FDLI Intro to Device: Digital Health April 13, 2022

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Agenda

- FDA's Intersection with mHealth
- How is Medical Device Defined?
- Perspective for Mobile Medical Applications (MMAs)
- Clinical Decision Support Software (CDS)
- FDA Enforcement

Who are the stakeholders?

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

FDA Authority

- FDA's authority to regulate medical devices flows directly from the Federal Food Drug and Cosmetic Act (FDCA)
  - Requires that an FDA approved marketing or research permit be obtained before certain commodities (e.g., medical devices) may enter interstate commerce - move across state lines

FDA Regulation

FDA has been working to provide clarity on the following topics wrt digital health

- Wireless medical devices
- Mobile Medical Apps
- Health IT
- Telemedicine
- Software as a Medical Device
- General Wellness
- Medical Device Data Systems
- Medical Device Intraoperability

FDA Regulation

- FDA regulation has broad impact
  - Medical Devices
  - Software as a Medical Device (SaMD)
  - Mobile Apps
- Reimbursement/Coverage
- Off-label promotion of new or modified devices

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

What is a Medical 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)

Medical Device Classification

- Class I - Premarket notification - 510(k) when required (most are exempt)
- Examination gloves, hand-held surgical instruments
- General Controls
- Most exempt from premarket submission

- Class II
- Diagnostic ultrasound, eye contacts
- Special Controls: Performance Standards, Post-market surveillance, Patient registries, guidelines, recommendations and “Other Appropriate Actions” as identified by Center for Devices and Radiological Health (CDRH)
- Premarket Notification (510k clearance)

- Class III
- support or sustain human life and are of substantial importance in preventing impairment of human health e.g., joint replacements, artificial heart, spinal implants
- General controls are insufficient
- Premarket Approval (PMA)

Mobile Medical Applications

- Mobile apps are software programs that run on smartphones and other mobile communication devices. They can also be accessories that attach to a smartphone or other mobile communication devices, or a combination of accessories and software.

- Mobile medical apps are medical devices that are mobile apps, meet the definition of a medical device and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.

MMA Regulation

- FDA considers the functionality of the software rather than platform.
- The intended use of a mobile app determines whether it meets the definition of a “device.”
- When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device.

MMA Regulation

- FDA intends to apply its regulatory oversight to only those software functions that are medical devices and whose functionality could pose a risk to a patient's safety if the device were to not function as intended.
- FDA strongly recommends that manufacturers of all software and mobile apps that may meet the definition of a device follow the Quality System regulation (that includes good manufacturing practices) in the design and development of their device software functions, and initiate prompt corrections to their devices, when appropriate, to prevent patient and user harm.

MMAs that 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**

MMAs that are Devices

- The following are software functions that FDA considers to be device software functions subject to regulatory oversight:
  - Software functions that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or analyzing medical device data.
    - Example: software that provides the ability to control inflation and deflation of a blood pressure cuff through a mobile platform

MMAs that are Devices

- Software functions (typically, mobile apps) that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Software functions that use attachments, display screens, sensors or other such similar components to transform a mobile platform into a regulated medical device are required to comply with the device classification associated with the transformed platform.
  - Example: a software function that uses a mobile platform for medical device functions, such as attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter

MMAs that are Devices

- Software functions that become a regulated medical device by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of functions are similar to or perform the same function as those types of software devices that have been previously cleared or approved.
  - Example: software functions that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy

Mobile Apps 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 & Training

- 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).

Note Devices – Patient Education

- 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 – 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

- 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.

Clinical Decision Support Software (CDS)

- CDS provides health care professionals (HCPs) and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.
- CDS is described as a variety of tools including, but not limited to: computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information.

CDS Cont.

- A software function is considered CDS from a regulatory perspective if it meets the following:
  - Not intended to acquire, process, or analyze;
  - Intended for the purpose of displaying, analyzing, or printing medical information; and
  - Intended for the purpose of supporting or providing recommendations.

CDS Cont.

CDS is not a device when an HCP can independently review the basis for the recommendation, e.g., the CDS is intended for the purpose of enabling an HCP to independently review the basis for a recommendation that the software presents so that it is not the intent that the HCP rely primarily on any such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient. However, software functions that support or provide such recommendations to patients or caregivers – not HCPs – meet the definition of device.

CDS Cont.

Is the Intended User an HCP?	Can the User Independently Review the Basis?	Is it Device CDS?
Yes	Yes	No, it is Non-Device CDS
	No	Yes, it is Device CDS
No, it is a patient or caregiver	Yes	Yes, it is Device CDS
	No	Yes, it is Device CDS

Device CDS

Device CDS includes software functions that meet criteria 1) (not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system) and 2) (intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information) and are intended for the purpose of supporting or providing recommendations to an HCP, patient, or caregiver about prevention, diagnosis, or treatment of a disease or condition.

Non-Device CDS

Under the 21st Century Cures Act, if all 4 criterion below are met, the CDS is not a device:

1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system
2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

Non-Device CDS

3) intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or; and
4) intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

FDA Enforcement of CDS

- Whether FDA will exercise enforcement discretion (e.g., not enforce its regulatory requirements) is determined by the device's risk categorization.
- non-serious: situations or conditions where an accurate diagnosis and treatment is important but not critical for interventions to mitigate long term irreversible consequences on an individual patient's health condition or public health.
- serious: situations or conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions (e.g., biopsy) or timely interventions are important to mitigate long term irreversible consequences on an individual patient's health condition or public health.
- critical: situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.

Inform Clinical Management

- Inform clinical management means the information provided by the SaMD will not trigger an immediate or near term action:
  - To inform of options for treating, diagnosing, preventing, or mitigating a disease or condition.
  - To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.).
- The SaMD functions provide information that is not necessary to decision-making for a patient's care.

Drive Clinical Management

- Driving clinical management infers that the information provided by the SaMD will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions:
  - To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
  - To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis.
  - To triage or identify early signs of a disease or condition.
- Drive functions are relied on to guide next diagnostics or treatment interventions.

Treat or Diagnose

- Treating and diagnosing infers that the information provided by the SaMD will be used to take an immediate or near-term action:
  - To treat/prevent or mitigate by connecting to other medical devices, medicinal products, general purpose actuators or other means of providing therapy to a human body.
  - To diagnose/screen/detect a disease or condition (i.e., using sensors, data, or other information from other hardware or software devices, pertaining to a disease or condition).
- Treatment or diagnosis functions provide the actual diagnosis or prompt an immediate or near-term action – functions that are well beyond the scope of supporting or providing recommendations.

FDA Policy

- CDS software functions intended to support or provide recommendations to patients or caregivers – not HCPs – to prevent, diagnose, or treat a disease or condition *are* devices.
- FDA considers such Device CDS functions, which are intended for patients or caregivers to inform clinical management for non-serious health care situations or conditions, to be *low risk* when the CDS function is intended for a patient or caregiver using the device to be able to independently review the basis for its recommendations. FDA does not intend at this time to enforce compliance with applicable device requirements of the FD&C Act for the devices.

FDA Policy Cont.

- Device CDS functions that inform clinical management of non-serious conditions that are not intended for the HCP to be able to independently review the basis for its recommendation, and therefore an HCP would primarily rely upon it, are considered low risk. FDA does not intend at this time to enforce compliance with applicable device requirements of the FD&C Act for the devices.
- FDA intends to focus its regulatory oversight on higher risk Device CDS software functions, e.g., device CDS functions intended for patients, caregivers, or HCPs that inform clinical management for serious and critical health care situations or conditions.

Enforcement Summary

		Intended User is HCP	Intended User is Patient or Caregiver
Risk Categorization	Can the User Independently Review the Basis?*	FDA Regulation	FDA Regulation
Informs Clinical Management of Critical Condition	Yes	Not a Device	Oversight Focus
Informs Clinical Management of Critical Condition	No	Oversight Focus	Oversight Focus
Informs Clinical Management of Serious Condition	Yes	Not a Device	Oversight Focus
Informs Clinical Management of Serious Condition	No	Oversight Focus	Oversight Focus
Informs Clinical Management of Non-Serious Condition	Yes	Not a Device	Enforcement Discretion
Informs Clinical Management of Non-Serious Condition	No	Enforcement Discretion	Oversight Focus

Examples

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

t:slim X2 Insulin Pump with Basal-IQ Technology

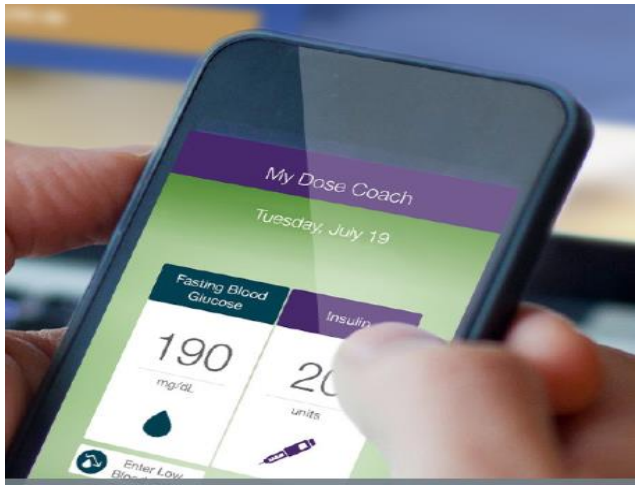
Continuous glucose monitor (CGM) and an insulin pump with Basal-IQ technology.

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's Digital Health Innovation Action Plan

FDA's traditional approach for the regulation of hardware-based medical devices is not well suited for the faster, iterative design and development, and type of validation used for software device functions, including SaMD.

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 a 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

Precertification Program

- The goal is a regulatory model that provides efficient regulatory oversight of certain software-based medical devices from manufacturers who have demonstrated a robust culture of quality and organizational excellence and are committed to monitoring real-world performance while assuring that these devices are safe and effective.

Review Framework

- Use De Novo pathway for novel types of low- to moderate-risk devices to obtain marketing authorization.
- The De Novo classification process is a pathway for certain new types of low to moderate risk devices for obtaining marketing authorization as class I or class II, rather than remaining automatically designated as a class III device that would require premarket approval.

Excellence Appraisal

- Review and appraise the developer's culture of quality and organizational excellence.
- Many of the QSR requirements may be satisfied by information the FDA collects through the Excellence Appraisal process, which is aimed at evaluating the quality and excellence of the software developer for Pre-Cert. By collecting this information early, the Excellence Appraisal may be leveraged to streamline a developer's De Novo submission, which will reduce content a developer would need to submit to the FDA under the De Novo pathway (since the information would already have been demonstrated and documented during the Excellence Appraisal).

Impact for Review

- The excellence-appraised manufacturer would submit a De Novo Request containing required submission content that was not already received by FDA through the Excellence Appraisal and documented in the device master file. This streamlined “Pre-Cert De Novo Request” would include those applicable submission elements of a traditional De Novo that, in addition to the elements reviewed and documented during the Excellence Appraisal, provide the required information necessary to determine that the device is of low to moderate risk and that general controls or general and special controls can provide a reasonable assurance of safety and effectiveness.

Parallel Pathways

- FDA will undertake a parallel submission review process and compare the new streamlined De Novo Pathway to the traditional submission pathway.
- FDA will review a firm's traditional De Novo submission for its device and using that same submission information FDA will, in parallel, review a firm's Excellence Appraisal information with the proposed streamlined submission content.

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.

FDCA Key Terms

- Adulteration – “adulterated product” generally describes a defect in the product (unsafe for its intended purpose, unacceptable toxicity, contamination with filth, inadequate manufacturing controls) or the lack of approval

- Misbranding – “misbranded product” generally describes a defect in the product’s labeling or advertising (false, misleading, failure to include required information), or the lack of compliance with FDA requirements other than approval

Sanctions & Penalties for Violating the FDCA

- Prohibited Acts – Generally some type of activity performed with an adulterated or misbranded product or resulting in an adulterated or misbranded product. 21 USC § 331(b).
- Remedies:
  - Seizure
  - Injunction
  - Civil Money Penalties
  - Civil and Criminal Penalties (strict liability)

- Other remedies include Warning Letters, untitled letters and other administrative penalties
- Note that enforcement actions by the FDA may establish important policies

FDA Enforcement

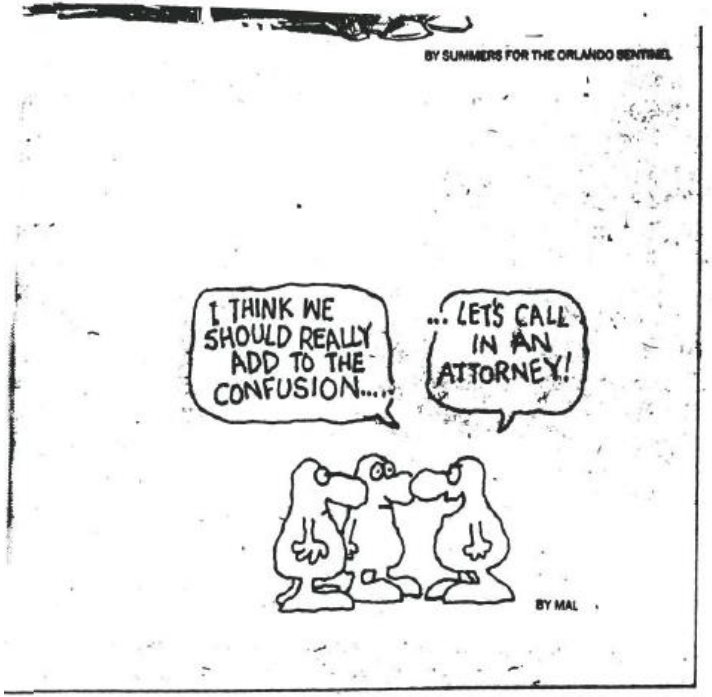
- Opternative, Inc. Warning Letter 10/30/17
- On-line eye examination
- FDA stated it requires a premarket submission in order to evaluate safety and effectiveness

Future?

- 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


BY SUMMERS FOR THE ORLANDO SENTINEL
I THINK WE SHOULD REALLY ADD TO THE CONFUSION....
... LET'S CALL IN AN ATTORNEY!
BY MAL

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