or pre-amendment (device marketed before May 28, 1976) Class III device - for which PMAs have not been called for by FDA.

Device Classifications (cont.)

Class III

- Must meet general controls;
- Must be *approved* by FDA prior to marketing; and
- Pre-amendment Class III devices - can be submitted and cleared by FDA via a 510(k) until a PMA is called for by FDA.
- Examples: Artificial hearts, lasers for ophthalmic surgery, many spinal implants.

Regulation of Mobile Apps

- Dr. Gottlieb's – plan for mobile app regulation:

"For these … digital technologies to take hold and reach their fullest potential, it is critical that FDA be forward-leaning in making sure that we have implemented the right policies and regulatory tools, and communicated them clearly, to encourage safe and effective innovation . . . . In this rapidly changing environment, ambiguity regarding how FDA will approach a new technology can lead innovators to invest their time and resources in other ventures. To encourage innovation, FDA should carry out its mission to protect and promote the public health through policies that are clear enough for developers to apply them on their own, without having to seek out, on a case-by-case basis, FDA's position on every individual technological change or iterative software development."

FDA's Digital Health Innovation Action Plan

From mobile medical apps and fitness trackers, to software that supports the clinical decisions doctors make every day, digital technology has been driving a revolution in health care.

FDA's Digital Health Innovation Action Plan (July 2017) outlines FDA's efforts to reimagine FDA's approach for assuring timely access to high-quality, safe and effective digital health products.

This plan includes:

- Guidance on the medical software provisions of the 21st Century Cures legislation;
- Launching an innovative pilot pre-certification program to develop a new approach to digital health technology oversight (FDA Pre-Cert for Software); and
- Building FDA's bench strength and expertise in CDRH's digital health unit

mHealth Apps Segmentation

- **Chronic care management** apps. They include mHealth apps for managing blood pressure, diabetes, cancer, mental health, other illnesses.
- **Medical Apps**. They are various diagnostic apps, medical apps that generate awareness among patients. Also those are the apps that create alerts, apps that serve as medical reference for patients and physicians etc.
- **Healthcare and Fitness Apps**. Different nutrition apps, health-tracking, fitness and weight loss apps belong to this segment.
- **Women's Health Apps** which include pregnancy, fertility, breastfeeding apps and other.
- **Medication Management Apps**. These mHealth apps include all apps that help to keep track of taking medication in order to improve its adherence among patients.
- **Personal Health Record Apps**. They are the applications that allows patients to store their medical conditions data, allergies etc. and share it with their doctors.

FDA – Mobile Medical Applications Feb 2015

- Contains Nonbinding Recommendations
  - Not legally enforceable
  - Provides the Agency's best thinking
- FDA recognizes the extensive variety and rapid pace of innovation
- FDA is considering functionality as opposed to platform
  - Apply regulatory oversight to apps whose functionality could pose a risk to patient safety
- FDA provides detailed feedback thru the Pre-Submission process
- https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

Examples of MMAs the FDA Regulates

- **Mobile apps that transform a mobile platform into a regulated medical device and therefore are mobile medical apps**
  - These mobile apps use a mobile platform's built-in features such as light, vibrations, camera, or other similar sources to perform medical device functions (e.g., mobile medical apps that are used by a licensed practitioner to diagnose or treat a disease).
- **Mobile apps that connect to an existing device type for purposes of controlling its operation, function, or energy source and therefore are mobile medical apps:**
  - These mobile apps are those that control the operation or function (e.g., changes settings) of an implantable or body worn medical device
- **Mobile apps that display, transfer, store, or convert patient-specific medical device data from a connected device and therefore are mobile medical apps**

Examples of Mobile Apps For Which the FDA Will Exercise Enforcement Discretion

Mobile apps that **MAY** meet the definition of medical device but for which FDA intends to exercise enforcement discretion, because they pose a lower risk to the public. These mobile apps **may be intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease**. Some examples include:

- Mobile apps that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women
- Mobile apps that use video and video games to motivate patients to do their physical therapy exercises at home
- Mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks
- Mobile apps that enable a patient or caregiver to create and send an alert or general emergency notification to first responders

Not Devices: Education and Training Apps

- Intended for health care providers to use as educational tools for medical training or to reinforce training
- More functionality than providing an electronic copy of text (e.g., videos, interactive diagrams), but are not devices because they are intended generally for user education and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by facilitating a health professional's assessment of a specific patient, replacing the judgment of clinical personnel, or performing any clinical assessment. Examples include mobile apps that are:
  - Medical flash cards with medical images, pictures, graphs, etc.;
  - Interactive anatomy diagrams or videos;
  - Surgical training videos;
  - Medical board certification or recertification preparation apps;
  - Games that simulate various cardiac arrest scenarios to train health professionals in advanced CPR skills;
  - Digital education tools, quizzes, games, and questionnaires that help engage patients to actively participate in their general health and wellness (calorie consumption, benefits of physical activity).

Not Devices: Patient Education Apps

- Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information. These apps can be patient-specific (i.e., filters information to patient-specific characteristics), but are **intended for increased patient awareness, education, and empowerment, and ultimately support patient-centered health care**. Examples include mobile apps that:
  - Provide a portal for healthcare providers to distribute educational information (e.g., interactive diagrams, useful links and resources) to their patients regarding their disease, condition, treatment or up-coming procedure;
  - Help match patients with potentially appropriate clinical trials and facilitate communication between the patient and clinical trial investigators;
  - Provide tutorials or training videos on how to administer first-aid or CPR;
  - Find the closest medical facilities and doctors to the user's location;
  - Provide lists of emergency hotlines and physician/nurse advice lines; and
  - Provide and compare costs of drugs and medical products at pharmacies in the user's location.

Not Devices: Apps to Automate Operations

- Mobile apps that automate general office operations in a health care setting. Examples include mobile apps that:
  - Determine billing codes like ICD-9 (international statistical classification of diseases);
  - Enable insurance claims data collection and processing and other apps that are similarly administrative in nature;
  - Generate reminders for scheduled medical appointments or blood donation appointments;
  - Help patients track, review and pay medical claims and bills online;
  - Manage shifts for doctors;
  - Manage or schedule hospital rooms or bed spaces;
  - Provide wait times and electronic check-in for hospital emergency rooms and urgent care facilities;
  - Allow healthcare providers or staff in healthcare setting to process payments (for example a HIPAA compliant app); and
  - Track or perform patient satisfaction survey after an encounter or a clinical visit.

Not Devices: General Purpose Apps

- Mobile apps that are generic aids or general purpose products.
- Examples include mobile apps that:
  - Use the mobile platform for recording audio, note-taking, replaying audio with amplification, or other similar functionalities;
  - Allow patients or healthcare providers to interact through email, web-based platforms, video or other communication mechanisms (but are not specifically intended for medical purposes);
  - Provide maps and turn-by-turn directions to medical facilities;
  - Allow health care providers to communicate in a secure and protected method (for example HIPAA compliant); and
  - Use the mobile platform to translate unintelligible speech for better clarity.

Representative Examples: Devices/Apps used to deliver care today.....

t:slim X2 Insulin Pump with Basal-IQ Technology

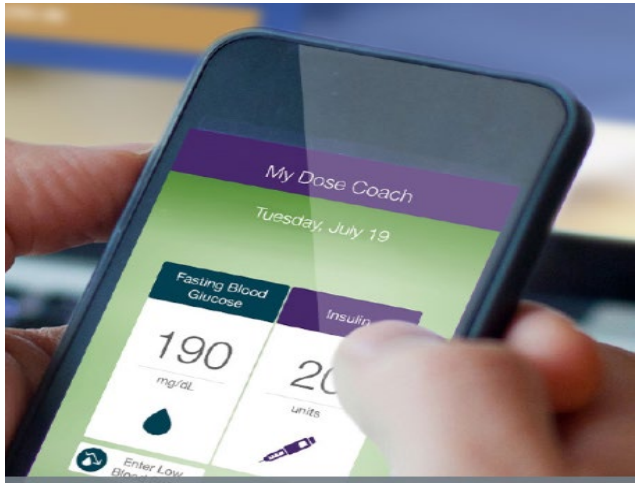
Continuous glucose monitor (CGM) and an insulin pump with Basal-IQ technology.

The System is intended to monitor glucose (sugar) levels and to deliver insulin for the management of diabetes.

The Basal IQ technology feature of the insulin pump predicts whether glucose levels will fall below a predefined threshold to suspend insulin delivery.

My Dose Coach – Sanofi, Inc.

- Aid to patient to provide insulin dose suggestions
  - Cleared in 2017
  - Not replace care or advice of a physician



  - https://www.mydosecoach.com/

GoSpiro® - Monitored Therapeutics, Inc.

- Conduct basic lung function and spirometry testing

"Lisa" the avatar based, real-time patient coaching and test review is available on the GoHome Platform.

Flow-time curve with ideal time to peak flow marker and 6 sec countdown timer provide patient performance quality cues.

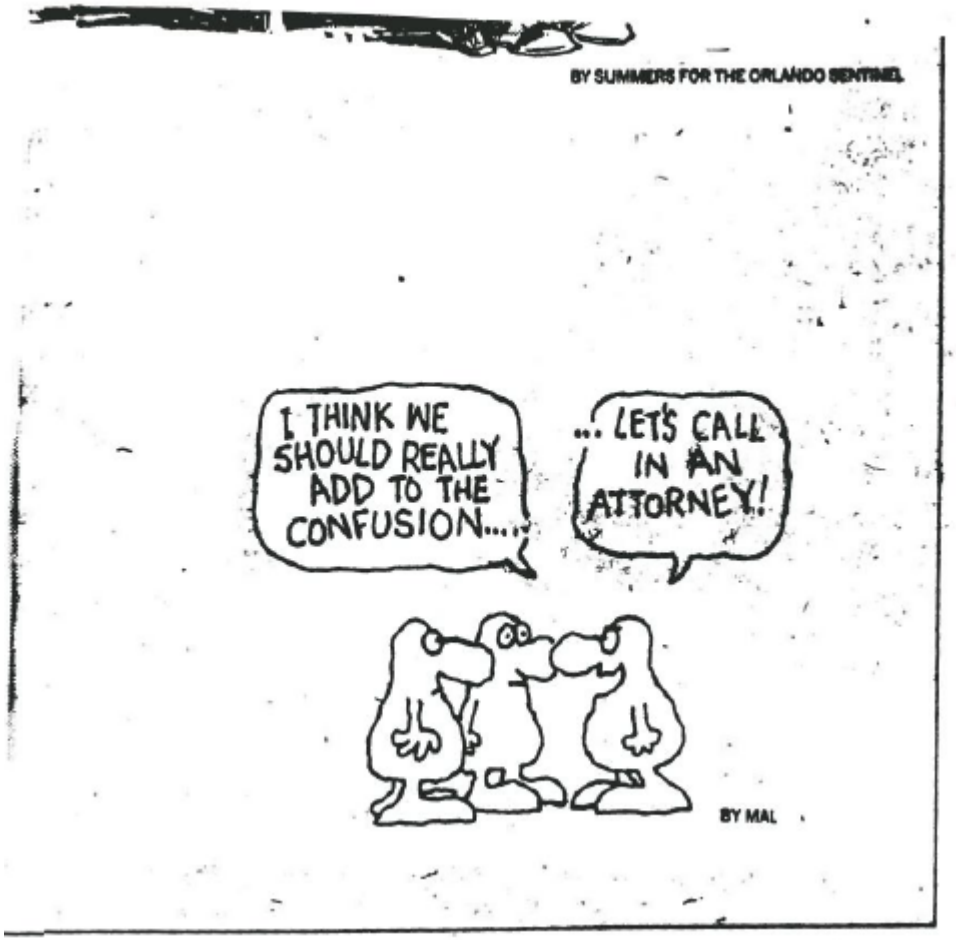
FDA Information

- List of Submissions that include Mobile Medical Apps Cleared or Approved by FDA

- https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm

Get FDA Feedback

- Contact the Center's Device Determination Officers, Office of Compliance, by e-mail at DeviceDetermination@fda.hhs.gov for an informal device determination whether or not a product is a device.
- Submit a 513(g) request, which provides a means for obtaining the agency's views about the classification and the regulatory requirements that may be applicable to a particular device.



Why do we care?

- The federal Food, Drug, and Cosmetic Act (FDCA) prohibits the "adulteration or misbranding" of any device or drug. 21 USC § 331(b).
- A drug or device is deemed misbranded if its label does not bear "adequate directions for use." 21 USC § 352(f).

Off-Label Promotion

- FDA prohibits companies from marketing medical devices for uses that the agency has not approved.
- Off-label promotion occurs when a firm:
  - markets a device that has not received FDA approval and
  - promotes an approved device for an unapproved use.
- Off-label promotion may result in legal regulatory, civil, and criminal penalties.

Sanctions and Penalties for Violations of the FD&C Act

- Regulatory Enforcement Action
  - Warning Letter
  - Untitled Letter
  - Import Detention
  - Seizure
  - Injunction
- Civil Monetary Penalties
- Criminal Liability

FDA Enforcement

- Opternative, Inc. Warning Letter 10/30/17
- On-line eye examination
- FDA stated it requires a premarket submission in order to evaluate its safety and effectiveness

DOJ & OIG Enforcement

- **Corporate Integrity Agreements (CIA).** A CIA results from negotiations between the OIG and a company after the OIG investigates suspected wrongful conduct such as off-label promotion. The CIA sets forth the actions the company will undertake to correct the alleged wrongful conduct. The typical term for a CIA is five years.

- **Deferred prosecution agreements (DPA)**. Companies that promote off-label use may enter into DPAs with the Department of Justice. DPAs allow companies to avoid indictment, trial, and conviction, although they must concede liability. The government files charges but then holds them in abeyance while the company implements certain agreed upon corrective measures, such as the adoption of a compliance program, over a specified period of time.

- **Product Liability Implications.** Off-label promotion can negatively impact a manufacturer's ability to defend itself against a lawsuit brought by an allegedly injured plaintiff. For example, a plaintiff can claim that a company acted negligently when it failed to seek FDA approval for a particular use. Promoting a device off-label may preclude a company from successfully utilizing legal defenses that are typically available in product liability actions, e.g., the "learned intermediary defense".

What the Future Holds

- Operability for a reasonable user experience
- Privacy over user information and PHI in full compliance with federal and state laws, rules and regulations
- Security protecting the app from external threats
- Accurate and current content in the app

- Impact on the home healthcare market
  - Enables patients to leave the hospital for home sooner
  - Access medical records easily
  - Communicate with healthcare professionals
  - Patient engagement

- Future of mobile health apps
  - Use of artificial intelligence
  - Offers healthcare professionals new decision-support tools
  - Application of Big Data and Analytics in mHealth Apps

Thank You & Questions

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